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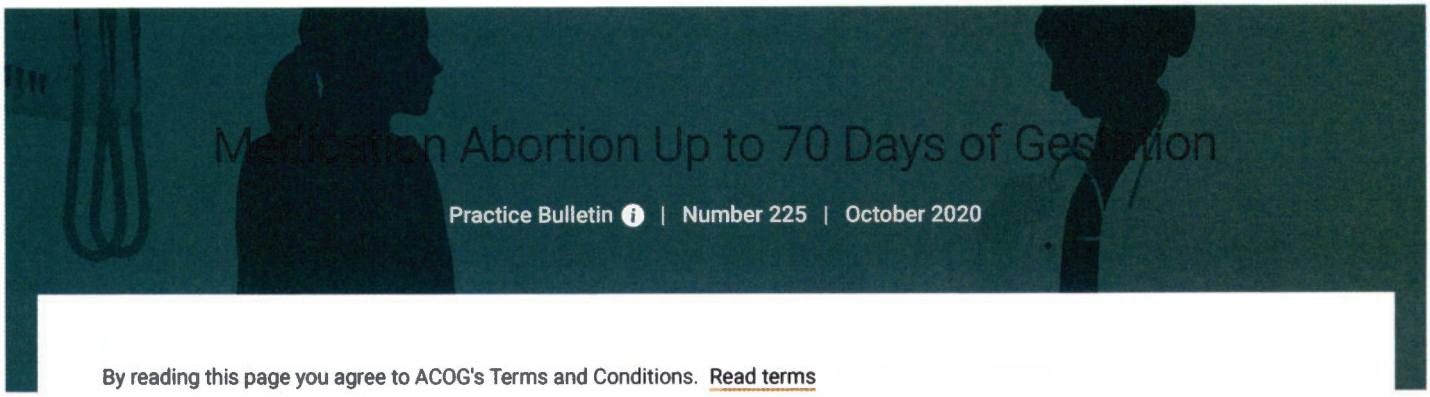
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EXHIBIT 27

ACOG Practice Bulletin No. 225: Medication Abortion Up to 70 Days of Gestation (Oct. 2020)

ACOG | Clinical

The American College of Obstetricians and Gynecologists



Medication Abortion Up to 70 Days of Gestation

Practice Bulletin | Number 225 | October 2020

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The following supplemental information has been issued for this document:

View the Clinical Practice Update, Rh D Immune Globulin Administration After Abortion or Pregnancy Loss at Less Than 12 Weeks of Gestation

View the March 2024 Practice Advisory

View the January 2023 Practice Advisory

Number 225 (Replaces Practice Bulletin Number 143, March 2014. Reaffirmed 2023)

Committee on Practice Bulletins—Gynecology and the Society of Family Planning. This Practice Bulletin was developed jointly by the Committee on Practice Bulletins—Gynecology and the Society of Family Planning in collaboration with Mitchell D. Creinin, MD, and Daniel A. Grossman, MD.

ABSTRACT: Medication abortion, also referred to as medical abortion, is a safe and effective method of providing abortion. Medication abortion involves the use of medicines rather than uterine aspiration to induce an abortion. The U.S. Food and Drug Administration (FDA)-approved medication abortion regimen includes mifepristone and misoprostol. The purpose of this document is to provide updated evidence-based guidance on the provision of medication abortion up to 70 days (or 10 weeks) of gestation. Information about medication abortion after 70 days of gestation is provided in other ACOG publications [1].

Background

Epidemiology

An estimated one in four women in the United States will have an abortion in her lifetime. In 2017, an estimated 60% of abortions in the United States occurred at or before 10 weeks of gestation and medication abortion comprised 39% of all abortions [2]. Between 2006 and 2015, there was a shift in the timing of abortion, with abortions taking place at earlier gestational ages; this is likely due, in part, to availability of medication abortion [3]. From 2014 to 2017, the number of nonhospital facilities that provided medication abortion increased by 25% [2]. A recent survey of American College of Obstetricians and Gynecologists (ACOG) Fellows and Junior Fellows found that 14% had provided medication abortion in the prior year [4].

Medication Abortion

The medication abortion regimen supported by major medical organizations nationally and internationally includes two medications, mifepristone and misoprostol [5] [6]. If mifepristone is unavailable, then a misoprostol-only regimen is an acceptable alternative [5]. Mifepristone is a selective progesterone receptor modulator that binds to the progesterone receptor with an affinity greater than progesterone itself but does not activate the receptor, thereby acting as an antiprogestin [7]. Mifepristone's known actions on a uterus during pregnancy include decidual necrosis, cervical softening, and increased uterine contractility and prostaglandin sensitivity [8] [9]. Misoprostol is a prostaglandin E1 analogue that causes cervical softening and uterine contractions. It is approved by the FDA for oral administration to prevent gastric ulcers in individuals who take anti-inflammatory drugs on a long-term basis, and it is included in the FDA-approved labeling of mifepristone for use in abortion [10].

The FDA currently restricts mifepristone access under the risk evaluation and mitigation strategy (REMS) program, which includes a requirement that the drug be "dispensed to patients only in certain health-care settings, specifically clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber" [10]. However, the REMS restrictions for mifepristone do not make the care safer, are not based on medical evidence or need, and create barriers to clinician and patient access to medication abortion [4] [11] [12]. The American College of Obstetricians and Gynecologists advocates the removal of REMS restrictions for mifepristone [12].

Clinical Considerations and Recommendations

How should patients be counseled about abortion methods?

Only when patients have considered their options and decided to have an abortion does the discussion about the different methods become clinically relevant. Patients who choose abortion should be counseled about all methods available as well as the risks, advantages, disadvantages, and the different features of these options [5] [6]. Most patients who initially are unsure about the method will have some preference after counseling [13]. Generally, patients are satisfied with the method they choose [12] [14] [15]. Patients who choose medication abortion tend to do so because of a desire to avoid a procedural intervention; a perception that medication abortion is safer, more natural, and private compared with uterine aspiration; or a combination of these reasons [16]. Compared with uterine aspiration, medication abortion takes longer to complete and requires more active patient participation as the pregnancy expels outside of a clinical setting. The uterine aspiration procedure for a first-trimester abortion takes place most commonly in one visit, is slightly more effective, and allows for direct assessment of pregnancy tissue by the clinician.

What information and counseling should be provided to patients who are considering medication abortion?

Eligibility and Contraindications

Most patients at 70 days of gestation or less who desire abortion are eligible for a medication abortion. There are medical conditions for which a medication abortion may be preferable to uterine aspiration. Such examples include uterine fibroids that significantly distort the cervical canal or uterine cavity [17] [18], congenital uterine anomalies [19], or introital scarring related to infibulation [20]. Patients with asthma are candidates for medication abortion because misoprostol does not cause bronchoconstriction and actually acts as a weak bronchodilator [21]. Multiple gestation pregnancy is not a contraindication; patients with twin gestations can be treated with the same regimens as those with singleton gestations [22].

Medication abortion is not recommended for patients with any of the following: confirmed or suspected ectopic pregnancy, intrauterine device (IUD) in place (the IUD can be removed before medication abortion), current long-term systemic corticosteroid therapy, chronic adrenal failure, known coagulopathy or anticoagulant therapy, inherited porphyria, or intolerance or allergy to mifepristone or misoprostol [23]. Patients with significant comorbidities may still have a medication abortion but may need more monitoring during the process depending on the stability of the conditions. The safety of medication abortion in patients with anemia is unknown because studies have excluded patients with anemia who have hemoglobin levels of less than 9.5 or 10 g/dL. Although the transfusion rates associated with medication abortion are low (less than 0.1%), they exceed those reported for uterine evacuation procedures in early pregnancy (0.01%) [24] [25]. Patients may also not be good candidates for medication abortion if they are unable or unwilling to adhere to care instructions, desire quick completion of the abortion process, are not available for follow-up contact or evaluation, or cannot understand the instructions because of comprehension barriers.

What to Expect

Most patients who have a medication abortion will experience bleeding and cramping, which are necessary for the process to occur. Patient counseling should emphasize that bleeding likely will be much heavier than menses (and potentially with severe cramping).

Adverse effects can occur after mifepristone administration but are more typically experienced after misoprostol administration. Adverse effects commonly associated with misoprostol use include nausea (43–66%), vomiting (23–40%), diarrhea (23–35%), headache (13–40%), dizziness (28–39%), and thermoregulatory effects such as fever, warmth, hot flushes, or chills (32–69%) [26] [27] [28] [29]. The incidence of each adverse effect varies by regimen used, the dose and route of administration of the prostaglandin analogue, and the gestational age.

Patient counseling before medication abortion should include discussion of when patients should contact their clinician in the case of heavy bleeding (soaking more than two maxi pads per hour for 2 consecutive hours) and when to access urgent intervention [5] [6] [30]. In rare cases, patients who undergo medication abortion may need to obtain an additional intervention, such as uterine aspiration. If the prescribing clinician does not perform the intervention, it is medically appropriate to provide a referral. In patients who receive mifepristone and vaginal misoprostol, the need for intervention within the first 24 hours of treatment is rare, occurring in 0.2% of patients [31]. The need for intervention is based on how the patient is feeling and whether the bleeding seems to be slowing. For patients with heavy bleeding, a baseline hemoglobin or hematocrit, if known, may also influence when to seek urgent care. Overall, less than 1% of patients will obtain an emergency intervention for excessive bleeding [13] [14] [15] [32], and the need for blood transfusion is rare (0.1% of patients or less) [24] [33]. Should a rare medical emergency arise, patients should be advised to seek care at the closest emergency facility.

Teratogenicity and Ongoing Pregnancy

Before undergoing medication abortion, patients should be counseled regarding the teratogenicity of misoprostol in the event of an unsuccessful medication abortion. All patients with a continuing pregnancy after using mifepristone and misoprostol should be provided with all pregnancy options and a thorough discussion of the risks and benefits of each. Most individuals with a continuing pregnancy opt to complete the abortion, but patients should be supported in their choice of how to proceed. No evidence exists to date of a teratogenic effect of mifepristone [34]. However, misoprostol can result in congenital anomalies, such as limb defects with or without Möbius' syndrome (ie, facial paralysis), when used during the first trimester [35] [36] [37] [38] [39]. Because misoprostol is the common agent used with every medication abortion regimen, clinicians should counsel all patients regarding potential teratogenic effects.

In the very rare case that patients change their mind about having an abortion after taking mifepristone and want to continue the pregnancy, they should be monitored expectantly [40]. There is no evidence that treatment with progesterone after taking mifepristone increases the likelihood of the pregnancy continuing [41] [42]. However, limited available evidence suggests that use of mifepristone alone without subsequent administration of misoprostol may be associated with an increased risk of hemorrhage [43].

What evaluation and ancillary testing are needed before a medication abortion?

Before medication abortion is performed, the clinician should confirm pregnancy and estimate gestational age. For patients with regular menstrual cycles, a certain last menstrual period within the prior 56 days, and no signs, symptoms, or risk factors for ectopic pregnancy, a clinical examination or ultrasound examination is not necessary before medication abortion. Rh testing is recommended in patients with unknown Rh status before medication abortion, and Rh D immunoglobulin should be administered if indicated [44]. In situations where Rh testing and Rh D immunoglobulin administration are not available or would significantly delay medication abortion, shared decision making is recommended so that patients can make an informed choice about their care. Other laboratory evaluations are not routinely indicated but may be required by local and state laws [2]. Preoperative assessment of hemoglobin or hematocrit is indicated only when anemia is suspected.

Most abortion care globally is provided without ultrasound examination. Although most U.S.-based studies have used ultrasonography to confirm gestational age and intrauterine location of the pregnancy, more recent evidence has shown that a patient's certain last menstrual period when within the prior 56 to 63 days is accurate [45] [46] [47] [48]. In one study, use of certain last menstrual period alone would have resulted in medication abortion being provided to only 26 of 3,041 (0.8%) patients with pregnancies beyond 70 days of gestation [45].

A potential concern when providing early abortion services is the possibility of an undiagnosed ectopic pregnancy. The overall ectopic pregnancy rate in the U.S. general population is low and declining and is approximately 6 per 1,000 pregnancies among insured patients and 14 per 1,000 among patients who receive Medicaid [49] [50]. However, in studies of patients who seek abortion, ectopic pregnancy rates generally are lower. A U.S. study of uterine evacuation procedures performed at less than 6 weeks of gestation found the ectopic pregnancy rate to be 5.9 per 1,000 pregnancies [51] at a time when the national rate was three times higher [52]. The largest published study of first-trimester medication abortion patients involved 16,369 patients with pregnancies of 49 days of gestation or less and yielded a calculated ectopic pregnancy rate of 1.3 per 1,000 pregnancies [53]. Although ectopic pregnancy among individuals who seek early abortion is rare, patients with a medical history of ectopic pregnancy, medical risk factors (prior tubal surgery, pregnancy with progestin-only or IUD contraception use) or symptoms (ie, unilateral pain, vaginal bleeding) suggestive of ectopic pregnancy should have pretreatment clinical evaluation, which may include ultrasonography [5] [6].

Most patients with clinical indications for an ultrasound examination before medication abortion can be initially screened with transabdominal ultrasonography, reserving transvaginal ultrasonography for situations in which further clarification is required [54] [55]. If ultrasonography is medically indicated, transabdominal ultrasonography is sensitive for diagnosing the presence or absence of a gestational sac in patients who are not obese [54]. A randomized trial that compared the use of transabdominal ultrasonography with transvaginal ultrasonography for eligibility assessment before medication abortion found that 80% of patients who received initial transabdominal ultrasonography did not require further testing to proceed with medication abortion, thus avoiding use of more invasive and resource-intensive screening with transvaginal ultrasonography [55].

Recommendations on whether Rh D immune globulin should be given to patients before medication abortion in early pregnancy are primarily based on expert opinion because available evidence is limited [6] [56]. Rh D alloimmunization that is left undiagnosed and untreated can lead to significant perinatal morbidity and mortality in future pregnancies [57]. And, guidelines from ACOG and various other major medical societies include recommendations for Rh D immune globulin prophylaxis for Rh D-negative patients undergoing medication abortion within the first 12 weeks of gestation [44] [58] [59] [60]. For patients undergoing medication abortion before 10 weeks of gestation, some experts recommend against routine Rh testing and anti-D prophylaxis [6] or advise that forgoing Rh typing and Rh prophylaxis can be considered [61]. Research regarding Rh alloimmunization during early pregnancy continues to evolve [62]. However, based on currently available indirect evidence and the theoretical risk of Rh D alloimmunization in future pregnancies, ACOG recommends Rh D immune globulin prophylaxis for Rh D-negative patients undergoing medication abortion. In situations where Rh testing and anti-D prophylaxis are not available or would significantly delay medication abortion, shared decision making is recommended so that patients can weigh the benefits and risks of their options and make an informed decision about their care.

What regimens are used for medication abortion, and how do they compare in effectiveness for treatment?

Combined mifepristone–misoprostol regimens are recommended as the preferred therapy for medication abortion because they are significantly more effective than misoprostol-only regimens. If a combined mifepristone–misoprostol regimen is not available, a misoprostol-only regimen is the recommended alternative [5] [63] [64]. Mifepristone is approved by the U.S. FDA to be used with misoprostol for medication abortion through 70 days of gestation [23], but evidence also exists to support use with more advanced gestations [1] [5]. The recommended medication abortion regimens are listed in **Table 1**. With all regimens, the mifepristone dose is the same: 200 mg taken orally. The misoprostol portion of the regimen is more variable in terms of dose, route, and timing. Oral use of misoprostol is not recommended because it may result in lower overall efficacy [65]. In general, patients prefer a shorter interval between the two medications [66]. These regimens have been extensively studied and are similarly safe and effective [5]. Offering options provides patients with flexibility in the timing of abortion and the ability to avoid possible adverse effects related to the misoprostol route. Gastrointestinal adverse effects are less common when misoprostol is administered vaginally as compared with regimens that use oral, buccal, or sublingual misoprostol [65] [67]. Buccal and sublingual administration cause similar adverse effects, with the sublingual route associated with a higher rate of chills [68].

Table 1. Medication Abortion Regimens Up to 70 Days of Gestation

Regimen	Mifepristone Dose	Misoprostol Dose	Interval Between Drugs
Preferred			
Combination, FDA-approved*	200 mg (orally)	800 micrograms (buccally)	24–48 h
Combination, WHO recommended†	200 mg (orally)	800 micrograms (vaginally, sublingually, or buccally)	24–48 h
Alternative			
Misoprostol only	N/A	800 micrograms (vaginally, sublingually, or buccally)	Repeat every 3 h for up to 3 doses‡

Abbreviations: h, hours; FDA, U.S. Food and Drug Administration; N/A, not applicable; WHO, World Health Organization.

*U.S. Food and Drug Administration. Mifeprex (mifepristone) information. Postmarket drug safety information for patients and providers. Silver Spring, MD: FDA; 2018. Available at: https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111323.htm. Retrieved March 3, 2020.

†World Health Organization. Medical management of abortion. Geneva: WHO; 2018. Available at: https://apps.who.int/iris/bitstream/handle/10665/278968/9789241550406-eng.pdf?ua=1. Retrieved March 3, 2020.

‡Although studies typically use no more than three doses for the initial treatment regimen, the World Health Organization guidelines do not specify a maximum number of misoprostol doses (Raymond EG, Harrison MS, Weaver MA. Efficacy of misoprostol alone for first-trimester medical abortion: a systematic review. Obstet Gynecol 2019;133:137-47 *and* World Health Organization. Medical management of abortion. Geneva: WHO; 2018. Available at: https://apps.who.int/iris/bitstream/handle/10665/278968/9789241550406-eng.pdf?ua=1. Retrieved March 3, 2020).

Complete abortion rates with all regimens are highest at earlier gestational ages **Table 2**. *Medication abortion failure* (defined as the need for uterine aspiration because of ongoing pregnancy or retained tissue) increases with advancing gestational age through 70 days of gestation **Table 2**, although failure rates remain low even at this point. Clinicians should counsel patients that medication abortion failure rates, especially continuing pregnancy rates, increase as gestational age approaches 10 weeks.

Table 2. Outcome by Gestational Age After Mifepristone 200 mg and Misoprostol for Outpatient Medication Abortion

	Misoprostol Dose	Interval Between Mifepristone and Misoprostol (h)	Gestational Age			
			≤49 days	50–56 days	57–63 days	64–70 days
Complete abortion	800 micrograms buccally*	24–48	98.1%	96.8%	94.7%	92.7%
	800 micrograms vaginally†‡§‖¶‡‡	24–72	98.3–99.7%	95.3–98.6%	95.1–98.3%	94.9%
	800 micrograms vaginally§	6–8	97.1%	94.2%	95.2%	N/A
	800 micrograms vaginally‖¶	0–0.25	95.5–95.7%	93.7–94.3%	91.6–95.3%	N/A
	400 micrograms sublingually#**	24–48	95.4%	N/A	94.8%	91.9%
Ongoing pregnancy	800 micrograms buccally*	24–48	0.3%	0.8%	2.0%	3.1%
	800 micrograms vaginally†‡§‖¶‡‡	24–72	0–0.4%	0–1.2%	0–2.2%	3.4%
	800 micrograms vaginally§	6–8	0.4%	0	0.8%	N/A
	800 micrograms vaginally‖¶	0–0.25	1.4–2.3%	1.9–2.8%	1.6–5.0%	N/A
	400 micrograms sublingually#**††	24–48	N/A	N/A	1.8–3.5%	2.2%

Abbreviations: h, hours; N/A, not available.

*U.S. Food and Drug Administration. Mifeprex (mifepristone) information. Postmarket drug safety information for patients and providers. Silver Spring, MD: FDA; 2018. Available at: https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111323.htm. Retrieved March 3, 2020.

†Schaff EA, Eisinger SH, Stadalius LS, Franks P, Gore BZ, Poppema S. Low-dose mifepristone 200 mg and vaginal misoprostol for abortion. Contraception 1999;59:1–6.

‡Schaff EA, Fielding SL, Westhoff C. Randomized trial of oral versus vaginal misoprostol at one day after mifepristone for early medical abortion. Contraception 2001;64:81–5.

§Creinin MD, Fox MC, Teal S, Chen A, Schaff EA, Meyn LA. A randomized comparison of misoprostol 6 to 8 hours versus 24 hours after mifepristone for abortion. MOD Study Trial Group. Obstet Gynecol 2004;103:851–9.

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#Raghavan S, Tsereteli T, Kamilov A, Kurbanbekova D, Yusupov D, Kasimova F, et al. Acceptability and feasibility of the use of 400 μg of sublingual misoprostol after mifepristone for medical abortion up to 63 days since the last menstrual period: evidence from Uzbekistan. Eur J Contracept Reprod Health Care 2013;18:104–11.

**Bracken H, Dabash R, Tsertsvadze G, Posohova S, Shah M, Hajri S, et al. A two-pill sublingual misoprostol outpatient regimen following mifepristone for medical abortion through 70 days' LMP: a prospective comparative open-label trial. Contraception 2014;89:181–6.

††von Hertzen H, Huong NT, Piaggio G, Bayalag M, Cabezas E, Fang AH, et al. Misoprostol dose and route after mifepristone for early medical abortion: a randomised controlled noninferiority trial. WHO Research Group on Postovulatory Methods of Fertility Regulation. BJOG 2010;117:1186–96.

‡‡Hsia JK, Lohr PA, Taylor J, Creinin MD. Medical abortion with mifepristone and vaginal misoprostol between 64 and 70 days' gestation. Contraception 2019;100:178–81.

Who is qualified to provide medication abortion, and in what settings can medication abortion be provided?

Any clinician with the skills to screen patients for eligibility for medication abortion and to provide appropriate follow-up can provide medication abortion. Clinicians who wish to provide medication abortion services should be trained to perform uterine evacuation procedures or should be able to refer to a clinician who has this training [5] [69].

In addition to physicians, advanced practice clinicians, such as nurse–midwives, physician assistants, and nurse practitioners, possess the clinical and counseling skills necessary to provide first-trimester medication abortion [70]. Randomized trials in Mexico, Nepal, and Sweden have consistently found that patients randomized to receive medication abortion under the care of a nurse or nurse–midwife had a statistically equivalent risk of complete abortion compared with those under the care of a physician, without increased risk of adverse events [71] [72] [73]. In some U.S. states, advance practice clinicians can provide medication abortion; however, many states require that a physician perform an abortion and prohibit provision of medication abortion by nonphysician clinicians [2].

According to the requirements of the FDA REMS program, clinicians who want to prescribe mifepristone must complete a "prescriber agreement form" before ordering and dispensing mifepristone, and the clinician and patient need to sign a "patient agreement form" before the drug is dispensed [10].

The actual location of where a patient takes the medication abortion drugs has evolved over time. Although the FDA REMS program for mifepristone continues to require dispensing in the clinician's office, the U.S. labeling for mifepristone no longer indicates that the medication should be used only in the clinician's office [10]. Patients can safely and effectively use mifepristone at home for medication abortion [74] [75] [76] [77]. A clinician can prescribe misoprostol and pain medications or can maintain an office supply and directly dispense to the patient. Patients can safely and effectively self-administer misoprostol at home for medication abortion [5] [78] [79] [80].

Medication abortion can be provided safely and effectively by telemedicine with a high level of patient satisfaction, and telemedicine improves access to early abortion care, particularly in areas that lack a health care practitioner [81] [82]. Telemedicine involves the use of video and information technology to provide a medical service at a distance. Medication abortion through telemedicine has been evaluated in observational studies and found to be equally effective as an in-person visit [33] [83] [84] [85]. In an analysis of nearly 20,000 medication abortions, adverse events were rare (0.3% overall) and did not differ between those who choose telemedicine or in-person services [33] [84]. Patients who choose telemedicine medication abortion are significantly more likely to say they would recommend the service to a friend compared with those who have an in-person visit (90% versus 83%) [83]. Telemedicine also may help reduce the rate of delays to care because of barriers in access to abortion care in remote areas [82]. After medication abortion through telemedicine was introduced in Iowa, a significant reduction in second-trimester abortion was reported, and patients in remote parts of the state were more likely to obtain a medication abortion [82]. Despite this evidence, some states have passed legislation that bans the use of telemedicine to provide medication abortion [86].

Should prophylactic antibiotics be used in medication abortion?

The routine use of prophylactic antibiotics is not recommended for medication abortion [6]. Following concern about serious, rare, and deadly infection with clostridial bacteria in patients undergoing medication abortion, it has since become evident that no specific connection exists between clostridial organisms and medication abortion [87] [88]. Uterine infection with medication abortion is uncommon, and published data do not support the routine use of prophylactic antibiotics in medication abortion. In a systematic review of 65 studies of heterogeneous design (prospective, retrospective, and randomized), the overall proportion of diagnosed or treated infection after medication abortion was 0.9% in more than 46,000 patients [89]. In these studies, as in most studies of abortion by uterine evacuation, the diagnostic criteria for infection were variable, leading to possible overestimation of infection.

Although serious infections occur rarely in patients after medication abortion, clinicians need to be aware of the signs and symptoms. Tachycardia, severe abdominal pain, or general malaise with or without fever that occur more than 24 hours after misoprostol administration should increase suspicion of a serious infection [90]. Clostridial toxic shock often resembles a flu-like illness, so clinicians should have a high level of suspicion for infection when symptoms consistent with flu are present [90]. Patients with such infections typically have hemoconcentration and significant leukocytosis without fever and can rapidly progress to refractory hypotension and death [91].

What is the recommended pain management approach for patients undergoing medication abortion?

Nonsteroidal anti-inflammatory drugs are recommended for pain management in patients who undergo a medication abortion. Pain management during medication abortion is an important consideration because many patients report pain that requires analgesia. Studies of pain control and medication abortion have found that the duration of pain for most patients is no longer than 24 hours after misoprostol administration [92] [93]. The most severe pain occurs approximately 2.5–4 hours after misoprostol use and lasts about 1 hour [94]. One randomized trial found that ibuprofen taken when needed was more effective than acetaminophen to reduce pain associated with medication abortion [95]. Another randomized trial found ibuprofen given prophylactically at the time of misoprostol administration did not significantly reduce pain associated with medication abortion compared with ibuprofen taken when needed [93]. Nonsteroidal anti-inflammatory drugs do not appear to counteract misoprostol or affect the success of the medication abortion [96]. Opioids have not been found to decrease the amount or duration of maximum pain associated with medication abortion up to 70 days of gestation [94]. Other medications, like pregabalin, have been studied for pain control but have not been effective [97].

Patients should be sent home with appropriate instructions for analgesia with over-the-counter medications. If opioids are requested or desired, the Centers for Disease Control and Prevention (CDC) advises that "clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids" [98].

What kind of assessment is recommended after medication abortion?

Routine in-person follow-up is not necessary after uncomplicated medication abortion. Clinicians should offer patients the choice of self-assessment or clinical follow-up evaluation to assess medication abortion success. If medically indicated or preferred by the patient, follow-up evaluation can be performed by medical history, clinical examination, serum human chorionic gonadotropin (hCG) testing, or ultrasonography [5] [6] [99].

The type of follow-up visit after medication abortion has evolved over time. The mifepristone FDA label includes recommendations for follow up [23]. However, some patients choose not to return for follow-up; this likely is due to the high success rates and because patients are able to self-assess abortion completion [100] [101] [102].

Remote Assessment and Self-Assessment

Follow-up can be performed by telephone at 1 week, with subsequent at-home urine pregnancy testing at 4 weeks after treatment, which avoids the need for the patient to go to a facility [103] [104] [105] [106]. Most studies have used a short series of questions that ask patients whether they have experienced bleeding and cramping (including how much and for how long) and whether they still feel pregnant or if they think the pregnancy has passed [104] [107]. When the clinician and the patient think that expulsion has occurred based on symptomatology, they are correct 96–99% of the time [104] [108]. Although urine pregnancy testing alone with standard high-sensitivity or low-sensitivity tests has not been shown to be a viable alternative to other forms of follow-up, newer semiquantitative or multilevel at-home urine hCG tests have shown promise in accurately identifying ongoing pregnancies after medication abortion [109] [110] [111] [112].

Clinical Follow-Up

When a patient obtains in-person follow-up after medication abortion, transvaginal ultrasonography is commonly used, although it is not required [5]. Incorrect interpretation of ultrasound examination results can lead to unnecessary interventions such as an unneeded uterine aspiration [5]. If an ultrasound examination is performed at follow-up after medication abortion, the sole purpose is to determine whether the gestational sac is present or absent. The measurement of endometrial thickness or other findings do not predict the need for subsequent uterine aspiration [113]. In research trials, when a transvaginal ultrasound examination shows no evidence of a gestational sac 1 week after mifepristone use, only 1.6% of patients needed subsequent uterine evacuation [113].

Serum hCG testing before treatment and 1 week after treatment is another option for follow-up examination after medication abortion; however, data about use of this approach are lacking for gestations beyond 63 days. This strategy may be more effective than ultrasonography to confirm abortion completion in patients who were below the threshold for visualization of a gestational sac at the time of their medication abortion [114]. Patients do not need to return to the same facility; they can obtain serum hCG testing at a convenient location [114] [115]. The patient should then be informed of the result. A serum hCG level decrease of at least 80% over 6–7 days after initiating treatment with mifepristone and misoprostol indicates a successful abortion [114]. In a randomized trial of in-clinic transvaginal ultrasound examination or serum hCG testing follow-up, 24.5% of patients were lost to follow-up, there were no significant differences reported in unplanned visits and interventions by 2 weeks (6.6% versus 8.2%, respectively) or in uterine evacuation rates by 4 weeks (4.4% and 1.4%, respectively) [116].

How is incomplete medication abortion or ongoing pregnancy managed?

Guidelines for intervention vary for patients who have delayed expulsion, an incomplete medication abortion (ie, persistent gestational sac on ultrasonography without evidence of embryonic cardiac activity or retained tissue), or an ongoing pregnancy (ie, continuing development with embryonic cardiac activity).

Delayed Expulsion

After induced or spontaneous expulsion, the uterus will normally contain sonographically hyperechoic tissue or "thick" endometrial stripe that consists of blood, blood clots, and decidua. Rarely does this ultrasound finding in patients who have undergone medication abortion indicate a need for intervention. In the absence of excessive bleeding or pain by patient report, clinicians can monitor such patients based on symptoms.

Incomplete Medication Abortion

An incomplete medication abortion can be treated with a repeat dose of misoprostol, uterine aspiration, or expectant management, depending on the clinical circumstances and patient preference [23] [30] [117] [118]. Studies indicate that even with a retained sac at 2 weeks after medication abortion, intervention is unnecessary, and that expulsion will typically occur in the ensuing weeks [30]. However, some patients with incomplete expulsion will have bothersome symptoms, such as prolonged and irregular bleeding episodes. Patients with incomplete medication abortion 1 week after treatment can safely receive another dose of misoprostol [28] [118] or repeat misoprostol doses can be used for a persistent gestational sac [117]. Patients who prefer not to wait or do not desire medical management can choose to have a uterine evacuation at any time.

Ongoing Pregnancy

Ongoing pregnancy after medication abortion can be treated with a repeat dose of misoprostol or uterine aspiration, depending on the clinical circumstances and patient preference. In an analysis of data from two randomized trials with 14 cases of ongoing pregnancy, treatment with a repeat dose of misoprostol, 800 micrograms administered vaginally, resulted in expulsion of the products of pregnancy in five cases (36%); in an additional four cases (29%), gestational cardiac activity was no longer present at the next follow-up visit [118]. If gestational cardiac activity persists at follow-up after a second dose of misoprostol, uterine aspiration should be performed.

What is the recommended timing of contraception initiation after medication abortion?

Patients undergoing medication abortion who desire contraception should be counseled that

- almost all contraceptive methods, except IUDs and permanent contraception, can be safely initiated immediately on day 1 (mifepristone intake) of medication abortion.
- all contraceptive methods can be safely initiated after successful medication abortion.

Patients who select depot medroxyprogesterone acetate (DMPA) for contraception should be counseled that administration of DMPA on day 1 of the medication abortion regimen may increase the risk of ongoing pregnancy [119].

Providing desired contraception as soon as possible to patients undergoing medication abortion enables the greatest flexibility in care and decreases barriers to initiating contraception. The CDC and World Health Organization (WHO) support the initiation of almost all methods of contraception on day 1 of the medication abortion or on the same day as mifepristone administration [5] [6] [120]. Permanent contraception procedures may be performed once abortion is confirmed complete.

Concern has been raised that the immediate use of hormonal contraception that contains progestins could theoretically interfere with medication abortion efficacy. Etonogestrel implant use does not affect medication abortion outcomes [121] [122]. However, DMPA injection at the time of mifepristone administration may slightly increase the risk of an ongoing pregnancy [119]. In a randomized trial that evaluated the effects of DMPA injection timing on medication abortion outcomes, ongoing pregnancy was more common among those randomized to receive DMPA injection on the day of mifepristone administration compared with those who received DMPA at a follow-up visit (3.6% versus 0.9%; 90% CI, 2.7 [0.4–5.6]), although the proportion undergoing aspiration for any reason did not significantly vary (6.4% versus 5.3%; 90% CI, 1.1 [–2.8 to 4.9]) [119]. Patients should be counseled about this small risk of ongoing pregnancy, which needs to be weighed against the risk of potentially not receiving their desired method of contraception.

Patients do not experience a higher rate of IUD expulsion with placement in the first week after medication abortion as compared with 3 to 6 weeks later [123] [124]. However, IUD placement within 6 weeks after medication abortion is associated with a higher expulsion rate compared with IUD placement remote from pregnancy; the time frame after 6 weeks at which this rate decreases is unknown. Placement of a copper or levonorgestrel IUD close to the time of abortion results in improved uptake of a desired IUD compared with placement at an additional follow-up visit several weeks after the abortion [123] [124] [125], although overall use rates at 6 months may not differ [126]. The IUD expulsion risk should be weighed against the potential for more patients to receive their desired IUD if it is placed sooner rather than later.

How should patients be counseled about the effect of medication abortion on future fertility and pregnancy outcomes?

Patients can be counseled that medication abortion does not have an adverse effect on future fertility or future pregnancy outcomes [5] [6]. Studies consistently demonstrate that medication abortion has no negative effect on future fertility or pregnancy outcomes. A study from China found that patients who had a prior mifepristone abortion had lower odds of preterm birth compared with those who had never been pregnant (adjusted OR, 0.77; 95% CI, 0.61–0.98), and the frequencies of low-birth-weight infants and mean lengths of pregnancy were similar in both groups [127]. No significant differences were reported in risk of preterm delivery, frequency of low-birth-weight infants, or mean infant birth weight in the comparisons of patients who had previous mifepristone abortion and patients who had uterine evacuation. In a registry-based study from Scotland, no association was found between prior abortion and subsequent preterm birth during the period 2000–2008, when 68% of abortions were medication-induced [128].

Summary of Recommendations

The following recommendations are based on good and consistent scientific evidence (Level A):

- Combined mifepristone–misoprostol regimens are recommended as the preferred therapy for medication abortion because they are significantly more effective than misoprostol-only regimens. If a combined mifepristone–misoprostol regimen is not available, a misoprostol-only regimen is the recommended alternative.

- Clinicians should counsel patients that medication abortion failure rates, especially continuing pregnancy rates, increase as gestational age approaches 10 weeks.

- Any clinician with the skills to screen patients for eligibility for medication abortion and to provide appropriate follow-up can provide medication abortion.

- Patients can safely and effectively use mifepristone at home for medication abortion.

- Patients can safely and effectively self-administer misoprostol at home for medication abortion.

- Nonsteroidal anti-inflammatory drugs are recommended for pain management in patients who undergo a medication abortion.

- Routine in-person follow-up is not necessary after uncomplicated medication abortion. Clinicians should offer patients the choice of self-assessment or clinical follow-up evaluation to assess medication abortion success. If medically indicated or preferred by the patient, follow-up evaluation can be performed by medical history, clinical examination, serum human chorionic gonadotropin (hCG) testing, or ultrasonography.

- If an ultrasound examination is performed at follow-up after medication abortion, the sole purpose is to determine whether the gestational sac is present or absent. The measurement of endometrial thickness or other findings do not predict the need for subsequent uterine aspiration.

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- Medication abortion is not recommended for patients with any of the following: confirmed or suspected ectopic pregnancy, intrauterine device (IUD) in place (the IUD can be removed before medication abortion), current long-term systemic corticosteroid therapy, chronic adrenal failure, known coagulopathy or anticoagulant therapy, inherited porphyria, or intolerance or allergy to mifepristone or misoprostol.

- Before undergoing medication abortion, patients should be counseled regarding the teratogenicity of misoprostol in the event of an unsuccessful medication abortion.

- Before medication abortion is performed, the clinician should confirm pregnancy and estimate gestational age. For patients with regular menstrual cycles, a certain last menstrual period within the prior 56 days, and no signs, symptoms, or risk factors for ectopic pregnancy, a clinical examination or ultrasound examination is not necessary before medication abortion.

- Most patients with clinical indications for an ultrasound examination before medication abortion can be initially screened with transabdominal ultrasonography, reserving transvaginal ultrasonography for situations in which further clarification is required.

- Medication abortion can be provided safely and effectively by telemedicine with a high level of patient satisfaction.

- The routine use of prophylactic antibiotics is not recommended for medication abortion.

- An incomplete medication abortion can be treated with a repeat dose of misoprostol, uterine aspiration, or expectant management, depending on the clinical circumstances and patient preference.

- Ongoing pregnancy after medication abortion can be treated with a repeat dose of misoprostol or uterine aspiration, depending on the clinical circumstances and patient preference.

- Patients undergoing medication abortion who desire contraception should be counseled that

  - almost all contraceptive methods, except IUDs and permanent contraception, can be safely initiated immediately on day 1 (mifepristone intake) of medication abortion.

  - all contraceptive methods can be safely initiated after successful medication abortion.

- Patients who select depot medroxyprogesterone acetate (DMPA) for contraception should be counseled that administration of DMPA on day 1 of the medication abortion regimen may increase the risk of ongoing pregnancy.

- Patients can be counseled that medication abortion does not have an adverse effect on future fertility or future pregnancy outcomes.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- Patients who choose abortion should be counseled about all methods available as well as the risks, advantages, disadvantages, and the different features of these options.

- Most patients at 70 days of gestation or less who desire abortion are eligible for a medication abortion.

- Patient counseling before medication abortion should include discussion of when patients should contact their clinician in the case of heavy bleeding (soaking more than two maxi pads per hour for 2 consecutive hours) and when to access urgent intervention.

- All patients with a continuing pregnancy after using mifepristone and misoprostol should be provided with all pregnancy options and a thorough discussion of the risks and benefits of each.

- In the very rare case that patients change their mind about having an abortion after taking mifepristone and want to continue the pregnancy, they should be monitored expectantly.

- Rh testing is recommended in patients with unknown Rh status before medication abortion, and Rh D immunoglobulin should be administered if indicated. In situations where Rh testing and Rh D immunoglobulin administration are not available or would significantly delay medication abortion, shared decision making is recommended so that patients can make an informed choice about their care.

- Clinicians who wish to provide medication abortion services should be trained to perform uterine evacuation procedures or should be able to refer to a clinician who has this training.

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Medication abortion up to 70 days of gestation. ACOG Practice Bulletin No. 225. American College of Obstetricians and Gynecologists. Obstet Gynecol 2020;136:e31–47.

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 2000 and February 2020. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician–gynecologists were used.

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- I Evidence obtained from at least one properly designed randomized controlled trial.
- II-1 Evidence obtained from well-designed controlled trials without randomization.
- II-2 Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A—Recommendations are based on good and consistent scientific evidence.

Level B—Recommendations are based on limited or inconsistent scientific evidence.

Level C—Recommendations are based primarily on consensus and expert opinion.

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Topics

Abortifacient agents | Counseling | Diagnostic imaging | First pregnancy trimester | Induced abortion | Obstetric surgical procedures | Pregnancy | Pregnancy trimesters | Reproductive control agents | Rh-Hr blood-group system | Ultrasonography

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EXHIBIT 28

Mary Gatter et al., *Efficacy and safety of medical abortion using mifepristone and buccal misoprostol through 63 days*, 91 Contraception 269 (2015)

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Contraception

Original research article

Efficacy and safety of medical abortion using mifepristone and buccal misoprostol through 63 days☆,☆☆

Mary Gatter[a], Kelly Cleland[b], Deborah L. Nucatola[a,*]

[a]*Planned Parenthood Los Angeles, 400 West 30th St., Los Angeles, CA 90007*

[b]*218 Wallace Hall, Office of Population Research, Princeton University, Princeton, NJ 08544*

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Abstract

Objective: The aim of this study was to report on the safety and efficacy of an evidence-based medical abortion regimen utilizing 200 mg of mifepristone orally followed by home use of 800 mcg misoprostol buccally 24–48 h later through 63 days estimated gestational age.

Study design: We analyzed outcomes in women presenting for medical abortion between April 1, 2006, and May 31, 2011, using an evidence-based alternative to the United States Food and Drug Administration (FDA)-approved regimen. Cases were identified for this descriptive study from our electronic practice management (EPM) database, and our electronic database on adverse events was queried for information on efficacy and safety. The primary outcome was successful abortion. Logistic regression was used to identify predictors of successful abortion.

Results: Among the 13,373 women who completed follow-up, efficacy of the regimen was 97.7%. Efficacy was highest at 29 to 35 days (98.8%) and 36 to 42 days (98.8%) of gestation and lowest at 57 to 63 days (95.5%). The odds of needing aspiration for any reason were greatest at higher gestational ages. Rates of infection requiring hospitalization and rates of transfusion were 0.01 and 0.03%, respectively.

Conclusions: An evidence-based regimen of 200 mg of mifepristone orally followed by home use of 800 mcg of buccal misoprostol 24–48 h later is safe and effective through 63 days estimated gestational age. Further, the need for aspiration for any reason was low, and hospitalization was rare.

Implications: This study reinforces the safety and efficacy of the evidence-based regimen for medical abortion (200 mg mifepristone orally followed by home use of 800 mcg of misoprostol buccally 24–48 h later) through 63 days estimated gestational age, and contributes to the existing evidence against restrictions requiring use of the FDA-approved regimen.

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Keywords: Medical abortion; Mifepristone; First-trimester abortion; Evidence-based regimen; Buccal misoprostol; Efficacy

1. Introduction

The United States Food and Drug Administration (FDA) approved the use of mifepristone and misoprostol for pregnancy termination in 2000. The regimen, labeled for use through 49 days estimated gestational age, required a minimum of three visits to the healthcare provider. Six hundred milligrams of mifepristone was taken orally at Visit 1, followed in 2 days by misoprostol 400 mcg, also taken orally. A third follow-up visit was required in 14 days to ensure that the abortion was complete. The efficacy of this regimen ranged from 92 to 97% [1–3]. Publications soon followed providing an evidence base for alterations to the regimen. Alterations included a lower dose of mifepristone, different routes of administration of misoprostol, variations in the timing of misoprostol administration, home use of misoprostol, and increasing the gestational age limit for the regimen [4–11]. A recent publication confirmed the low rate of significant adverse events with use of the evidence-based regimen [11].

In 2008, a prospective study was published describing the use of 200 mg of mifepristone followed in 24 to 36 h by 800 mcg of buccal misoprostol for pregnancy termination to 63

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* Corresponding author at: 400 W. 30th Street, Los Angeles, CA 90007. Tel.: +1 212 261 4632; fax: +1 818 986 5035.

E-mail address: deborah.nucatola@ppfa.org (D.L. Nucatola).

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days of gestation with a success rate for the regimen of 96.2% [8]. Despite the growing literature supporting evidence-based provision of medical abortion, some providers are required by law to limit the provision of medical abortion to that regimen, which was FDA-approved more than a decade ago [12]. The goal of the current study was to assess, in a much larger cohort of patients, the safety and efficacy of an evidence-based medical abortion regimen utilizing 200 mg of mifepristone orally followed by home use of 800 mcg of misoprostol buccally 24–48 h later through 63 days estimated gestational age.

2. Materials and methods

2.1. Medical abortion protocols and monitoring

Our large network of urban healthcare centers includes 19 health centers providing approximately 15,000 abortions per year, of which about 30% are medical abortions. Demographic information, treatment dates, and diagnostic codes for all patients were retrieved using the electronic practice management (EPM) billing system. Some clinical information was retrieved from an electronic medical records (EMR) system, which was gradually implemented across all study sites between 2008 and 2010. All patients undergo an ultrasound examination for pregnancy dating prior to abortion. The clinician administering the medication abortion performed and interpreted the ultrasound. All clinicians had undergone the same standardized training and were monitored regularly to ensure accuracy and to maintain consistency. Ultrasound machines using a Hadlock scale calculated gestational age in days; herein, we analyze and report gestational age in 7-day increments (e.g., 22 to 28 days). Since April 2006, our medical abortion regimen has consisted of 200 mg of mifepristone taken orally at the health center followed by 800 mcg of buccal misoprostol used by the patient at home 24 to 48 h later. Medical protocols during the study period allowed for repeat doses of misoprostol for patients who had an incomplete medical abortion. Data on which patients received a repeat dose are not available from the EPM system, but only in the EMR system; therefore, for patients seen at sites that had not yet implemented EMR at the time of treatment, information on whether a repeat dose of misoprostol was given is not available. For the first 3 years of the study period, the upper gestational age limit for this regimen was 56 days. In February 2009, based on newly published data, the upper limit was increased to 63 days [8]. All patients were scheduled to return in 7 to 14 days for a postabortion evaluation. Beginning in 2007, all patients also received routine antibiotic coverage beginning on the day of the mifepristone administration. The standard antibiotic regimen was a 7-day course of doxycycline (100 mg twice a day), with an alternative regimen of one dose of azithromycin (1 g) for cases in which doxycycline was contraindicated.

Our EPM database contains information on all patients undergoing medical abortion, including patient demographics and the ultrasound-determined gestational age. We also maintain a separate electronic database of adverse events including ongoing pregnancy, aspiration for symptoms and/or retained products of conception, infection requiring hospitalization, and hemorrhage requiring transfusion.

2.2. Statistical methods

Bivariate and multivariate logistic regression were used to assess predictors of successful medical abortion. Covariates available in our data set were poverty level, race/ethnicity, gestational age, and patient age; other patient-level data were not available. Results were considered statistically significant at $p < .05$. Statistical analysis was performed using Stata/SE 11.2 (College Station, TX).

The primary outcome of interest was successful abortion. A successful abortion was defined as expulsion of the pregnancy without the need for aspiration. Patients who required aspiration for an ongoing pregnancy or symptoms such as pain or bleeding were considered to have had unsuccessful medical abortions. We queried our adverse events database to identify continuing pregnancies (those pregnancies with documented fetal growth or cardiac activity seen at the follow-up), all cases of aspiration, and hospitalization for either infection or transfusion. We cross-checked this against the list of postprocedure visits in our EPM system in order to ensure that all cases had been identified.

Institutional review board (IRB) approval was obtained from the Ethical and Independent Review Service of Independence, MO, and an exemption for analysis of the existing data was granted by the Princeton University IRB.

3. Results

3.1. Sample description

For this descriptive study, we queried our EPM database and identified 15,890 patients who had a medical abortion between April 1, 2006, and May 31, 2011. During the period under review, medical abortions were provided at 14 different clinic sites belonging to our network in one urban area, all using the same evidence-based protocol. There were 2470 (15.5%) patients who failed to return for a follow-up visit and were excluded from analysis. An additional 20 patients were excluded from the analysis due to missing data on gestational age, and a further 27 patients were excluded because they did not complete the medical abortion (these patients either changed their mind and chose a surgical abortion, were ineligible for a medical abortion because they were beyond the 63-day gestational limit, or began the regimen but did not take all of the medications). This left 13,373 patients for analysis.

Demographic characteristics of the 13,373 women who had a medical abortion between April 1, 2006, and May 31, 2011, and who returned for follow-up are shown in Table 1. Half of the women were between the ages of 18 and 24, and small proportions were under the age of 18 (4.5%) or 40 or

Table 1
Demographic characteristics of women having a medical abortion with mifepristone 200 mg and misoprostol 800 mcg buccally (N=13,373)

	n	%
Gestational age (days)		
22–28	554	4.1
29–35	1080	8.1
36–42	2495	18.7
43–49	4816	36.0
50–56	3142	23.5
57–63	1286	9.6
Poverty level (% FPL)		
0–100	9679	72.4
>100	3694	27.6
Race/ethnicity		
Hispanic/Latino	6215	46.5
White	3235	24.2
African American	1263	9.5
Asian	1172	8.8
Other/declined	1487	11.1
Patient age (years)		
<18	605	4.5
18–24	6684	50.0
25–29	3317	24.8
30–34	1613	12.1
35–39	855	6.4
40+	299	2.2

older (2.2%). Nearly half of women identified as Hispanic or Latino, and 72% reported an income at or below the poverty line. The most frequent gestational age in our data set was 43 to 49 days (36.0%), and the least frequent was 22 to 28 days (4.1%).

3.2. Frequency and predictors of successful abortion

Termination of pregnancy with 200 mg of oral mifepristone followed by 800 mcg of buccal misoprostol 24–48 h later was successful among 97.7% of women who completed follow-up. Only 307 (2.3%) of the 13,373 women included in this study underwent aspiration for any reason. Specifically, 70 (0.5%) women had a continuing pregnancy, and 237 (1.8%) women required aspiration for reasons other than continuing pregnancy, most commonly due to reported symptoms of pain and/or bleeding. Data on the need for a repeat dose of misoprostol were available from a subset of women from clinics in which the EMR system was used, which included 7335 women (54.8% of the total sample). Of these 7335 women, 87 (1.2%) received a repeat dose of misoprostol.

Table 2 shows the proportion of patients requiring aspiration for ongoing pregnancy or for symptoms, such as heavy bleeding, by gestational age. The proportion with ongoing pregnancy ranged from 0.15% for those at 36 to 42 days of gestation to 1.63% at 57 to 63 days of gestation. Compared with the reference category (43 to 49 days), odds of ongoing pregnancy were greater for those at the highest gestational age. The proportion of women treated with aspiration for symptoms, not ongoing pregnancy, ranged from 0.65 to 2.49%. The incidence of hospitalization for infection or hemorrhage requiring transfusion was very low (Table 3). In total, six women required hospitalization for any reason (two women were hospitalized for infection, and four were hospitalized for transfusion), and incidence was at or below 0.1% among all gestational ages.

In a multivariate logistic regression model (Table 4), poverty level and race/ethnicity were not significant predictors of successful abortion. Certain categories of gestational age were significantly associated with success; compared with the reference category (43 to 49 days), those at 36 to 42 days of gestation had greater odds of success, whereas those at 50 to 56 days and 57 to 63 days had lower odds of success. Compared with the reference category (18 to 24), those in the middle three age groups had significantly lower odds of success, but differences for those in the youngest (17 and under) and highest (40 and older) age groups were not significant.

3.3. Loss to follow-up

A comparison of patients who completed follow-up and those who were lost to follow-up is presented in Table 5. Compared with patients at 43 to 49 days of gestation, patients at higher gestational ages were more likely to be lost to follow-up. For patients with incomes at or below the Federal Poverty Level (FPL), the odds of being lost to follow-up were greater than those above FPL. Odds of being lost to follow-up were greater for those younger than 18 (compared with those 18 to 24) and lower for those aged 40 and older.

4. Discussion

4.1. General implications

This study demonstrates that the evidence-based regimen for medical abortion (mifepristone 200 mg orally followed by home use of misoprostol 800 mcg buccally 24–48 h later) is highly effective through 63 days estimated gestational age, with an overall success rate of 97.7%. This is higher than the efficacy rates reported in two pivotal trials used in submission for FDA approval of mifepristone,[1,2] yet utilizes one-third the dose of mifepristone (200 mg rather than 600 mg) and buccal administration and home use of misoprostol rather than oral administration in the clinic. Repeat dosing of misoprostol was administered in only 1.2% of patients for whom this information is available, and given the way in which the EMR system was implemented across study sites, we can assume that this rate would be representative of the entire sample. Although efficacy is lower at later gestational ages, even in the 57- to 63-day range, this evidence-based regimen was still more effective than rates reported in the FDA-approved regimen, which sets the upper gestational age limit at 49 days. Furthermore, the rates of unsuccessful abortion in this study are lower than the rates reported in the two trials that were initially submitted to the FDA for approval of mifepristone.

Table 2
Aspiration for ongoing pregnancy, symptoms or any indication among those who completed follow-up, by gestational age.

Gestational age	Aspiration for ongoing pregnancy n (%)	OR	95% CI	Aspiration for symptoms n (%)	OR	95% CI	Aspiration for any reason * n (%)	OR	95% CI
22–28 days	4 (0.72)	2.69	0.87–8.27	11 (1.99)	1.39	0.73–2.65	15 (2.71)	1.39	0.80–2.43
29–35 days	5 (0.46)	1.72	0.61–4.83	7 (0.65)	0.45	0.21–0.98	13 (1.20)	0.61	0.34–1.10
36–42 days	4 (0.16)	0.59	0.19–1.82	25 (1.00)	0.70	0.44–1.10	30 (1.20)	0.61	0.40–0.92
43–49 days	13 (0.27)	ref		69 (1.43)	ref		94 (1.95)	ref	
50–56 days	23 (0.73)	2.72	1.38–5.39	64 (2.04)	1.43	1.01–2.02	97 (3.09)	1.60	1.20–2.13
57–63 days	21 (1.63)	6.13	3.06–12.28	32 (2.49)	1.76	1.15–2.80	58 (4.51)	2.37	1.70–3.31
Totals	70 (0.5)			237 (1.8)			307 (2.3)		

OR: odds ratio; CI: confidence interval
* This column includes 29 cases wherein reason for aspiration is unknown.

This study adds to the growing literature supporting provision of medical abortion using evidence-based regimens, and supports the conclusion that legislative efforts to restrict medical abortion to the FDA regimen are based on political goals to restrict abortion services, not efficacy or patient safety.

4.2. Limitations

Our study has some limitations. It is retrospective in nature and relies on the accuracy of our EPM database. However, review of our EPM system has shown a high degree of accuracy when compared with patient records [13]. In addition, we are not a closed system, and it is possible and even likely that some patients who experienced complications did not return to us for care. However, since many patients need to pay for aftercare obtained outside our system, but not within our system, it is more likely than not that the patients who did not return for follow-up did so because they did not feel that they needed follow-up, rather than that they were experiencing a complication. In that case, excluding them from our analysis would have tended to overestimate, rather than underestimate, the need for aspiration in our population. We based our analysis of efficacy only on those patients who did return for a follow-up visit, so we cannot exclude the possibility of additional visits or treatment elsewhere.

Loss to follow-up is common in studies of medical abortion, as many patients may determine on their own that their abortion is complete and that follow-up is not needed. The rate of loss to follow-up in this study (15.5%) is lower than loss to follow-up found in other clinical medical abortion studies, which report loss of follow-up of 18 to 45% [14–17]. We found that loss to follow-up was significantly more common among those at higher gestational ages; given that odds of success are lower among those with more advanced pregnancies, it is possible that this study underestimates the true odds of unsuccessful abortion. Loss to follow-up was significantly higher among the youngest age group and lower among the oldest age group, but as these age categories were unrelated to whether the abortion was successful, we do not believe that these differences would systematically bias our results.

Table 3
Hospitalizations for infection or transfusion in women having a medical abortion with mifepristone 200 mg and misoprostol 800 mcg buccally (*N*=13,373)

Gestational age	Patients *n*	Infections *n* (%)	Transfusions *n* (%)
22–28 days	554	0 (0.00)	1 (0.18)
29–35 days	1080	1 (0.09)	0 (0.00)
36–42 days	2495	0 (0.00)	0 (0.00)
43–49 days	4816	1 (0.02)	0 (0.00)
50–56 days	3142	0 (0.00)	3 (0.10)
57–63 days	1286	0 (0.00)	0 (0.00)
Total	13,373	2 (0.01)	4 (0.03)

4.3. Conclusion

In summary, an evidence-based regimen of mifepristone 200 mg orally followed by misoprostol 800 mcg buccally

Table 4
Factors associated with successful medical abortion in women using mifepristone 200 mg and misoprostol 800 mcg buccally (N=13,373)

	Successful *n* (%)	Unsuccessful *n* (%)	OR	95% CI
Gestational age (days)				
22–28	539 (97.3)	15 (2.7)	0.72	0.41–1.25
29–35	1067 (98.8)	13 (1.2)	1.68	0.94–3.01
36–42	2465 (98.8)	30 (1.2)	1.65	1.09–2.50
43–49	4722 (98.1)	94 (2.0)	Ref	
50–56	3045 (96.9)	97 (3.1)	0.62	0.47–0.83
57–63	1228 (95.5)	58 (4.5)	0.42	0.30–0.58
Total patients	13,066 (97.7)	307 (2.3)		
Poverty level (% FPL)				
0–100	9466 (97.8)	213 (2.2)	0.95	0.74–1.23
>100	3600 (97.5)	94 (2.5)	Ref	
Race/ethnicity				
Hispanic/Latino	6074 (97.7)	141 (2.3)	Ref	
White	3163 (97.8)	72 (2.2)	1.02	0.76–1.37
African American	1228 (97.2)	35 (2.8)	0.90	0.62–1.31
Asian	1146 (97.8)	26 (2.2)	1.02	0.67–1.57
Other/declined	1454 (97.8)	33 (2.2)	1.08	0.74–1.59
Patient age (years)				
<18	597 (98.7)	8 (1.3)	1.44	0.70–2.98
18–24	6560 (98.1)	124 (1.9)	Ref	
25–29	3233 (97.5)	84 (2.5)	0.72	0.54–0.96
30–34	1556 (96.5)	57 (3.5)	0.51	0.37–0.70
35–39	829 (97.0)	26 (3.0)	0.58	0.37–0.89
40+	291 (97.3)	8 (2.7)	0.68	0.33–1.40

OR, odds ratio; CI, confidence interval.

Table 5
Loss to follow-up analysis among women having a medical abortion with mifepristone 200 mg and misoprostol 800 mcg buccally (N=13,373)

	Completed follow-up *n* (%)	Lost to follow-up *n* (%)	OR[a]	95% CI
Gestational age (days)				
22–28	554 (85.1)	97 (14.9)	1.00	0.79–1.25
29–35	1080 (86.3)	172 (13.7)	0.91	0.76–1.08
36–42	2495 (85.6)	419 (14.4)	0.96	0.84–1.09
43–49	4816 (85.1)	845 (14.9)	Ref	
50–56	3142 (83.0)	645 (17.0)	1.17	1.05–1.31
57–63	1286 (81.7)	288 (18.3)	1.28	1.10–.48
Poverty level (% FPL)				
0–100	9679 (83.7)	1887 (16.3)	1.24	1.12–1.38
>100	3694 (86.5)	579 (13.6)		
Race/ethnicity				
Hispanic/Latino	6215 (84.1)	1173 (15.9)		
White	3235 (83.4)	643 (16.6)	1.05	0.95–1.17
African American	1263 (82.8)	262 (17.2)	1.10	0.95–1.27
Asian	1172 (91.1)	115 (8.9)	0.52	0.43–0.64
Other/declined	1487 (84.5)	273 (15.5)	0.97	0.84–1.12
Patient age (years)				
<18	605 (80.0)	152 (20.0)	1.42	1.17–1.71
18–24	6684 (84.9)	1186 (15.1)		
25–29	3317 (83.7)	646 (16.3)	1.10	0.99–1.22
30–34	1613 (84.8)	289 (15.2)	1.01	0.88–1.16
35–39	855 (84.6)	156 (15.4)	1.03	0.86–1.23
40+	299 (89.0)	37 (11.0)	0.70	0.49–0.99

OR, odds ratio; CI, confidence interval.
[a] OR represents odds of being lost to follow-up.

48–72 h later is safe and effective through 63 days estimated gestational age. Further, need for aspiration for any reason was low, the chance of needing aspiration increased with gestational age at the time of medical abortion, and the frequency of hospitalization was rare. This study reinforces the safety and efficacy of the evidence-based regimen for medical abortion, and contributes to the evidence against restrictions that require use of the FDA-approved regimen.

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EXHIBIT 29

AAPLOG Citizen Petition (Mar. 29, 2019)

Citizen Petition

March 29, 2019

The undersigned submit this petition to request the Commissioner of Food and Drugs to: (I) restore and strengthen elements of the Mifeprex regimen and prescriber requirements approved in 2000, and (II) retain the Mifeprex Risk Evaluation and Mitigation Strategy (REMS), and continue limiting the dispensing of Mifeprex to patients in clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber.

A. Action Requested

I. RESTORE AND STRENGTHEN ELEMENTS OF THE MIFEPREX REGIMEN AND PRESCRIBER REQUIREMENTS APPROVED IN 2000.

Current language and requested language for the Mifeprex Label and the Mifeprex *Risk Evaluation and Mitigation Strategy* (REMS) are included in Exhibit A.[1] Requests include:

A. Indications and Usage. Mifeprex, in a regimen with misoprostol, for the termination of intrauterine pregnancy, should be limited to 49 days' gestation.

B. Dosage and Administration.

1. Mifeprex should be administered by or under the supervision of a physically present and certified physician who has ruled out ectopic pregnancy.

2. The use of Mifeprex and misoprostol for the termination of pregnancy should require three office visits by the patient.

C. Contraindications. Mifeprex use is contraindicated for patients who do not have convenient access to emergency medical care.

D. Adverse Event Reporting. Certified prescribers, emergency medical personnel, physicians treating complications, and Danco Laboratories should report to FDA's MedWatch Reporting system any deaths, hospitalizations, blood transfusions, emergency room visits, failures requiring surgical completion, ongoing pregnancy, or other major complications following the use of Mifeprex and misoprostol.

[1] Other documents will require corresponding modifications, including the Mifeprex Medication Guide, Prescriber Agreement Form, and Patient Agreement Form.

E. Additional studies. The Mifeprex REMS should require a formal study of outcomes for at-risk populations, including: patients under the age of 18; patients with repeat Mifeprex abortions; patients who have limited access to emergency room services; and patients who self-administer misoprostol.

II. RETAIN THE MIFEPREX RISK EVALUATION AND MITIGATION STRATEGY (REMS), AND CONTINUE LIMITING THE DISPENSING OF MIFEPREX TO PATIENTS IN CLINICS, MEDICAL OFFICES, AND HOSPITALS, BY OR UNDER THE SUPERVISION OF A CERTIFIED PRESCRIBER.

A. Retain the Mifeprex REMS.

B. Continue limiting the dispensing of Mifeprex to patients in clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber.

1. Mifeprex should be dispensed only in clinics, medical offices, and hospitals.

   a. The "TelAbortion" Direct-to-Consumer Mifeprex Study

   b. The Mifeprex through Pharmacy Dispensing Study

   c. Beyond the Current Studies

2. Mifeprex Prescribers Should be Certified.

B. Statement of Grounds

I. RESTORE AND STRENGTHEN ELEMENTS OF THE MIFEPREX REGIMEN AND PRESCRIBER REQUIREMENTS APPROVED IN 2000.[2]

A. Indications and Usage. Mifeprex, in a regimen with misoprostol, for the termination of intrauterine pregnancy, should be limited to 49 days' gestation.

In 2016, FDA increased the maximum gestational age for Mifeprex use for abortion from 49 days (7 weeks) to 70 days (10 weeks), and changed the method of administration of misoprostol from oral to buccal (*i.e.*, in the cheek pouch). However drug-induced abortion[3] regimens demonstrate an increase in complications and failures after 49 days' gestation.

In a 2011 study of thousands of patients, the majority of whom had a drug-induced abortion using what is now the Mifeprex regimen, the rate of infection and the rate of failure requiring surgical intervention increased with gestational age.[4] The American College of Obstetricians and Gynecologists (ACOG) has stated: "the risk of clinically significant bleeding and transfusion may be lower in women who undergo medical abortion of gestations up to 49 days compared with those who undergo medical abortion of gestations of more than 49 days."[5]

Further, a 2015 meta-analysis examined all the existing publications on buccal administration of misoprostol, 20 studies in all, from November 2005 through January 2015. The failure rate of the buccal misoprostol regimen increased as the gestational age

[2] The FDA approved Mifeprex for use in the United States on September 28, 2000, with safeguards considered necessary to ensure patient safety. The drug's initial approval was for termination of pregnancy, in a regimen with misoprostol, through 49 days of pregnancy. FDA significantly modified the drug's label at the application of the manufacturer, Danco Laboratories, in 2016, extending approved use to 70 days of pregnancy. Additional changes included: a new dosage of both Mifeprex and misoprostol; permitting home administration of Mifeprex and misoprostol; a new route of administration for the misoprostol (buccal, in the cheek pouch); permitting non-physicians to become certified prescribers; a decrease from 3 to 1 mandatory office visits by the patient; and reduced reporting requirements. U.S. Gov't Accountability Office, GAO-18-292, Food and Drug Administration: Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts 4-7 (2018); Mifeprex Risk Evaluation and Mitigation Strategy (REMS), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2016-03-29_REMS_full.pdf; Mifeprex Medication Guide, https://www.fda.gov/downloads/Drugs/DrugSafety/ucm088643.pdf.

[3] The terms "Medication abortion," "medical abortion," "chemical abortion," and "drug-induced abortion" [or termination of pregnancy] share the same meaning and refer to the use of abortion-inducing drugs, rather than surgery, to induce abortion. The current FDA-approved regimen uses two drugs, mifepristone (a.k.a. Mifeprex or RU-486) and misoprostol.

[4] Mentula MJ, Niinimaki M, Suhonen S, Hemminki E, Gissler M, and Heinkinheimo O, *Immediate Adverse Events after Second Trimester Medical Termination of Pregnancy: Results of a Nationwide Registry Study,* Human Reproduction 26(4), 927-932 (2011).

[5] ACOG Practice Bulletin 143: *Medical Management of First-Trimester Abortion*, p. 5 (Mar. 2014, reaffirmed 2016).

increased, especially at gestational ages greater than 49 days.[6] The current FDA label also acknowledges this fact.[7]

Given the serious risks of failure, hemorrhage, infection, and ongoing pregnancy that increase as pregnancy advances, the gestational limit for the Mifeprex regimen should have never been increased.

B. Dosage and Administration.

1. Mifeprex should be administered by or under the supervision of a physically present and certified physician who has ruled out ectopic pregnancy.

The 2000 Mifeprex regimen required Mifeprex to be "provided by or under the supervision of a *physician*" who meets qualifications discussed in this section below.[8] However, the 2016 regimen replaced "physician" with "healthcare provider," thus permitting non-physicians to apply to be certified prescribers.[9] Given the regimen's serious risks, the FDA should limit the ability to prescribe and dispense Mifeprex to qualified, licensed physicians. Physicians are better trained to diagnose patients who have contraindications to Mifeprex and to verify gestational age.

The current Mifeprex Risk Evaluation and Mitigation Strategy (REMS), discussed in Section II below, continues to provide that "Mifeprex must be dispensed to patients only in certain healthcare settings, specifically clinics, medical offices, and hospitals, *by or under the supervision of a certified prescriber*."[10] Yet, abortion providers today are promoting and performing "telemedicine abortions," where the certified prescriber's "supervision" of the dispensing of Mifeprex is limited to a videoconference.[11] This practice demonstrates a flagrant disregard for FDA safeguards.

To ensure true supervision, the FDA should require certified prescribers to be physically present when Mifeprex is dispensed so that they can appropriately examine patients and rule out contraindications to the use of Mifeprex. This requirement would be consistent with other requirements in the Mifeprex Label and REMS.

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[6] Chen MJ, Creinin MD, *Mifepristone with Buccal Misoprostol for Medical Abortion*, Obstet. Gynecol 126 (1) July 2015 12-21.
[7] Mifeprex 2016 label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.
[8] Mifeprex 2000 label, Dosage and Administration, emphasis added.
[9] Mifeprex 2016 label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.
[10] Mifeprex 2016 REMS, emphasis added, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2016-03-29_REMS_full.pdf.
[11] *See* Planned Parenthood Releases New Educational Video on Telemedicine Abortion (Feb. 6, 2018), https://www.plannedparenthood.org/about-us/newsroom/press-releases/planned-parenthood-releases-new-educational-video-on-telemedicine-abortion.

In the Mifeprex Label, the FDA emphasizes that "Mifeprex is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS)" because of the drug's "risks of serious complications." In a bold-print box, the FDA states that before prescribing Mifeprex, a provider must inform a patient: about the risks of serious events; whom to call and what to do if certain symptoms occur; and to take the Medication Guide with her if she visits an emergency room or healthcare provider who did not prescribe Mifeprex, so that she receives appropriate, informed care.[12]

Further, a provider must sign a Provider Agreement Form, attesting that he or she can:

- **Assess the duration of pregnancy accurately.**[13] Failures and complications of Mifeprex abortion increase with increasing gestational age. Mifeprex use is approved through 70 days' gestation.[14] FDA should strengthen this requirement by mandating that gestational age be accurately assessed by ultrasound in order to both ensure compliance with FDA restrictions and adequately inform the patient of gestational age-specific risks, which rise with increasing gestational age.

- **Diagnose ectopic pregnancies**[15] (*i.e.,* extrauterine pregnancy; pregnancy outside the uterus), which Mifeprex cannot end. When an ectopic pregnancy progresses, it can rupture the fallopian tube, causing bleeding, severe pain, or death. If a woman with an extrauterine pregnancy is given Mifeprex, she may believe the symptoms for ectopic pregnancy are simply the side effects of drug-induced abortion, which are similar. As of December 31, 2017, at least 97 women with ectopic pregnancies in the United States had been given Mifeprex.[16] Of these women, at least two bled to death from an undiagnosed ectopic pregnancy.[17] They likely did not recognize that their cramps, abdominal pain, and perhaps vaginal bleeding were dangerous—not side effects expected in a Mifeprex abortion.[18]

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[12] Mifeprex 2016 label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.
[13] Mifeprex Prescriber Agreement Form, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2016-03-29_Prescriber_Agreement_Form.pdf.
[14] *See* Section I.A, *supra.*
[15] Mifeprex Prescriber Agreement Form, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2016-03-29_Prescriber_Agreement_Form.pdf.
[16] Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2017, RCM # 2007-525, NDA 20-687, https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM603000.pdf).
[17] *Id.*
[18] Donna Harrison, M.D. & Michael J. Norton Testimony before the Iowa Board of Medicine, p. 3 (Aug. 21, 2013), *citing* Postmarket Drug Safety Information for Patients and Providers, Questions and Answers on Mifeprex,

- **Provide surgical intervention if needed, or has made plans to provide such care through others.**[19] He or she must assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.[20]

Clearly, a provider who does not physically meet with and examine a patient, but simply consults with the patient over the Internet, is not capable of fulfilling these requirements, or of ruling out additional contraindications (*i.e.*, circumstances that make a treatment or medication *unadvisable*) to Mifeprex use. These physical contraindications include pelvic infections, ovarian masses, cardiac arrhythmias, and liver abnormalities.[21] A physician bears responsibility to diagnose and rule out contraindications prior to Mifeprex use. It is inadequate to entrust this critical care to another healthcare provider who is not trained in diagnosis. Further, a healthcare provider who is not physically accessible to a patient cannot provide adequate follow-up care to patients, as required by the FDA Mifeprex regimen.

Thirty-four states permit only physicians to prescribe Mifeprex,[22] with nineteen states requiring the provider to be physically present with the patient.[23] For example, the law in Alabama states that the physical presence and care of a physician are necessary because "the failure and complications from medical abortion increase with advancing gestational age, because the physical symptoms of medical abortion can be identical to the symptoms of ectopic pregnancy, and because abortion-inducing drugs do not treat ectopic pregnancies but rather are contraindicated in ectopic pregnancies."[24]

Lawmakers in these states recognize that abortion providers cannot diagnose contraindications and cannot adequately care for their patients through a videoconference. Fundamentally, telemedicine "may be legitimate when it comes to discrete, document-based tasks such as reading X-rays," but it "is not the standard of care when it comes to abortion or the management of miscarriage."[25]

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https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm492705.htm.

[19] Mifeprex Prescriber Agreement Form, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2016-03-29_Prescriber_Agreement_Form.pdf.

[20] *Id.*

[21] Harrison & Norton Testimony, p. 3.

[22] Donovan MK, *Self-Managed Medication Abortion: Expanding the Available Options for U.S. Abortion Care*, Guttmacher Policy Review, Vol. 21, p. 44 (2018).

[23] *Id*.

[24] Ala. Code § 26-23E-7.

[25] Harrison & Morton Testimony, p. 19.

2. The use of Mifeprex and misoprostol for the termination of pregnancy should require three office visits by the patient.

The 2016 regimen significantly diminished doctor-patient interaction. While the 2000 Mifeprex label required three patient visits with the abortion provider, women may now obtain Mifeprex at a clinic and self-administer it at home. They are no longer required to return to the clinic for the administration of misoprostol, which prevents abortion providers from ensuring that they take the drugs at the correct times. Further, providers may now "confirm" that a patient's drug-induced abortion was successful without a clinic visit,[26] increasing the threat that Rh-negative patients will not receive administration of Rhogam, which is necessary to prevent serious risks in subsequent pregnancies.

The 2016 regimen directs that patients be given or prescribed misoprostol to take 24 to 48 hours after taking Mifeprex. However, without monitoring, a patient may take misoprostol before 24 hours have passed since she consumed Mifeprex, rendering the regimen ineffective and increasing the likelihood that she will experience a failed drug-induced abortion and require surgery.

Using buccal misoprostol sooner than 24 hours after administering mifepristone leads to a significantly increased failure rate. In one study investigating the timing of buccal misoprostol after mifepristone, nearly one out of every three to four women who took buccal misoprostol shortly after mifepristone failed to abort.[27] The failure rate ranged from 27% to 31%, depending on the pregnancy gestation.[28] Given these results, the authors of this study strongly recommended that buccal misoprostol not be taken immediately after mifepristone because of the very high abortion failure rate.[29] However, with home administration of misoprostol, healthcare providers have no control over when their patients consume the drug.

A woman may also choose to swallow misoprostol rather than keep the pill between her cheek and gum for 30 minutes, converting a "buccal" administration into an "oral" administration. An oral administration of misoprostol following the lower dose of mifepristone in the current regimen is not as effective in ending the pregnancy.

Further, waiting until 24 hours after Mifeprex to administer misoprostol does not guarantee success, and the failure rate of buccal misoprostol is higher than that under the 2000 regimen. A comprehensive systematic review and meta-analysis of the existing

[26] *See* Mifeprex 2016 label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.
[27] Lohr PA, Reeves MF, Hayes JL, Harwood B, Creinin MD, *Oral Mifepristone and buccal misoprostol administered simultaneously for abortion: a pilot study*, Contraception 76 (2007) 215-220.
[28] *Id.*
[29] *Id.*

studies of the 2016 regimen found that women who take misoprostol earlier than 48 hours after mifepristone are more likely to fail the regimen.[30]

Under the 2000 regimen, doctors were also able to provide care to patients during the most challenging and painful time in the drug-induced abortion. According to the World Health Organization, up to 90% of women will abort within 4-6 hours after taking misoprostol.[31] The 2000 regimen permitted a patient to be in a clinic for this period of time, during which she would be under the observation and care of medical personnel. This observation period is for "both patient safety and compassion. . . . This is the time when women should be in a place where their bleeding can be monitored, their vital signs can be observed by trained medical personnel, and they can receive sufficient pain medication during the most difficult part of the expulsion."[32]

Abortion complications are also more frequent when women abort at home, without the oversight of a healthcare provider. A 2018 combined retrospective and longitudinal follow-up study of complications related to induced abortion in Sweden determined that "[t]he complication frequency [of drug-induced abortion] was significantly higher among women <7 gestational weeks who had their abortions *at home*."[33]

In-person contact with a healthcare provider is critical to post-abortion care as well. Abortion providers should perform a "follow-up [physical exam] after the use of mifepristone in order to confirm abortion and rule out life-threatening infection."[34] Before FDA approved the 2016 regimen, the follow-up visit was considered "very important to confirm by clinical examination or ultrasonographic scan that a complete termination of pregnancy has occurred."[35] In fact, the 2000 label provided that "[e]ach patient must understand the necessity of completing the treatment schedule, including a follow-up visit approximately 14 days after taking Mifeprex."[36] ACOG's current policy explains that:

> Women are not good candidates for medical abortion if they … desire quick completion of the abortion process [or] are not available for follow-up contact or evaluation….[37]

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[30] Chen MJ, Creinin MD, *Mifepristone with Buccal Misoprostol for Medical Abortion*, Obstet.Gynecol 126 (1) July 2015 12-21.
[31] World Health Organization, *Safe Abortion: Technical and Policy Guidance for Health Systems* 45.
[32] Donna Harrison, M.D., Aff. *Okla. Coalition for Reproductive Justice v. Cline*, Case No. CV-2014-1886 (Feb. 24, 2015) ¶ 136.
[33] Carlsson I, Breding K, and Larsson PG, *Complications Related to Induced Abortion: a Combined Retrospective and Longitudinal Follow-up Study*, BMC Women's Health (2018) 18:158, p. 4 (emphasis added).
[34] Harrison & Norton Testimony, p. 18.
[35] Mifeprex 2000 label, Day 14: Post-Treatment Examination.
[36] Mifeprex 2000 label, Information for Patients.
[37] ACOG Practice Bulletin 143, p. 6.

In addition to ensuring for all drug-induced abortion patients that the uterus has been emptied of retained tissue and that they are not suffering from infection, the follow-up examination is particularly critical for Rh-negative patients. These patients must be administered Rhogam in order to prevent Rh isoimmunization in subsequent pregnancies. Without follow-up, women will not receive the Rhogam after the abortion, greatly increasing their risk of subsequent Rh isoimmunization, which can endanger future pregnancies.[38]

Nonetheless, abortion advocates strongly supported the reduction in required visits, and continue to advocate for the elimination of direct provider-patient contact. Gynuity Health Projects (an organization that "has been at the forefront of efforts to increase women's access to medical abortion in settings throughout the world")[39] has conducted at least three domestic and five international studies[40] on eliminating pelvic ultrasound or exam after drug-induced abortion. Following one study, researchers determined that "[s]emi-quantitative pregnancy tests … could be used in lieu of transvaginal ultrasound and/or serum hCG at clinic-based follow-up or by women themselves for home-based follow-up."[41]

In a more recent study, researchers asserted that the "common practice of scheduling a clinical contact after every medical abortion may not be necessary to ensure safety; enabling patients to determine for themselves whether or not a contact is needed can be a

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[38] ACOG Practice Bulletin 181*: Prevention of Rh D Alloimmunization* (Aug. 2017); and SOGC Clinical Practice Guidelines: *Prevention of Rh Alloimmunization* (No. 133, Sept. 2003).

[39] *See* Gynuity Health Projects, Medical Abortion, https://gynuity.org/programs/medical-abortion. Founded by Beverly Winikoff, M.D, M.P.H., in 2003, Gynuity outlines on its "Medical Abortion" page the organization's research projects, including efforts to: "Develop innovative service delivery systems through telemedicine; Simplify and de-medicalize medical abortion services; Expand access to medical abortion in the 1st and 2nd trimesters of pregnancy; Conduct clinical research to develop new abortion medications; Develop a 'missed menses pill'/menstrual regulation method; Develop additional clinical indications for mifepristone." Gynuity has launched a "coalition to expand access to mifepristone in the United States," co-created a "medical abortion commodities database," "introduce[d] medical abortion in new settings," "incorporate[ed] new clinical evidence into service guidelines," and "expanded medical abortion access through education and local champions."

[40] *See*, *e.g., Self-Assessment of Medical Abortion Outcome Using Serial Multi-level Pregnancy Tests* [NCT02570204] (Sept. 2015 – Dec. 2016), https://www.clinicaltrials.gov/ct2/show/NCT02570204?term=Self-Assessment+of+Medical+Abortion+Outcome+Using+Serial+Multi-level+Pregnancy&rank=1; *Exploring the Role of At-home Semi-Quantitative Pregnancy Tests for Medical Abortion Follow-up* [NCT01150279] (Aug. 2009 – May 2014), https://www.clinicaltrials.gov/ct2/show/NCT01150279?term=Exploring+the+Role+of+At-home+Semi-Quantitative+Pregnancy+Tests+for+Medical+Abortion+Follow-up&rank=1; *De-Medicalizing Mifepristone Medical Abortion* [NCT00120224] (May 2005 – Apr. 2007), https://www.clinicaltrials.gov/ct2/show/NCT00120224?term=De-Medicalizing+Mifepristone+Medical+Abortion&rank=1.

[41] Lynd K, et al., *Simplified Medical Abortion Using a Semi-Quantitative Pregnancy Test for Home-Based Follow-up,* Int J Gynaecol Obstet. 2013 May;121(2):144-8.

reasonable approach."[42] They reached this conclusion even with 26% of participants failing to provide sufficient follow-up information.[43]

Gynuity researchers also conducted a recent systematic review of existing studies on "the accuracy and acceptability of a strategy for identifying ongoing pregnancy after medical abortion treatment using a low-sensitivity pregnancy test (LSPT)." While the researchers acknowledged that "the LSPT strategy had *moderate* sensitivity for identifying ongoing pregnancy" and "the LSPT itself had a limited role in the detection of treatment failures [*i.e.*, ongoing pregnancy] in the studies," they stated that the "LSPT strategy shows promise for reducing the need for in-person follow-up after medical abortion. A range of home-based options should be validated to meet the varied needs of women and abortion providers in diverse settings."[44]

In reality, a de-emphasis on follow-up care increases risks of post-abortion complications. As discussed above, the 2000 regimen's requirement that women return approximately 14 days after ingesting mifepristone was considered necessary to ensure that all pregnancy tissue had been passed.[45] This determination is crucial, because retained pregnancy tissue can lead to continued bleeding and serious intrauterine infections. The return visit permits healthcare providers to ensure that a patient is not experiencing these or other complications from the abortion procedure, and that Rh negative patients are administered Rhogam to protect future pregnancies.

Abortion advocates argue that three clinic visits make accessing abortion-inducing drugs more difficult for patients with transportation challenges; however, as noted above, ACOG acknowledges that drug-induced abortion is *contraindicated* for patients who "are not available for follow-up contact or evaluation."[46] Surgical abortion is a better choice for these patients, because it "[d]oes not require follow-up in most cases."[47]

Drug-induced abortion is a longer process that requires more attention and care from healthcare providers. Three visits to a physician in the interest of patient safety should not be sacrificed for the convenience of healthcare providers or even their patients.

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[42] Raymond EG, et al., *Self-assessment of Medical Abortion Outcome Using Symptoms and Home Pregnancy Tests*, Contraception 97 (2018) 324-28.
[43] *Id.*
[44] Raymond EG, et al., *Low-sensitivity Urine Pregnancy Testing to Assess Medical Abortion Outcome: A Systematic Review*, Contraception (2018), https://doi.org/10.1016/j.contraception.2018.03.013 (emphasis added).
[45] Mifeprex 2000 label, Day 14: Post-Treatment Examination.
[46] ACOG Practice Bulletin 143, p. 6.
[47] *Id*.

C. Contraindications. Mifeprex use is contraindicated for patients who do not have convenient access to emergency medical care.

The 2000 Mifeprex Label stated:

> Because it is important to have access to appropriate medical care if an emergency develops, the treatment procedure is contraindicated if a patient does not have adequate access to medical facilities equipped to provide emergency treatment of incomplete abortion, blood transfusions, and emergency resuscitation during the period from the first visit until discharged by the administering physician.[48]

This critical language was excluded from the 2016 Mifeprex Label. Yet, studies comparing the outcome of surgical versus drug-induced abortion "have clearly demonstrated that Mifeprex abortions have a greater risk of hemorrhage, infection, continued pregnancies, retained tissue and need for emergency reoperation than surgical abortions."[49] ACOG acknowledges that "[c]ompared with surgical abortion, medical abortion takes longer to complete, requires more active patient participation, and is associated with higher reported rates of bleeding and cramping," and has lower success rates.[50]

Drug-induced abortion is optional. If a woman does not meet the criteria necessary to use abortion-inducing drugs, then surgical abortion is still an option. For women with transportation difficulties, an abortion provider can complete surgical abortion "in a predictable period of time," and the procedure "[d]oes not require follow-up in most cases."[51]

Efforts to promote abortion-inducing drugs to women in rural areas where access to emergency medical care is scarce are detrimental to women's health. It is better for a patient in a remote region to have a surgical abortion, "which requires a single visit, and is less likely to result in serious or life-threatening complications."[52]

[48] Mifeprex 2000 label, Contraindications.
[49] Harrison Aff. ¶ 115.
[50] ACOG Practice Bulletin 143, p. 3 & Box 1.
[51] *Id.*
[52] Harrison & Norton p. 9.

D. Adverse Event Reporting. Certified prescribers, emergency medical personnel, physicians treating complications, and Danco Laboratories should report to FDA's MedWatch Reporting system any deaths, hospitalizations, blood transfusions, emergency room visits, failures requiring surgical completion, ongoing pregnancy, or other major complications following the use of Mifeprex and misoprostol.

The 2016 regimen dramatically reduced accountability for Mifeprex providers by limiting adverse event reporting (AER) requirements, a critical safety mechanism.[53] While prescribers were required to report any serious adverse event associated with Mifeprex under the 2000 label, they are now required to report only deaths associated with Mifeprex.

Even with the 2000 regimen requirements, collecting accurate and complete adverse event information was highly difficult. Adverse events were often not reported or were interpreted by emergency health care providers as the results of spontaneous abortion.[54] The Mifeprex label instructs prescribers to "[a]dvise the patient to take the Medication Guide with her if she visits an emergency room or a healthcare provider who did not prescribe Mifeprex, so that the provider knows that she is undergoing a medical abortion."[55] Yet, many Mifeprex prescribers violate FDA protocol, instructing their patients to lie to emergency medical personnel. The organization Aid Access instructs patients that if they need to go to an emergency room:

> You do not have to tell the medical staff that you tried to induce an abortion; you can tell them that you had a spontaneous miscarriage. Doctors have the obligation to help in all cases and know how to handle a miscarriage. The symptoms of a miscarriage and an abortion with pills are exactly the same and the doctor will not be able to see or test for any evidence of an abortion, as long as the pills have completely dissolved.[56]

Such deception prevents emergency healthcare providers from appropriately caring for their patients, and further decreases the likelihood that adverse events will be reported.

With reduced AER reporting requirements under the 2016 label, what was previously difficult is now virtually impossible. The FDA cannot adequately assess the safety of the current Mifeprex regimen without comprehensive information on adverse events. AERs are the only objective means by which FDA has any data whatsoever on the effects of the

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[53] Mifeprex 2016 label.
[54] *See* GAO-18-292, pp 24-25.
[55] Mifeprex 2016 label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.
[56] Aid Access, *How do you know if you have complications, and what should you do?*, https://aidaccess.org/en/page/459/how-do-you-know-if-you-have-complications-and-what-should-you-do.

Mifeprex regimen on women, and the voluntary and minimal nature of the current AERs means that FDA has no accurate information about the actual number of women injured by drug-induced abortion, or the nature of complications caused by this drug.

After prescribing Mifeprex and misoprostol, certified prescribers should at minimum be required to report the following directly to the FDA Medwatch reporting system, copying Danco Laboratories: deaths, hospitalizations, blood transfusions, emergency room visits, failures requiring surgical completion, ongoing pregnancy, or other major complications. Detailed information must also be included, such as pulse, blood pressure, temperature, pre- and post-transfusion hemoglobin/hematocrit, white blood count, number of units of blood transfused, surgeries, and any other pertinent laboratory or hospital course information, as well as emergency room and hospital discharge diagnoses.

Further, FDA should provide guidance to emergency healthcare providers and physicians responsible for treating complications so that they know how to distinguish complications following drug-induced abortion from complications following spontaneous miscarriage. The guidance should also instruct these providers on how to report adverse events.[57]

The abysmal quality of the current AERs received from Danco Laboratories shows the lack of concern that Danco has demonstrated for the safety of the women who have undergone drug-induced abortion. Responsible reporting is a fundamental safety mechanism that should not be sacrificed in the interest of convenience for abortion providers.

E. Additional Studies. The Mifeprex REMS should require a formal study of outcomes for at-risk populations, including: patients under the age of 18; patients with repeat Mifeprex abortions; patients who have limited access to emergency room services; and patients who self-administer misoprostol.

Mifeprex was approved for use in the pediatric population in 2000 after the FDA waived, without explanation, the requirement for studies in the pediatric population. The developmental stage of puberty involves a complex interplay of both progesterone and estrogen effects on the developing female reproductive system. The use, and especially the potential multiple use, of Mifeprex, which is a powerful progesterone blocker, is

[57] The Self-Induced Abortion Legal Team has created a document titled "Self-Induced Abortion and the Law: What Emergency Room Staff Need to Know." This document heavily emphasizes patient privacy requirements, including the penalties that healthcare providers may face if they disclose patient information. While these concerns are valid, emergency healthcare providers should also have training on public health reporting requirements and how such reporting does not violate HIPAA or other laws regarding patient privacy. *See,* https://www.sialegalteam.org.

likely to significantly impact the developing reproductive system of the adolescent female.[58] It is irresponsible to allow the continued uninvestigated use of Mifeprex in the pediatric female population[59] without requiring long-term studies on the impact of Mifeprex use on pubertal development.

More than one out of every three abortions in the U.S. is a repeat abortion.[60] The repeat use of Mifeprex has been associated in some studies with adverse reproductive health outcomes in future wanted pregnancies.[61] This concern requires further study.

The adverse events of hemorrhage, retained tissue, and infection are common after Mifeprex use. The hemorrhage is often significant enough to warrant transfusion. When patients lack access to emergency medical facilities, such complications could easily translate to deaths. Thus a study of deaths and of severe hemorrhages requiring transfusion should be done to compare outcomes in women with and without access to emergency medical facilities.

II. RETAIN THE MIFEPREX RISK EVALUATION AND MITIGATION STRATEGY (REMS), AND CONTINUE LIMITING THE DISPENSING OF MIFEPREX TO PATIENTS IN CLINICS, MEDICAL OFFICES, AND HOSPITALS, BY OR UNDER THE SUPERVISION OF A CERTIFIED PRESCRIBER.

A. Retain the Mifeprex REMS.

Mifeprex, when used for abortion, is subject to a Food and Drug Administration (FDA) *Risk Evaluation and Mitigation Strategy* (REMS) with *elements to assure safe use* (ETASU). FDA determined that the Mifeprex REMS is necessary to ensure the safety and efficacy of the drug, because it carries risks of life-threatening hemorrhage, infection, continued pregnancy, retained tissue, need for emergency surgery, and death. The approved Mifeprex regimen includes the use of another potent drug, misoprostol, which carries its own risks.

Under the Mifeprex REMS with ETASU, a healthcare provider must be certified to prescribe Mifeprex by reviewing the prescribing information and completing a

[58] Arain M, et al., *Maturation of the adolescent brain*, Neuropsychiatric Disease and Treatment, 2013:9 449-461.
[59] Because of their immaturity, minors are also less likely to understand the importance of following prescriber instruction or of recognizing when they need to seek emergency medical treatment.
[60] Jones R, et al., *Which Abortion Patients Have Had a Prior Abortion? Findings from the 2014 U.S. Abortion Patient Survey*, Journal of Women's Health, DOI: 10.1089/jwh.2017.6410 (2014).
[61] Fang L, et al., *Repeated Abortion Affects Subsequent Pregnancy Outcomes in BALB/c Mice*, PLoS ONE 7(10): e48384. doi:10.1371/journal.pone.0048384 (2012).

"Prescriber Agreement Form," attesting that they can: assess the duration of pregnancy accurately; diagnose ectopic pregnancies; and provide surgical intervention in cases of incomplete abortion or severe bleeding, or designate someone else to provide that care. Further, they must agree to follow the guidelines for use of Mifeprex.

The REMS also requires Mifeprex to "be dispensed to patients only in certain healthcare settings, specifically clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber." Mifeprex may not be distributed or dispensed through retail pharmacies. Also, a patient must sign a "Patient Agreement Form" and be fully informed of the risks by a certified prescriber. She must receive the Mifeprex Medication Guide, informing her that she needs a "follow-up assessment" 7 to 14 days after she has taken Mifeprex to ensure that she is well and has terminated her pregnancy.[62]

The REMS remains the lone safeguard to monitor and mitigate the risks of death and adverse events from the Mifeprex regimen. Gynuity Health Projects and researchers from the University of California, San Francisco (UCSF) obtained approval from FDA through Investigational New Drug Applications (INDs) to conduct studies that *do not* comply with the Mifeprex REMS. They intend to use the results of these studies to press for the elimination of the Mifeprex REMS.[63] [See Section II.B, below.]

The Mifeprex Medication Guide acknowledges that serious risks accompany FDA's approved regimen for drug-induced abortion, which includes the use of Mifeprex and another potent drug, misoprostol. The document improperly downplays the risks, however, stating that "*rarely*, serious and potentially life-threatening bleeding, infections, or other problems can occur following . . . medical abortion." Specifically, "in about 1 out of 100 women [administered Mifeprex and misoprostol] bleeding can be so heavy that it requires a surgical procedure."[64]

In fact, the internationally used criteria for reporting complications from drugs demonstrate that complications from drug-induced abortions are common, not rare. The Council for International Organizations of Medical Sciences (CIOMS)[65] defines the word

[62] GAO-18-292, pp 4-7 (2018); Mifeprex Risk Evaluation and Mitigation Strategy (REMS), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2016-03-29_REMS_full.pdf; 21 U.S.C. § 355-1; Mifeprex Medication Guide, https://www.fda.gov/downloads/Drugs/DrugSafety/ucm088643.pdf.
[63] *See* Daniel Grossman, MD, Research Protocol: *Alternative Provision of Medication Abortion via Pharmacy Dispensing*, Version #:1.3 (July 17, 2018) p. 14.
[64] Mifeprex Medication Guide, https://ww.w.fda.gov/downloads/Drugs/DrugSafety/ucm088643.pdf.
[65] The Council for International Organizations of Medical Sciences (CIOMS) is an international, non-governmental, nonprofit organization established jointly by WHO and UNESCO in 1949. Through its membership, CIOMS is representative of a substantial proportion of the biomedical scientific community. In 2013, the membership of CIOMS included 49 international, national, and associate member organizations, representing many of the biomedical disciplines, national academies of sciences, and medical research councils.

"rare" in adverse event reporting as an event that happens in between "1 out of 1,000" to "1 out of 10,000" uses. "Common" is the uniform term used for events that happen in between "1 out of 10" to "1 out of 100" uses.[66] Given that "about 1 out of 100 women" using Mifeprex/misoprostol require surgery, serious complications are common, not rare.[67]

Also, as discussed in Section I.C above, Mifeprex abortions carry greater risks than surgical abortions.[68] A study of over 42,000 women in Finland who had abortions from 2000 to 2006 found that "overall, medical abortion had roughly four times the rate of adverse events than surgical abortion, and hemorrhaging was experienced by 16 percent of medical abortion patients compared with 2 percent of surgical abortion patients."[69]

A combined retrospective and longitudinal follow-up study of complications related to induced abortion in Sweden published in 2018 determined that the share of complications related to drug-induced abortions at less than 12 weeks *increased* significantly during 2008-2015 without an evident cause. The increase was from 4.2% in 2008 to 8.2% in 2015, with incomplete abortion as the most common complication related to drug-induced abortions at less than 12 weeks.[70]

Abortion advocates are also attacking the REMS by advocating for mifepristone use in spontaneous miscarriage management. In a small recent study, researchers compared the efficacy and safety of using mifepristone with misoprostol for the management of early miscarriages to using misoprostol alone.[71] Notably, 6-10% of study participants had a gestational age of "4-5 weeks gestation."[72] It is not clear from the authors how participants of that gestational age could meet the published guidelines for diagnosis of non-viable pregnancy recently published by the Society of Radiologists in Ultrasound multispecialty consensus panel.[73] The panel requires the crown-rump length cutoff to 7 mm for embryos without a heartbeat and the mean sac diameter cutoff to 25 mm for

[66] CIOMS training manual on medicine safety, http://www.who.int/medicines/areas/quality_safety/safety_efficacy/trainingcourses/definitions.pdf.
[67] *See* Mifeprex Medication Guide; CIOMS training manual on medicine safety, *supra.*
[68] *See* Harrison Aff. ¶ 115; ACOG Practice Bulletin 143, p. 3 & Box 1.
[69] GAO-18-292, p. 25, *discussing* Niinimaki M, et al., *Immediate Complications after Medical Compared with Surgical Termination of Pregnancy,* Obstetrics & Gynecology, vol. 114, no. 4 (October 2009): 795-804.
[70] Carlsson I, Breding K, and Larsson PG, *Complications Related to Induced Abortion: A Combined Retrospective and Longitudinal Follow-up Study*, BMC Women's Health (2018) 18:158.
[71] Schreiber CA, et al, *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, N Engl J Med 2018; 378:2161-70.
[72] *Id.* Table 1.
[73] Doubilet PM, Benson CB, Bourne T, et al., *Diagnostic criteria for nonviable pregnancy early in the first trimester*, N Engl J Med 2013; 369:1443–1451.

"empty" sacs, in order to minimize interventions that "interrupt a pregnancy that otherwise would have had a normal outcome."[74]

The authors admit that the study "was not powered to show differences between groups in the proportions of serious adverse events,"[75] an important consideration prior to recommending a change in spontaneous abortion management protocols. Yet, the authors incorrectly stated "such events were rare."[76] Table 3 gives a total number of serious adverse events as 3.4% for the mifepristone pretreatment group, and 2.0% for the misoprostol alone group.[77] Under the CIOMS criteria for reporting complications from drugs, discussed above, the rate of 2%-3.4% of adverse events in each study arm demonstrates clearly that adverse events are common, not rare, in both misoprostol alone and mifepristone + misoprostol miscarriage management.

Further, the Mifeprex + misoprostol arm raises a concern about the need for further study of adverse events, especially hemorrhage. Mifepristone is known to inhibit endometrial hemostasis (*i.e.*, arrest of bleeding),[78] as demonstrated by many reports of hemorrhage with transfusions reported to the FDA after use of mifepristone and misoprostol for elective abortions.[79]

Of additional concern is the vaginal route of administration of misoprostol. After reports of overwhelming sepsis following vaginal administration of misoprostol, Planned Parenthood changed the route of administration of misoprostol from vaginal to buccal,[80] with subsequent decrease in reported infections. Animal studies have demonstrated that both mifepristone[81] and misoprostol[82] can profoundly suppress innate immunity and the ability to fight infections.

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[74] Hu M, Poder L, Filly R, *Impact of New Society of Radiologists in Ultrasound Early First-Trimester Diagnostic Criteria for Nonviable Pregnancy*, J Ultrasound Med 2014; 33:1585–1588.
[75] Schreiber, *supra* p. 2168.
[76] *Id.*
[77] *Id.* p. 2169.
[78] Miech RP, *Pathopharmacology of excessive hemorrhage in mifepristone abortions*, Ann Pharmacother 2007 Dec; 41(12):2002-7.
[79] Gary MM, Harrison DJ. "Analysis of severe adverse events related to the use of mifepristone as an abortifacient." Ann Pharmacother. 2006 Feb;40(2):191-7; Food and Drug Administration "Mifepristone U.S. Postmarketing Adverse Events Summary" 2011, https://www.minnpost.com/sites/default/files/attachments/Mifeprex_April2011_AEs.pdf.
[80] Fjerstad M, Trussell J, Sivin I, Lichtenberg ES, Cullins V, *Rates of Serious Infection after Changes in Regimens for Medical Abortion*, N Engl J Med 2009; 361:145-51.
[81] Sternberg EM, Hill JM, Chrousos GP, Kamilaris T, Listwak SJ, Gold PW, Wilder RL, *Inflammatory mediator-induced hypothalamic-pituitary-adrenal axis activation is defective in streptococcal cell wall arthritis-susceptible Lewis rats*, Proc Natl Acad Sci U S A. 1989 Apr;86(7):2374-8; Miech RP, *Pathophysiology of mifepristone-induced septic shock due to Clostridium sordellii*, Ann Pharmacother. 2005 Sep;39(9):1483-8. Epub 2005 Jul 26.
[82] Aronoff DM et al., *Misoprostol impairs female reproductive tract innate immunity against clostridium sordellii*, 180 J. Immunol. 8222-8230 (2008).

Despite the clear methodological errors, including a failure to accurately diagnose fetal death according to accepted criteria as well as lack of adherence to the stated inclusion criteria, and despite the absence of power to evaluate safety, abortion advocates are calling for the routine use of mifepristone to manage spontaneous miscarriages.[83] Any change in spontaneous miscarriage management with mifepristone should require an FDA New Drug Application (NDA) with two randomized controlled trials (RCTs) comparing the arms of mifepristone and misoprostol, misoprostol alone, surgical management, and expectant management. Without blinded RCTs to evaluate not only efficacy but also safety, it is premature to remove the REMS for Mifeprex to facilitate mifepristone access for spontaneous miscarriage management.

Despite the presence of serious risks and contraindications to the Mifeprex regimen, Gynuity, the University of California, San Francisco (UCSF), and other abortion advocates want the FDA to eliminate the remaining safeguards that were enacted to ensure the safety and efficacy of Mifeprex. They are pursuing their goals through publication, advocacy, litigation,[84] and/or controversial research enabled by FDA.[85]

Further, as Section II.B below explains, lifting the REMS is only the starting point for abortion advocates.

B. Continue limiting the dispensing of Mifeprex to patients in clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber.

1. Mifeprex should be dispensed only in clinics, medical offices, and hospitals.

The Mifeprex REMS requires that Mifeprex "be dispensed to patients only in clinics, medical offices and hospitals, by or under the supervision of a certified prescriber." That prescriber must be capable of assessing the duration of a pregnancy accurately, diagnosing ectopic pregnancies, and providing or referring for surgical intervention in cases of incomplete abortion or hemorrhaging.[86]

Abortion advocates, however, want the FDA to permit healthcare providers to prescribe Mifeprex to pregnant patients over the Internet or phone, with the drug available at pharmacies or through the mail, and through advance provision (*i.e.*, before a patient is pregnant). Eliminating or relaxing the REMS to facilitate Internet or telephone prescriptions would be dangerous to women and adolescent girls. Healthcare providers

[83] Molly Walker, *Mifepristone: Better for Managing Early Miscarriage*, Medpage Today, (June 6, 2018), https://www.medpagetoday.com/obgyn/pregnancy/73336.
[84] *Chelius v. Azar*. CIV. NO. 1:17-cv-00493-DKW-KSC (Dist. Ct. HI 2018).
[85] See Section II.B, below.
[86] Mifeprex Risk Evaluation and Mitigation Strategy (REMS), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2016-03-29_REMS_full.pdf.

prescribing abortion-inducing drugs over the Internet or phone or before a patient is even pregnant cannot adequately evaluate patients for contraindications to the drugs.[87] Further, as discussed above, Rh-negative patients must be administered Rhogam in order to prevent Rh isoimmunization in subsequent pregnancies. Without direct patient contact, women will not receive the Rhogam after the abortion, greatly increasing their risk of subsequent Rh isoimmunization, which can endanger future pregnancies.[88] [See Section I.B.2, *supra*.]

Telemedicine abortion further distances women from the practitioners responsible for caring for them, and approval by FDA would further absolve abortion providers of responsibility for the well-being of their patients. Promoting telemedicine abortion to women and adolescent girls in rural areas with limited access to healthcare is extremely dangerous—they will have little recourse if they face known and predictable emergency complications such as severe hemorrhage.[89]

Nonetheless, Gynuity Health Projects and researchers from UCSF obtained approval from FDA through Investigational New Drug Applications (INDs) to conduct studies that *do not* comply with the Mifeprex REMS. They will use the results of these studies to press for the elimination of the Mifeprex REMS.

a. The "TelAbortion" Direct-to-Consumer Mifeprex Study

Gynuity Health Projects is the sponsor of the study "Feasibility of Medical Abortion by Direct-to-Consumer Telemedicine."[90] Gynuity filed an IND with the FDA.[91] The status is listed as "recruiting," with age eligibility that includes 11-year-old children and an estimated enrollment of 1,000 participants at five locations.[92] The start date is listed as March 22, 2016, and the estimated completion date was extended from June 2018 to June 2019.

The study's brief summary states: "This pilot study is designed to obtain preliminary data on the safety, acceptability, and feasibility of direct-to-consumer telemedicine

[87] Harrison & Norton Testimony, p. 2.
[88] ACOG Practice Bulletin 181*: Prevention of Rh D Alloimmunization* (Aug. 2017); and SOGC Clinical Practice Guidelines: *Prevention of Rh Alloimmunization* (No. 133, Sept. 2003).
[89] Harrison & Norton Testimony, p. 9.
[90] (NCT02513043), https://www.clinicaltrials.gov/ct2/show/NCT02513043?term=NCT02513043&rank=1.
[91] Raymond EG, Chong E, & Hyland P, *Increasing Access to Abortion with Telemedicine*, JAMA Internal Medicine Vol. 176, N. 5 (May 2016).
[92] Hawaii – University of Hawaii Women's Options Center; Maine – Maine Family Planning; New York – Choices Women's Medical Center (active, but not recruiting according to ClinicalTrials.gov, and not listed on TelAbortion.org); Oregon and Washington – Planned Parenthood Columbia Willamette; Oregon Health and Sciences University Women's Health Research Unit. Washington State patients may also participate because an Oregon abortion provider is also licensed in Washington State. Claire Lampen, *Webcam Abortion Services Offer Crucial Access—So What's Stopping them?* Gizmodo (Apr. 17, 2018).

abortion."[93] The study's website states that "[a] TelAbortion involves all the same steps and procedures as a regular medical abortion, but you do them without going into an abortion clinic."[94]

Women who participate in the study have a video "evaluation" with the study abortion provider over the Internet, during which they can ask questions, provide medical history, and learn about the pre-abortion tests that they need. They also electronically sign consent forms for the study. Afterwards, they are required to obtain the tests and direct the reports to be sent to the study provider.

Once a patient is determined eligible, the study provider will send her a package containing Mifeprex and misoprostol, with instructions that she must follow on her own. She is also instructed to have additional tests to verify that the abortion is complete, and later have another consultation with the study provider to review the results.[95]

Obviously, a woman may *not* take the abortion drugs in the manner prescribed, nor obtain the follow-up care that is recommended. With a doctor-patient relationship limited to online chats, she has virtually no accountability or support as she navigates a complicated procedure. The responsibility of the provider of the drugs to follow up with the patient is obviated as well.

b. The Mifeprex through Pharmacy Dispensing Study

The University of California, San Francisco (UCSF) is the sponsor of the "Alternative Provision of Medication Abortion via Pharmacy Dispensing" study.[96] Daniel Grossman, M.D., with UCSF is listed as the study's "responsible party."[97] Like Gynuity, UCSF filed an IND with the FDA to obtain authorization for this study.[98] The status is listed as "recruiting," with July 2019 as the estimated completion date. The sponsors plan to recruit 300 patients at four study clinic sites and survey 50 pharmacists at associated study pharmacy sites.[99]

[93] NCT02513043, https://www.clinicaltrials.gov/ct2/show/NCT02513043?term=NCT02513043&rank=1.
[94] TelAbortion: The Telemedicine Abortion Study: FAQs, http://telabortion.org/faq/.
[95] *Id.*
[96] NCT03320057, https://www.clinicaltrials.gov/ct2/show/NCT03320057?term=NCT03320057&rank=1; Daniel Grossman, MD, Research Protocol: *Alternative Provision of Medication Abortion via Pharmacy Dispensing*, Version #:1.3 (JUL. 17, 2018) p. 5.
[97] *Id.*
[98] In a May 2018 phone conversation with a contact for the UCSF study, she stated that the study was approved through an IND application with FDA.
[99] Grossman, pp. 5-7; 16-17.

The stated aim of the study is to "investigate the feasibility, acceptability, and effectiveness of pharmacy dispensing of Mifeprex; safety data will also be collected. . . . *The results of this study eventually could lead to changes in the Mifeprex REMS. . . .*"[100]

The sponsors intend to measure "pharmacist satisfaction with dispensing Mifeprex and the proportion of pharmacists who refuse to dispense the medication to patients." They secondarily intend to assess patient satisfaction, describe clinical outcomes, including effectiveness and adverse events, and compare pharmacists' knowledge about medication abortion before and after.[101]

Patients enroll at one of the study clinic sites on Day 1, where they choose medication abortion, have an ultrasound if one has not been done, and obtain pre-abortion counseling. They then are prescribed Mifeprex, misoprostol, and anything else necessary to be filled at the associated study pharmacy site.[102] Some patients have serum hCG measured on the day of Mifeprex administration and again around eight days later "to assess for completion of the abortion."[103] The "follow-up" for patients "may include a follow-up visit or a phone call from clinic staff approximately 7-14 days after the initial visit."[104] However, as discussed extensively above, a clinician needs to perform an exam to rule out retained tissue—even if the patient has a negative serum hCG. A phone call that "may" be placed, or fail to connect, is not enough.

Notably, "[a]ll except one of [the participating] pharmacies is [sic] located within the same building as the clinic…."[105] While UCSF is using a community pharmacy not affiliated with the University, the other three study clinic sites are using affiliated pharmacies.[106]

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[100] Grossman, p.14 (emphasis added). The sponsors dubiously assert that "pharmacy dispensing could [] help increase the number of clinicians willing and able to provide medication abortion by enabling them to avoid the associated costs and logistical challenges of stocking and dispensing the medication at their facilities." They reference a survey of Fellows of the American College of Obstetricians and Gynecologists that sought to determine if doctors not presently practicing abortion would prescribe Mifeprex if their patients could obtain the drug at a pharmacy. Fifty-four percent responded to the survey. Seventy-seven percent of respondents *do not* perform abortions and nine percent perform surgical abortions only—of those, 19% said they would prescribe Mifeprex if it could be obtained at a pharmacy, and an additional 18% said they were unsure. Based on this, the sponsors claim "the proportion of obstetrician-gynecologists providing [Mifeprex] would at least double (from 14% to 29%) "if the dispensing restriction in the REMS were removed and physicians could write a prescription for Mifeprex that could be dispensed at a pharmacy." The fact that 46 percent of the fellows surveyed did not take the time to respond, however, places this conclusion in doubt. *See* Grossman, pp. 12-14.
[101] Grossman, pp. 15-16.
[102] Grossman, p. 23.
[103] Grossman, p. 23.
[104] Grossman, p. 24.
[105] Grossman, p. 20.
[106] Grossman, pp 16-17.

While the rationale for the study states that pharmacy dispensing of Mifeprex could "help facilitate provision of medication abortion through telemedicine,"[107] the sponsors emphasize that the only difference between this study and FDA protocol "is that the patient would obtain the mifepristone directly from the pharmacist, rather than in a clinic facility."[108] In fact, the schedules for the participating pharmacists are "mapped" to "ensure that trained pharmacists are available to dispense to study participants during business hours."[109]

The following demonstrates the extensive assistance that the sponsors offer patients in obtaining the drugs from the participating pharmacies:

> [The patient] will be told that only a limited number of pharmacies are able to dispense Mifeprex and given information about how to get to the participating pharmacy (as well as the hours during which a participating pharmacist will be working, if needed). If there are any gaps in staffing at the pharmacy, the patient will be notified of the timing of those gaps in coverage before leaving the clinic via the pharmacy directions/handout. If this will be an issue for the patient, a solution will be found at the clinic before the patient leaves or she will not be enrolled in the study. Patients will be told that if they have any problems accessing the medications at the clinic, they should come back to the clinic [where they can obtain Mifeprex].[110]

While this assistance may ensure that the study does not deviate dramatically from FDA protocol, the study *certainly* does not model the experience a patient would have outside of this controlled environment—particularly a patient who obtains Mifeprex through telemedicine and has no physical contact with her prescriber.

The physical proximity of the study pharmacy sites to the study clinic sites, the probable professional associations between participating doctors and pharmacists, and the extensive assistance offered by the clinics to ensure that patients access abortion-inducing drugs at participating pharmacies, raise questions as to whether the study is fundamentally biased and will inaccurately forecast widespread behavior and experiences if the REMS is removed. Therefore, any results of the study cannot provide a justification for permitting pharmacy distribution of Mifeprex, much less abortion through telemedicine.

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[107] Grossman, p. 6.
[108] Grossman, p. 6.
[109] Grossman, p. 18.
[110] Grossman, pp. 19-20.

Further, as discussed below, eliminating the REMS to enable pharmacy dispensing of Mifeprex is only the beginning of a long-term strategy to achieve over-the-counter status for Mifeprex, further diminishing patient care and abortion provider accountability.

c. Beyond the Current Studies

A recent article by Dr. Grossman and colleagues reveals that they want Mifeprex access extended even beyond the parameters contained in their Pharmacy Dispensing study. They used an online survey to gauge women's "personal interest in and general support for three alternative methods for accessing abortion pills: (1) in advance from a doctor for future use, (2) over-the-counter (OTC) from a drugstore and (3) online without a prescription."[111]

None of the options in the survey require a healthcare provider to provide patient care comparable to even the *inadequate* care provided in the two studies discussed above. Only the first option requires a prescription from a doctor; however, the doctor would not know in advance when his patient actually becomes pregnant and chooses to use the drugs. The survey disingenuously stated that "[m]edication abortion, or the abortion pill, is a safe and effective way to terminate a pregnancy up to 10 weeks," without informing participants of a single risk associated with the regimen.[112]

Further, in a November, 21, 2018 op-ed, Dr. Grossman advocated for providing abortion pills before women are pregnant. He stated:

> The idea is simple: Give women abortion pills *before* they need them – "advance provision," as it's known – so that they can take them as soon as they discover a pregnancy. Women could get the pills from their gynecologist at the time of their annual exam, say, or the pills could be made available online.[113]

Incredibly, Dr. Grossman stated that he has "few medical concerns about handing out abortion pills in advance."[114] He asserts that evidence from advance provision research "could strengthen the case for making [abortion-inducing drugs] available without a prescription."[115]

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[111] Biggs MA, et al, *Support for and interest in alternative models of medication abortion provision among a national probability sample of U.S. women,* Contraception (2018), https://doi.org/10.1016/j.contraception.2018.10.007.
[112] *See id.*
[113] Daniel Grossman, *American women should have access to abortion pills before they need them*, Los Angeles Times (Nov. 21, 2018).
[114] *Id.*
[115] *Id.*

In addition to his failure to address all of the dangers posed by abortion-inducing drugs, Dr. Grossman does not acknowledge the risk that women will share their abortion-inducing pills with other women. While an abortion provider may screen his patient for contraindications to Mifeprex, nothing will stop his patient from giving her stored Mifeprex to a friend who is unaware that she is Rh negative, for instance, which poses health risks for future pregnancies (See section I.B.2, *supra*).

In fact, Dr. Grossman's research program has listed a study titled "Alternative Provision of Medication Abortion Via Advance Provision" on ClinicalTrials.gov, with May 2019 listed as the estimated study start date.[116] In the study, patients who are "at risk of unintended pregnancy and with a desire to avoid pregnancy will be assessed by a clinician and provided counseling on pregnancy recognition and testing, as well as how to administer [drug-induced abortion] at home." They will then receive Mifeprex and misoprostol while *not* pregnant. If/when the patient becomes pregnant and wants to take the drugs, she is instructed to contact a study clinician for an "over-the-phone assessment of eligibility" for drug-induced abortion, "including evaluation of contraindications and gestational age" before taking the drugs, and "then attend a follow-up visit with the clinician."[117] However, it is impossible for the study sponsors to truly assess the patient for contraindications, verify gestational age, prevent patients from sharing the drugs with others, or ensure that patients attend a follow-up visit.

In a 2018 Policy Review, the Guttmacher Institute also advocated for lifting the Mifeprex REMS. However, the article did not stop there. The author argues:

> [w]hile lifting the REMS on mifepristone would open new possibilities for medication abortion access, stopping there would fall short of realizing the full potential of this method, particularly when it comes to self-managed abortion care. In a self-management model, anyone who needs to terminate a pregnancy would be able to legally access mifepristone and misoprostol without a requirement to see a health care provider or pharmacist first. . . . To fully integrate self-managed medication abortion with existing abortion practices in the United States, misoprostol and mifepristone must first become available without a prescription.[118]

These recent publications demonstrate how abortion advocates will continue to pressure FDA to eliminate the REMS and move towards over-the-counter access for Mifeprex. In spite of the serious risks and contraindications to the Mifeprex regimen, abortion advocates will not rest until Mifeprex is available to all, without a prescription

[116] NCT03829696, https://clinicaltrials.gov/ct2/show/NCT03829696?term=NCT03829696&rank=1.
[117] *Id.*
[118] Donovan MK, *Self-Managed Medication Abortion: Expanding the Available Options for U.S. Abortion Care*, Guttmacher Policy Review, vol. 21 (2018).

or mandatory medical management of any kind. The FDA's vigilance in protecting women from such negligence is critically important.

2. Mifeprex Prescribers Should be Certified.

The 2016 regimen requires Mifeprex prescribers to be certified as qualified. This is simply common sense—only healthcare providers qualified to prescribe an abortion-inducing drug should do so. The prescriber form attests that the healthcare provider must be able to assess pregnancy duration, diagnose ectopic pregnancy, and provide or refer for surgical intervention if necessary.

Given that drug-induced abortion is contraindicated beyond 10 weeks' gestation and when the pregnancy is not in the uterus, and that *at least* 1 out of 100 women using Mifeprex need surgery,[119] these qualifications are entirely logical. Yet, abortion advocates, ignoring the best interests of their patients, claim such restrictions are onerous.[120]

CONCLUSION

The Mifeprex REMS with ETASU remains critical for patient safety. Mifeprex carries risks of life-threatening hemorrhage, infection, continued pregnancy, retained tissue, need for emergency surgery, and death. The 2000 regimen provided significantly more protections for patients than the 2016 regimen. FDA should restore and strengthen elements of the Mifeprex regimen and provider requirements, including: limiting Mifeprex use to 49 days' gestation; requiring that Mifeprex be administered only by or under the supervision of a physically present physician; requiring three office visits by a patient who has been prescribed Mifeprex; clarifying that Mifeprex use is contraindicated for patients who do not have convenient access to emergency medical care; expanding mandatory adverse event reporting; and requiring additional studies of Mifeprex use in at-risk populations.

At the very least, FDA should not further erode patient protections. The agency should retain the Mifeprex REMS, and continue limiting the dispensing of Mifeprex to patients in clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber.

[119] Mifeprex Risk Evaluation and Mitigation Strategy (REMS), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2016-03-29_REMS_full.pdf.
[120] Mifeprex REMS Study Group, *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, N Engl. J. Med. 376;8 (Feb. 23, 2017).

C. Environmental Impact

This petition is categorically excluded under 21 C.F.R. § 25.30.

D. Economic Impact

Available upon Commissioner's request, pursuant to 21 C.F.R. §10.30(3).

E. Certification

The undersigned certify, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners, which are unfavorable to the petition.

Signature: /s/ Donna J. Harrison M.D., Executive Director

Name of petitioner: American Association of Pro-Life Obstetricians and Gynecologists

Mailing address: PO Box 395, Eau Claire, MI 49111-0395

Telephone number: (202) 230-0997

Signature: /s/ Quentin L. Van Meter, M.D., FCP, President

Name of petitioner: American College of Pediatricians

Mailing address: PO Box 357190, Gainesville, FL 32635-7190

Telephone number: (352) 376-1877

EXHIBIT 30

ANDA Approval Letter from FDA to GenBioPro (Apr. 11, 2019)

ADMINISTRATION

ANDA 091178

ANDA APPROVAL

(b) (6), (b) (4)
GenBioPro, Inc.
(b) (6), (b) (4)
Attention: (b) (6), (b) (4)

Dear Sir:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on February 3, 2009, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Mifepristone Tablets, 200 mg.

Reference is also made to the complete response letter issued by this office on February 23, 2018, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the ANDA is **approved**, effective on the date of this letter. The (b) (6) has determined your Mifepristone Tablets, 200 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Mifeprex Tablets, 200 mg, of Danco Laboratories, LLC.

Under section 506A of the FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

Section 505-1 of the FD&C Act authorizes FDA to require the submission of a risk evaluation and mitigation strategy (REMS), if FDA determines that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks [section 505-1(a)]. In accordance with section 505-1(i) of the FD&C Act, a drug that is the subject of an ANDA under section 505(j) is subject to certain elements of the REMS required for the applicable listed drug.

The details of the REMS requirements were outlined in our letter dated June 15, 2011. In that letter, you were also notified that pursuant to section 505-1(i) of the FD&C Act, a drug that is the subject of an ANDA and the listed drug it references must use a single, shared system for elements to assure safe use (ETASU), unless FDA waives that requirement.

Your REMS, known as the Mifepristone REMS Program, submitted on May 30, 2017; is approved, and will be posted on the FDA REMS website: http://www.fda.gov/rems

The REMS consists of ETASU and an implementation system.

Your REMS must be fully operational before you introduce Mifepristone Tablets, 200 mg, into interstate commerce.

The Mifepristone REMS uses a single, shared system for the ETASU. This single, shared system REMS Program currently includes the products listed on the FDA REMS website, available at http://www.fda.gov/rems. Other products may be added in the future if additional NDAs or ANDAs are approved.

Under section 505-1(g)(2)(C) of the FD&C Act, FDA can require the submission of a REMS assessment if FDA determines an assessment is needed to evaluate whether the REMS should be modified to ensure the benefits of the drug outweigh the risks or to minimize the burden on the healthcare delivery system of complying with the REMS.

We remind you that you must include an adequate rationale to support a proposed REMS modification for the addition, modification, or removal of any goal or element of the REMS, as described in section 505-1(g)(4) of the FD&C Act.

We also remind you that section 505-1(f)(8) of the FD&C Act prohibits holders of an approved covered application from using any element to assure safe use to block or delay approval of an application under section 505(b)(2) or (j). A violation of this provision in 505-1(f) could result in enforcement action.

Prominently identify any submission containing a REMS assessment or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

ANDA 091178 REMS ASSESSMENT

NEW SUPPLEMENT FOR ANDA 091178/S-000
CHANGES BEING EFFECTED IN 30 DAYS
PROPOSED MINOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR ANDA 091178/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED MAJOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR ANDA 091178/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED REMS MODIFICATIONS DUE TO SAFETY LABELING CHANGES
SUBMITTED IN SUPPLEMENT XXX

Should you choose to submit a REMS revision, prominently identify the submission containing the REMS revisions with the following wording in bold capital letters at the top of the first page of the submission:

REMS REVISION FOR ANDA 091178

To facilitate review of your submission, we request that you submit your proposed modified REMS and other REMS-related materials in Microsoft Word format. If certain documents, such as enrollment forms, are only in PDF format, they may be submitted as such, but the preference is to include as many as possible in Word format.

SUBMISSION OF REMS DOCUMENT IN SPL FORMAT

In addition to submitting the proposed REMS as described above, you can also submit the REMS document in Structured Product Labeling (SPL) format. If you intend to submit the REMS document in SPL format, include the SPL file with your proposed REMS submission.

For more information on submitting REMS in SPL format, please email REMSWebsite@fda.hhs.gov

REPORTING REQUIREMENTS

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98 and at section 506I of the FD&C Act. The Agency should be advised of any change in the marketing status of this drug or if this drug will not be available for sale after approval. In particular, under section 506I(b) of the FD&C Act, you are required to notify the Agency in writing within 180 days from the date of this letter if this drug will not be available for sale within 180 days from the date of approval. As part of such written notification, you must include (1) the identity of the drug by established name and proprietary name (if any); (2) the ANDA number; (3) the strength of the drug; (4) the date on which the drug will be available for sale, if known; and (5) the reason for not marketing the drug after approval.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling materials prior to publication or dissemination. Please note that these submissions are voluntary. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert (PI), Medication Guide, and patient PI (as applicable) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

You must also submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

ANNUAL FACILITY FEES

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions[1] with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1st of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the *Federal Register* notice announcing facility fee amounts.

All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

(b) (6)

Center for Drug Evaluation and Research

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[1] Some of these provisions were amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II) (Public Law 115-52, Title III).



(b) (6)

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Date: 4/11/2019 02:22:21PM
GUID: 54078879000a1b9e15dd31ed6f0343ca

EXHIBIT 31

Letter from ACOG and SMFM to FDA (April 20, 2020)

April 20, 2020

Stephen M. Hahn, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue NW
Silver Spring, MD 20993

Re: Docket Number: FDA-2020-D-1106; Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency Guidance for Industry and Health Care Professionals

Dear Commissioner Hahn:

On behalf of more than 60,000 of the nation's primary care obstetrician-gynecologists and subspecialty and high-risk obstetric practitioners dedicated to advancing women's health, thank you for your recent action to suspend enforcement of Risk Evaluation and Mitigation Strategy (REMS) requirements for certain drugs with laboratory testing or imaging requirements for the duration of the COVID-19 public health emergency. The American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine urge the U.S. Food and Drug Administration (FDA) to immediately expand this policy to REMS and Elements to Assure Safe Use (ETASU) requirements for certain prescription drugs requiring in-person health care professional administration, where treatment could safely occur through telehealth or self-administration. In addition, physicians who provide such services in accordance with current clinical guidelines during this pandemic should not be held liable.

Obstetrician-gynecologists are serving on the front lines responding to the COVID-19 crisis. In order to provide the safest care for their patients and themselves, in-person visits are limited to emergency and essential physically necessary visits. We support the FDA's acknowledgment that REMS-required health care professional in-person dispensation is difficult because patients may need to avoid public places and patients suspected of having COVID-19 may be self-isolating and/or subject to quarantine. Under these circumstances, undergoing in-person clinic administration in order to obtain a drug subject to a REMS can put patients and others, including health care professionals and their families, at risk for COVID-19 transmission. As referenced in ACOG Committee Opinion #798, *Implementing Telehealth in Practice*, evidence suggests that telehealth provides comparable health outcomes when compared with traditional methods of health care delivery without compromising the patient–physician relationship.[1] Telehealth has quickly become integrated into nearly every aspect of obstetrics and gynecology. During this pandemic, it is essential to use telehealth services to limit COVID-19 transmission.

It is critical that the FDA promptly expand its recent policy to apply to the REMS and ETASU requirements for certain drugs requiring in-person dispensation, especially mifepristone. The current REMS and ETASU requirements for mifepristone are outdated and serve as a barrier to accessing this safe, effective medication. Further, they cause unnecessary delays in obtaining time-sensitive health care, without supporting improvements to patient safety or outcomes. During this federally declared public health emergency, these antiquated and superfluous requirements put patients and their physicians at risk, with no demonstrated benefit. As noted in the ACOG Position Statement, *Improving Access to*

Mifepristone for Reproductive Health Indications, mifepristone has been used by over 3 million women in the United States since FDA approval in 2000 and strong evidence exists regarding the safety of mifepristone for medication-induced abortion and medical management of early pregnancy loss.[2,3,4,5]

Restricting access to mifepristone interferes with the ability of obstetrician–gynecologists and other women's health clinicians to deliver the highest quality care for their patients, especially during the COVID-19 pandemic. Abortion is an essential component of comprehensive health care and is a time-sensitive service for which a delay of several weeks, or in some cases days, may increase the risks or potentially make it completely inaccessible.[6] Temporarily waiving REMS and ETASU requirements that certain drugs be dispensed in-person by certain medical professionals is particularly important for patients who suffer from other medical conditions and are at higher risk of serious complications from COVID-19, as well as those in rural areas for whom hours of travel for in-person administration would disallow social distancing recommendations and travel advisories.

In addition, we urge you to consider waiving the requirement for health care professional administration of subcutaneous depot medroxyprogesterone acetate (DMPA). Several studies have shown patient interest in self-administration and increased continuation of DMPA via subcutaneous at-home delivery.[7,8,9] In a period when limiting patient interactions with the health care system is essential to prevent COVID-19 transmission, it is in our patients' best interest to have unencumbered access to the contraceptive method of their choice, including DMPA.

Ensuring the safety of patients and physicians during the COVID-19 pandemic requires policy changes such as those already enacted by FDA to waive the REMS requirements for certain drugs with laboratory testing or imaging requirements. We strongly urge FDA to further protect patients and their health care professionals from the risk of transmission by promptly expanding the existing policy to waive REMS and ETASU requirements that certain drugs be dispensed in-person by certain medical professionals. Thank you for your consideration. We are available to answer any questions you may have regarding these issues.

Sincerely,

Maureen G. Phipps, MD, MPH, FACOG
Chief Executive Officer
American College of Obstetricians and Gynecologists

Judette Louis, MD, MPH
President
Society for Maternal-Fetal Medicine

Matt J. Granato, LL.M., MBA
Chief Executive Officer
Society for Maternal-Fetal Medicine

[1] Implementing telehealth in practice. ACOG Committee Opinion No. 798. American College of Obstetricians and Gynecologists. Obstet Gynecol 2020;135:e73–9.
[2] Improving Access to Mifepristone for Reproductive Health Indications. Position Statement. American College of Obstetricians and Gynecologists. June 2018. Available at https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/improving-access-to-mifepristone-for-reproductive-health-indications.
[3] Cleland K, Smith N. Aligning mifepristone regulation with evidence: Driving policy change using 15 years of excellent safety data. *Contraception*. 2015;92(3):179-181. doi:10.1016/j.contraception.2015.06.016.
[4] Sixteen Years of Overregulation: Time to Unburden Mifeprex. *N Engl J Med*. 2017;376(8):790-794.
[5] Song LP, Tang SY, Li CL, Zhou LJGYK, Mo XT. Early medical abortion with self-administered low-dose mifepristone in combination with misoprostol. *J Obstet Gynaecol Res*. 2018;44(9):1705-1711. doi:10.1111/jog.13716.
[6] Joint Statement on Abortion Access During the COVID-19 Outbreak. March 18, 2020. Available at https://www.acog.org/news/news-releases/2020/03/joint-statement-on-abortion-access-during-the-covid-19-outbreak.
[7] Upadhyay UD, Zlidar VM, Foster DG. Interest in self-administration of subcutaneous depot medroxyprogesterone acetate in the United States. *Contraception*. 2016;94(4):303-313. doi:10.1016/j.contraception.2016.06.006.
[8] Kohn JE, Simons HR, Della Badia L, et al. Increased 1-year continuation of DMPA among women randomized to self-administration: results from a randomized controlled trial at Planned Parenthood. *Contraception*. 2018;97(3):198-204. doi:10.1016/j.contraception.2017.11.009.
[9] Burke HM, Chen M, Buluzi M, et al. Effect of self-administration versus provider-administered injection of subcutaneous depot medroxyprogesterone acetate on continuation rates in Malawi: a randomised controlled trial. *Lancet Glob Heal*. 2018;6(5):e568-e578. doi:10.1016/S2214-109X(18)30061-5.

EXHIBIT 32

Letter from FDA to ACOG and SMFM (Apr. 12, 2021)

April 12, 2021

Maureen G. Phipps, MD, MPH, FACOG
Chief Executive Officer
American College of Obstetricians and Gynecologists
c/o Rachel Tetlow, Federal Affairs Director
rtetlow@acog.org

Skye Perryman, General Counsel
sperryman@acog.org

William Grobman, MD, MBA
President
Society for Maternal-Fetal Medicine
w-grobman@northwestern.edu

Dear Drs. Phipps and Grobman,

In your letter of April 20, 2020, to former Commissioner Stephen Hahn, you expressed concerns about the in-person dispensing requirements for certain prescription drugs during the current public health emergency. In my letter to you of March 19, 2021, I indicated that staff in the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) were evaluating the issues you raised.

Following up on my March 19, 2021, letter I am writing to report the results of CDER's review and analysis.

CDER conducted a literature search for studies pertinent to the in-person dispensing requirement in the Mifepristone REMS Program during the COVID-19 pandemic. Based on this literature search, CDER identified four publications that included relevant clinical outcome data.[1] CDER

[1] Chong E, et al. Expansion of a Direct-to-Patient Telemedicine Abortion Service in the United States and Experience during the COVID-19 Pandemic. Contraception 2021 (accepted manuscript). https://www.sciencedirect.com/science/article/pii/S0010782421000913; Kerestes C, et al. Provision of medication abortion in Hawai'i during COVID-19: Practical experience with multiple care delivery models. Contraception 2021 (accepted manuscript). https://doi.org/10.1016/j.contraception.2021.03.025; Aiken A et al. Effectiveness, Safety and Acceptability of No-test Medical Abortion Provided Via Telemedicine: a National Cohort Study. British J Obstet Gynecol 2021. https://obgyn.onlinelibrary.wiley.com/doi/10.1111/1471-0528.16668; Reynolds-Wright JJ et al. Telemedicine medical abortion at home under 12 weeks' gestation: a prospective observational cohort study during the COVID-19 pandemic. BMJ Sex Reprod Health 2021. https://srh.bmj.com/content/early/2021/02/04/bmjsrh-2020-200976

found that although there are limitations to the study designs, the overall findings from these studies do not appear to show increases in serious safety concerns (such as hemorrhage, ectopic pregnancy, or surgical interventions) occurring with medical abortion as a result of modifying the in-person dispensing requirement during the COVID-19 pandemic.

CDER also reviewed postmarketing adverse events that reportedly occurred from January 27, 2020 - January 12, 2021, with mifepristone use for medical termination of early pregnancy, along with available information about deviations or noncompliance events associated with the Mifepristone REMS Program.[2] CDER found that the small number of adverse events reported to FDA during the COVID-19 public health emergency (PHE) provide no indication that any program deviation or noncompliance with the Mifepristone REMS Program contributed to the reported adverse events.

In summary, provided the other requirements of the Mifepristone REMS Program are met, and given that the in-person dispensing of mifepristone for medical termination of early pregnancy may present additional COVID-related risks to patients and healthcare personnel because it may involve a clinic visit solely for this purpose, CDER intends to exercise enforcement discretion during the COVID-19 PHE with respect to the in-person dispensing requirement of the Mifepristone REMS Program, including any in-person requirements that may be related to the Patient Agreement Form. Further, to the extent all of the other requirements of the Mifepristone REMS Program are met, CDER intends to exercise enforcement discretion during the COVID-19 PHE with respect to the dispensing of mifepristone through the mail either by or under the supervision of a certified prescriber, or through a mail-order pharmacy when such dispensing is done under the supervision of a certified prescriber.

CDER is communicating this decision to the approved application holders subject to the Mifepristone REMS Program.

Sincerely yours,



Janet Woodcock, M.D.
Acting Commissioner of Food and Drugs

[2] See Mifepristone REMS Program at https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390. CDER's analysis covers both products that are subject to the Mifepristone REMS Program (Mifeprex and the approved generic, Mifepristone Tablets, 200 mg).

EXHIBIT 33

Letter from FDA Center for Drug Evaluation & Research Director Patrizia Cavazzoni to Dr. Graham Chelius (Dec. 16, 2021)

December 16, 2021

Graham Chelius, M.D.
The Society of Family Planning
The California Academy of Family Physicians

Dear Dr. Chelius:

This letter is to inform you that FDA has completed its review of the Mifepristone Risk Evaluation and Mitigation System (REMS) Program.[1] The agency has determined that the Mifepristone REMS Program continues to be necessary to ensure that the benefits of the drug outweigh the risks. However, we have determined that it must be modified to minimize the burden on the health care delivery system of complying with the REMS and to ensure that the benefits of the drug outweigh the risks. See 21 USC 355-1(g)(4)(B). The modifications to the REMS will consist of: (1) removing the requirement that mifepristone be dispensed only in certain healthcare settings, specifically clinics, medical offices, and hospitals (i.e., the "in-person dispensing requirement"); and (2) adding a requirement that pharmacies that dispense the drug be specially certified.

A REMS Modification Notification letter has been sent to both Applicants subject to the Mifepristone REMS Program. The letter describes the modifications and directs the Applicants to submit prior approval supplements within 120 days. We have also answered a related citizen petition from the American Association of Pro-Life Obstetricians and Gynecologists and the American College of Pediatricians. That response will be posted in the public docket (Docket No. FDA-2019-P-1534; available at www.regulations.gov).

Sincerely,

Patrizia A. Cavazzoni -S

Digitally signed by Patrizia A. Cavazzoni -S
Date: 2021.12.16 15:05:01 -05'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research

[1] We also note your letter of September 29, 2021 to us on this subject.

EXHIBIT 34

Letter from FDA to AAPLOG Largely Denying their 2019 Citizen Petition (Dec. 16, 2021)



Donna J. Harrison, M.D.
Executive Director
American Association of Pro-Life Obstetricians and Gynecologists
P.O. Box 395
Eau Claire, MI 49111-0395

Quentin L. Van Meter, M.D., FCP
President
American College of Pediatricians
P.O. Box 357190
Gainesville, FL 32635-7190

December 16, 2021

Re: Docket No. FDA-2019-P-1534

Dear Drs. Harrison and Van Meter:

This letter responds to your citizen petition submitted to the Food and Drug Administration (FDA or Agency) on March 29, 2019, on behalf of the American Association of Pro-Life Obstetricians and Gynecologists and the American College of Pediatricians (Petition). In the Petition, you request that FDA: (1) restore and strengthen elements of the Mifeprex regimen and prescriber requirements approved in 2000, and (2) retain the Mifeprex Risk Evaluation and Mitigation Strategy (REMS) and continue limiting the dispensing of Mifeprex to patients in clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber.

Specifically, in your Petition you request that the Agency:

(1) Restore and strengthen elements of the Mifeprex regimen and prescriber requirements approved in 2000, to include the following:

- Indications and Usage - Mifeprex, in a regimen with misoprostol, for the termination of intrauterine pregnancy, should be limited to 49 days gestation.

- Dosage and Administration:
  - Mifeprex should be administered by or under the supervision of a physically present and certified physician who has ruled out ectopic pregnancy.

  - The use of Mifeprex and misoprostol for the termination of pregnancy should require three office visits by the patient.

U.S. Food & Drug Administration
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w ww.fda.gov

- Contraindications - Mifeprex use is contraindicated for patients who do not have convenient access to emergency medical care.

- Adverse Event Reporting - Certified prescribers, emergency medical personnel, physicians treating complications, and Danco Laboratories should report to FDA's MedWatch Reporting system any deaths, hospitalizations, blood transfusions, emergency room visits, failures requiring surgical completion, ongoing pregnancy, or other major complications following the use of Mifeprex and misoprostol.

- Additional studies - The Mifeprex REMS should require a formal study of outcomes for at-risk populations, including: patients under the age of 18; patients with repeat Mifeprex abortions; patients who have limited access to emergency room services; and patients who self-administer misoprostol.

(2) Retain the Mifeprex REMS and continue limiting the dispensing of Mifeprex to patients in clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber.

We have carefully considered the information submitted in your Petition and other relevant data available to the Agency. Based on our review of this information, your Petition is granted in part and denied in part.

I. BACKGROUND

A. Mifeprex

On September 28, 2000, FDA approved Mifeprex for the medical termination of intrauterine pregnancy through 49 days' pregnancy (new drug application (NDA) 020687). The application was approved under part 314, subpart H (21 CFR part 314, subpart H), "Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses" (subpart H). Specifically, § 314.520 of subpart H provides for approval with restrictions that are needed to assure the safe use of the drug product. In accordance with § 314.520, FDA restricted the distribution of Mifeprex as specified in the September 2000 approval letter.[1]

Subsequently, Mifeprex was identified as one of the products that was deemed to have in effect an approved REMS under the Food and Drug Administration Amendments Act of 2007 (FDAAA) because on the effective date of Title IX, subtitle A of FDAAA (March 28, 2008), Mifeprex had in effect elements to assure safe use.[2] Accordingly, in June 2011, we approved a REMS for Mifeprex, consisting of a Medication Guide, elements to assure safe use (ETASU), an implementation system, and a timetable for submission of assessments of the REMS.

Elements to assure safe use included: (1) prescriber certification (ETASU A); (2) that Mifeprex is dispensed only in certain healthcare settings by or under the supervision of a certified prescriber

[1] See https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.pdf.
[2] 73 FR 16313 (Mar. 27, 2008).

(ETASU C); and (3) that Mifeprex is dispensed only with documentation of safe use conditions (ETASU D). Documentation of safe use conditions consists of a Patient Agreement Form between the prescriber and the patient indicating that the patient has received counseling from the prescriber regarding the risk of serious complications associated with Mifeprex.

On March 29, 2016, we approved an efficacy supplement (S-020) to NDA 020687 for Mifeprex submitted by the applicant Danco Laboratories, LLC (S-020 efficacy supplement). The approval included changes in the dose of Mifeprex and the dosing regimen for taking Mifeprex and misoprostol (including the dose of misoprostol and a change in the route of misoprostol administration from oral to buccal (in the cheek pouch); the interval between taking Mifeprex and misoprostol; and the location at which the patient may take misoprostol). The approval also modified the gestational age up to which Mifeprex has been shown to be safe and effective, as well as the process for follow-up after administration of the drug.

Specifically, the following changes, among others, were made as part of the 2016 approval:[3]

- Revised the dosing regimen to consist of 200 mg of Mifeprex taken by mouth, followed in 24-48 hours by 800 mcg of misoprostol taken buccally (in the cheek pouch). This differs from the originally approved dosing regimen of 600 mg of oral Mifeprex followed 48 hours later by 400 mcg of oral misoprostol.

- Revised the indication for use of Mifeprex, in a regimen with misoprostol, to extend the maximum gestational age for the medical termination of intrauterine pregnancy from 49 days to 70 days.

- Reduced the number of office visits by the patient under the approved regimen from three to one.

- Replaced the term "physician" with the term "healthcare provider."

In addition, after reviewing the data and information submitted by the applicant in the S-020 efficacy supplement, and after taking into consideration the safety data that had become available since the initial approval of Mifeprex in 2000, we determined the Mifeprex REMS continued to be necessary to ensure the benefits of the product outweigh the risks. However, we approved modifications to the Mifeprex REMS that reflected the changes approved in the efficacy supplement. These changes to the REMS included, among others:[4]

- Updating the Prescriber Agreement Form to reflect the revised indication and dosing regimen.

- Removing the Medication Guide as a REMS element (but retaining the Medication Guide as labeling).

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[3] See https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/020687Orig1s020ltr.pdf and https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

[4] See https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020RemsR.pdf.

- Removing the requirement that certified prescribers report certain enumerated adverse events to the applicant (specifically, any hospitalization, transfusion or other serious adverse events), but retaining the requirement that certified prescribers report all deaths to the sponsor.

Under the March 2016 approval, the Mifeprex REMS also continued to require that Mifeprex be dispensed to patients only in certain healthcare settings, specifically, clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber.[5]

B. Generic Version of Mifeprex

On April 11, 2019, we approved GenBioPro, Inc.'s generic version of Mifeprex, Mifepristone Tablets, 200 mg (abbreviated new drug application (ANDA) 091178). This action took place after this Petition was submitted to the Agency. As required by 21 CFR 314.94(a)(8), GenBioPro's approved generic version of Mifeprex, Mifepristone Tablets, 200 mg, has the same labeling (with certain permissible differences) as the brand product it references, Mifeprex. Accordingly, although we refer to the Mifeprex labeling in several sections of this response, our discussions in this response apply equally to both the NDA and the generic product labeling, unless otherwise specifically noted.[6]

GenBioPro's generic version of Mifeprex is subject to the same ETASU as its listed drug (21 U.S.C. -1(i)). At the time we approved GenBioPro's generic version of Mifeprex, that ANDA product was required to use a single, shared system for the ETASU with the brand drug product, Mifeprex, unless the requirement was waived by FDA (21 U.S.C. 355-1(i)). FDA did not waive this requirement. Accordingly, at the same time that FDA approved GenBioPro's generic version of Mifeprex in 2019, FDA approved a supplemental new drug application (sNDA) for Mifeprex, approving modifications to the existing, approved REMS for Mifeprex to establish a single, shared system REMS for mifepristone products for the medical termination of intrauterine pregnancy through 70 days gestation (referred to as the Mifepristone REMS Program). In establishing the single, shared system REMS in 2019, no substantive changes were made to the ETASU in the March 2016 Mifeprex REMS. References to the REMS in this response refer to the Mifepristone REMS Program established in 2019, unless otherwise noted.

C. In-Person Dispensing Requirement During the COVID-19 PHE

[5] See https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/020687Orig1s020ltr.pdf.

[6] We note that Korlym and the generic version of Korlym (Mifepristone Tablets, 300 mg) contain the same active ingredient – mifepristone - as Mifeprex and the generic version of Mifeprex (Mifepristone Tablets, 200 mg). Although these drug products contain the same active ingredient, their intended uses target different receptors, and the products have different strengths and use different dosing regimens. Korlym and the generic version of Korlym are approved for the control of hyperglycemia (high blood sugar levels) due to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes or glucose intolerance, and have failed surgery or are not candidates for surgery. References to mifepristone in this response refer to the use of mifepristone for the medical termination of intrauterine pregnancy through 70 days gestation, unless otherwise noted.

FDA has recognized that during the COVID-19[7] public health emergency (PHE),[8] certain REMS requirements for various products may be difficult to comply with because patients may need to avoid public places and patients suspected of having COVID-19 may be self-isolating and/or subject to quarantine. The Agency has also received queries concerning products with REMS that have ETASUs, including REMS with ETASUs that restrict distribution, and the impact of such ETASUs on patient access when patients self-isolate or are subject to quarantine.

In April 2021, FDA communicated its intent to exercise enforcement discretion during the COVID-19 PHE regarding the requirement in the Mifepristone REMS Program that mifepristone used for medical termination of intrauterine pregnancy through 70 days gestation be dispensed to patients by or under the supervision of a certified prescriber only in certain healthcare settings, specifically clinics, medical offices, and hospitals (referred to as the "in-person dispensing requirement").

Specifically, FDA communicated that provided all other requirements of the Mifepristone REMS Program are met, the Agency intends to exercise enforcement discretion with respect to the in-person dispensing requirement of the Mifepristone REMS Program, including any in-person requirements that may be related to the Patient Agreement Form, during the COVID-19 PHE. This determination, which FDA made on April 12, 2021, was effective immediately. We also note that from July 13, 2020 to January 12, 2021, per a court order, FDA was enjoined from enforcing the in-person dispensing requirement of the Mifepristone REMS Program.[9]

Further, and as we also communicated on April 12, 2021, to the extent all of the other requirements of the Mifepristone REMS Program are met, the Agency intends to exercise enforcement discretion during the COVID-19 PHE with respect to the dispensing of Mifeprex or the approved generic version of Mifeprex, Mifepristone Tablets, 200 mg, through the mail, either by or under the supervision of a certified prescriber, or through a mail-order pharmacy when such dispensing is done under the supervision of a certified prescriber.

FDA's intent to exercise enforcement discretion with respect to these requirements during the COVID-19 PHE was the result of a thorough scientific review by experts within FDA's Center for Drug Evaluation and Research (CDER), who evaluated relevant information, including available clinical outcomes data and adverse event reports.

D. Minor Modification

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[7] The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19).

[8] Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), *available at* https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.

[9] *Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183, 233 (D. Md. July 13, 2020), order clarified, 2020 WL 8167535 (D. Md. Aug. 19, 2020) (preliminarily enjoining FDA from enforcing the in-person dispensing requirement and any other in-person requirements of the Mifepristone SSS REMS); *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (Jan. 12, 2021) (staying the preliminary injunction imposed by the District Court).

In response to a request submitted by the applicants, FDA approved a minor modification to the Mifepristone REMS Program on May 14, 2021. This minor modification revised the Patient Agreement Form to use gender neutral language. Specifically, the pronouns "she" and "her" in the Patient Agreement Form were replaced with "the patient." The minor modification also included revisions to the REMS document to be consistent with the revisions to the Patient Agreement Form. These changes did not affect the substance of the Patient Agreement Form, the REMS document, or the Mifepristone REMS Program.

E. Review of the Mifepristone REMS Program

In 2021, FDA also undertook a full review of the Mifepristone REMS Program.[10] In conducting this review, FDA reviewed multiple different sources of information, including published literature, safety information submitted to the Agency during the COVID-19 PHE, FDA Adverse Event Reporting System (FAERS) reports, the first REMS assessment report for the Mifepristone REMS Program, and information provided by advocacy groups, individuals, and the Plaintiffs in ongoing litigation, as well as information submitted by the sponsors of the NDA and the ANDA (together, the Applicants). As discussed in more detail below, based on our review of this information, FDA has determined that certain elements of the Mifepristone REMS Program remain necessary to assure the safe use of mifepristone for medical termination of intrauterine pregnancy through 70 days gestation; and therefore, the Mifepristone REMS Program continues to be necessary to ensure the benefits outweigh the risk. Specifically, we find that the healthcare provider certification and dispensing of mifepristone to patients with evidence or other documentation of safe use conditions continue to be necessary components of the REMS to ensure the benefits of mifepristone outweigh the risks for this indication.

We also find that the in-person dispensing requirement is no longer necessary to assure the safe use of mifepristone for medical termination of intrauterine pregnancy through 70 days gestation. We have concluded that mifepristone will remain safe and effective for medical abortion if the in-person dispensing requirement is removed, provided all the other requirements of the REMS are met and pharmacy certification is added.[11] Removing the in-person dispensing requirement will render the REMS less burdensome to healthcare providers and patients, and provided all other requirements of the REMS are met, including the additional requirement for pharmacy certification, the REMS will continue to ensure that the benefits of mifepristone for medical abortion outweigh the risks. Accordingly, today we are sending a REMS Modification Notification letter to both Applicants in the Mifepristone REMS Program. As stated in that letter, FDA has concluded that a modification is necessary and must include the following changes:

- Removing the requirement that mifepristone be dispensed only in certain healthcare settings, specifically clinics, medical offices, and hospitals.

[10] We note that the Agency is in litigation regarding the Mifepristone REMS Program and committed to conducting a full review of the Mifepristone REMS Program, including reviewing any relevant data and evidence submitted to the Agency by the Plaintiffs in that litigation (*Chelius et al v. Becerra*, Joint Mot. to Stay Case Pending Agency Review, ECF No. 148, May 7, 2021, Civ. No. 1:17-00493 (D. Haw.)).

[11] Although we have determined that the Mifepristone REMS Program must be modified to add a requirement for pharmacy certification, this was not raised in your Petition and therefore is not discussed further in this response.

- Adding a requirement that pharmacies that dispense the drug be specially certified.

II. DISCUSSION OF ISSUES RAISED

A. Mifeprex Regimen

1. Indications and Usage

In the Petition, you ask FDA to restore and strengthen elements of the Mifeprex regimen and prescriber requirements approved in 2000, to limit Mifeprex, in a regimen with misoprostol, for the termination of intrauterine pregnancy, to 49 days gestation (Petition at 1 and 3). For the reasons explained below, we deny this request.

Citing to a 2011 study and a practice bulletin issued by the American College of Obstetricians and Gynecologists (ACOG), you state that medical abortion[12] regimens demonstrate an increase in complications and failures, including serious risks of hemorrhage, infection, and ongoing pregnancy, after 49 days gestation (Petition at 3-4).

Our review of the S-020 efficacy supplement in 2016 concluded that Mifeprex, in a regimen with misoprostol, is safe and effective for medical termination of intrauterine pregnancy through 70 days gestation.[13] Complete medical abortion rates from the pivotal clinical trials relied on for the initial approval of Mifeprex (with an indication for medical termination of intrauterine pregnancy through 49 days gestation) were 92.1 percent and 95.5 percent in the United States and French trials, respectively.[14] The studies reviewed in support of the 2016 approval for Mifeprex (with an indication for medical termination of intrauterine pregnancy through 70 days gestation) showed comparable efficacy. The 2016 Clinical Review of the S-020 efficacy supplement summarized clinical outcomes and adverse effects from 22 studies (7 in the United States and 15 from outside the United States) through 70 days gestation, using the currently approved regimen of 200 mg oral mifepristone with 800 mcg buccal misoprostol. The ranges of complete medical abortion rates calculated by the clinical reviewer were 93.2 percent to 98.7 percent in the United States studies, and 92 percent to 98 percent in the non-United States studies.[15]

Serious adverse events associated with the use of mifepristone through 70 days gestational age are rare. Per the current mifepristone labeling, the rates of serious adverse events are low: transfusions are 0-0.1 percent, sepsis is less than 0.01 percent, hospitalization related to medical abortion is 0-0.7 percent, and hemorrhage is 0.1 percent.[16] As discussed

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[12] In this response, the terms "medical abortion" and "medication abortion" both refer to the use of mifepristone, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy.

[13] See 2016 Clinical Review available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf, at 32-38 and 47-47.

[14] See 1999 Medical Officer's Review, available at http://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_Mifepristone_medr_P1.pdf, at 11 (Table 1) and 16.

[15] See 2016 Clinical Review, supra n. 13, at 28-31.

[16] See https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020687s022lbl.pdf.

throughout this response, the benefit/risk assessment supported our 2016 conclusion that the product is safe and effective through 70 days gestation.

In support of your assertion that medical abortion demonstrates an increase in complications after 49 days gestation, you cite to Mentula, et al.,[17] a register-based, retrospective cohort study that included 18,248 women in Finland who underwent medical abortion between January 1, 2003, and December 31, 2006 (Petition at 3). As an initial matter, we note that the Mentula study was primarily designed to assess the immediate adverse events following medical abortion in the second trimester (13 to 24 gestational weeks as defined by the authors) and then compare those events to those identified with medical abortion in the first trimester (up to 12 gestational weeks as defined by the authors). The study was not designed to compare rates of complications across gestational weeks within the first trimester. It is true that the Mentula publication includes information on the percentages of women who had surgical evacuation following medical abortion and the percentages of women who had infection following medical abortion, based on weekly gestational age, from 5 weeks to 20 weeks gestation.[18] However, the data in the Mentula study are relatively old (2003-2006); in our 2016 review of the S-020 efficacy supplement, we conducted an extensive review of more recent data[19] and concluded that Mifeprex, in a regimen with misoprostol, is safe and effective for medical termination of intrauterine pregnancy through 70 days gestation.

You also cite to ACOG Practice Bulletin No. 143, which states: "the risk of clinically significant bleeding and transfusion may be lower in women who undergo medical abortion of gestations up to 49 days compared with those who undergo medical abortion of gestations of more than 49 days."[20] This statement is based on a 1998 publication which evaluated patients undergoing medical abortion with mifepristone 600 mg and then oral misoprostol 400 mcg two days later.[21] The regimen studied in this 1998 publication is not the currently approved regimen for mifepristone in the United States. Further, ACOG Practice Bulletin No. 143 has been withdrawn and replaced by Practice Bulletin No. 225, which was published in October 2020 and no longer contains this statement.[22]

You also state that the failure rate of the approved regimen (which you refer to as the "buccal misoprostol regimen") increases as the gestational age increases, especially at

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[17] Mentula MJ, Niinimake M, Suhonen S, et al. Immediate Adverse Events After Second Trimester Medical Termination of Pregnancy: Results of a nationwide registry study, Human Reproduction. 2011;26(4):927-932.
[18] Id. at Fig. 2 and Fig. 3. Surgical intervention after medical abortion and infection after medical abortion are two distinct adverse events. The calculation of abortion completion rates accounts for the need for surgical intervention. In clinical studies we reviewed, success of medical abortion was defined as the complete expulsion of the products of conception without the need for surgical intervention.
[19] See 2016 Cross-Discipline Team Leader Review, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020CrossR.pdf, at 37 (Table 4).
[20] Petition at 3. See Medical Management of First-Trimester Abortion. ACOG Practice Bulletin Number 143. March 2014 (Reaffirmed 2016. Replaces Practice Bulletin Number 67, October 2005); Obstet Gynecol. 2014 Mar;123(3):676-692 at 680.
[21] Spitz I, Bardin CW, Benton L, Robbins A. Early pregnancy termination with mifepristone and misoprostol in the United Sates, NEJM. 1998;338 (18):1241-1247.
[22] See ACOG Practice Bulletin No. 225. Medication Abortion Up to 70 Days of Gestation. Obstetrics and Gynecology 2020; 136(4); e31 to e47.

gestational ages greater than 49 days, relying on a 2015 meta-analysis,[23] and that the gestational limit should not have been increased (Petition at 3-4). We agree that the failure rate of medical abortion regimens, including the currently approved regimen, generally increases with increasing gestational age. However, the increase in failure rate with each incremental week of gestation, as described in approved mifepristone labeling and in this 2015 meta-analysis, is small, and we believe that the benefit/risk profile for medical termination of intrauterine pregnancy between 49 and 70 days gestation remains acceptable.

For these reasons, we deny your request that FDA limit mifepristone, in a regimen with misoprostol for the termination of intrauterine pregnancy, to 49 days gestation.

2. Dosage and Administration

a. Prescriber Qualifications

You state that FDA should limit the "ability" to prescribe and dispense Mifeprex to qualified, licensed physicians, rather than permitting non-physicians to apply to be certified prescribers, because of the regimen's serious risks and because physicians are better trained to diagnose patients who have contraindications to Mifeprex and to verify gestational age (Petition at 4). We do not agree.

Healthcare providers who are licensed to prescribe can become certified in REMS programs if they are able to meet the applicable REMS requirements. To become certified to prescribe mifepristone under the Mifepristone REMS Program, the prescriber must review the prescribing information for mifepristone and complete a Prescriber Agreement Form. By signing the form, the prescriber agrees that they meet certain qualifications, including the ability to date pregnancies accurately and to diagnose ectopic pregnancies. These healthcare providers must also: (1) be able to provide any necessary surgical intervention or have made arrangements for others to provide for such care; or (2) be able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.[24]

In our review of the S-020 efficacy supplement in 2016, we determined that available data support that Mifeprex is safe and effective when prescribed by midlevel providers, such as physician assistants and nurse practitioners, as well as by physicians.[25] Our 2016 review included four studies that evaluated the safety and efficacy of medical abortion when performed by non-physician healthcare providers. Two trials evaluated the currently

[23] Petition at 4, fn. 6 (citing Chen MJ, Creinin MD, *Mifepristone with Buccal Misoprostol for Medical Abortion*, Obstet. Gynecol 126 (1) July 2015 12-21).
[24] See https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020687s022lbl.pdf; see also https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390.
[25] See 2016 Clinical Review, supra n. 13, at 79; see also 2016 Cross-Discipline Team Leader Review, supra n. 19, at 17-18. We also note that in most states, midlevel clinicians, such as physician assistants and nurse practitioners, are licensed to prescribe medications.

approved Mifeprex and buccal misoprostol regimen (Olavarrieta and Kopp Kallner);[26,27] one trial studied a regimen using vaginal misoprostol (Warringer);[28] a fourth study did not specify the route of misoprostol administered (Puri).[29] Olavarrieta reported a completion rate of 97.9 percent when medical abortion was provided by nurses as compared with 98.4 percent with physicians. Kopp Kallner reported a completion rate of 99 percent with certified nurse midwives versus 97.4 percent with physicians. Warriner reported an abortion completion rate of 97.4 percent with nurses as compared with 96.3 percent with physicians. Puri reported an abortion completion rate of 96.8 percent when the service was provided by nurse-midwives as compared with 97.4 percent in the "standard care" group.[30] Our 2016 review also included a systematic review of six controlled clinical studies by Renner;[31] the authors concluded that the evidence "indicates that trained mid-level providers may effectively and safely provide first trimester surgical and medical termination of pregnancy services." Additionally, Barnard et al., in a Cochrane systematic review, assessed the safety and effectiveness of abortion procedures administered by mid-level providers (nurse practitioners, midwives, other non-physician healthcare providers) compared to doctors.[32] The authors concluded, based in part on two of the studies that we had reviewed in 2016,[33] that there was no statistically significant difference in the risk of failure for medical abortions performed by mid-level providers compared with doctors.

We also believe that the identification of patients for whom the use of mifepristone is contraindicated can be done by mid-level healthcare providers, as well as physicians. Mifepristone in a regimen with misoprostol for medical termination of intrauterine pregnancy through 70 days gestation is contraindicated in patients with any of the following conditions:[34]

- Confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass

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[26] Olavarrieta CD, Ganatra B, Sorhaindo A, et al. Nurse versus Physician-provision of Early Medical Abortion in Mexico: A Randomized Controlled Non-Inferiority Trial. Bull World Health Organ. 2015;93:249-258.

[27] Kopp Kallner H, Gomperts R, Salomonsson E, et al. The efficacy, safety and acceptability of medical termination of pregnancy provided by standard care by doctors or by nurse-midwives: a randomised controlled equivalence trial. BJOG. 2015; 122: 510-517.

[28] Warriner IK, Wang D, et al. Can midlevel health-care providers administer early medical abortion as safely and effectively as doctors? A randomized controlled equivalence trial in Nepal. Lancet. 2011; 377: 1155-61.

[29] Puri M, Tamang A, Shrestha P, et al. The role of auxiliary nurse-midwives and community health volunteers in expanding access to medical abortion in rural Nepal. Reproductive Health Matters. 2015; 22(44) 94-103.

[30] 2016 Clinical Review, supra n. 13, at 43.

[31] Renner RM, Brahmi D, Kapp N. Who can provide effective and safe termination of pregnancy care? A systematic review. BJOG 2013 Jan;120(1):23-31.

[32] Barnard S, Kim C, Park MN, Ngo TD. Doctors or mid-level providers for abortion (Review). Cochran Database of Systematic Reviews. 2015, Issue 7.

[33] Of the medical abortion studies reviewed by Barnard et al (Id.), two were reviewed by the Agency as part of the review of the S-020 supplement in 2016. See Warriner et al (supra n. 28) and Kopp Kallner et al (supra n. 27). The third used a different dose of misoprostol than the currently approved regimen. See Jejeebhoy SJ, Kalyanwalaa S, Zaviera AJF, Kumara R, Mundleb S, Tankc J, et al. Feasibility of expanding the medication abortion provider based in India to include avurvedic physicians and nurses. International Perspectives on Sexual and Reproductive Health 2012;38(3)133-42)

[34] See https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020687s022lbl.pdf.

- An intrauterine device in place
- Chronic adrenal failure
- Concurrent long-term corticosteroid therapy
- History of allergy to mifepristone, misoprostol, or other prostaglandins
- Hemorrhagic disorder or concurrent anticoagulant therapy
- Inherited porphyrias

These contraindications can be assessed by trained healthcare providers who prescribe mifepristone by obtaining a medical history, from medical records, and/or from physical examination or ultrasound if appropriate. We continue to believe that available data support the conclusion that mid-level healthcare providers, as well as physicians, possess the clinical and counseling skills necessary to provide medical abortion. We note this is consistent with ACOG's statement in its current practice bulletin that "[i]n addition to physicians, advanced practice clinicians, such as nurse-midwives, physician assistants, and nurse practitioners, possess the clinical and counseling skills necessary to provide first-trimester medical abortion."[35] Further, if necessary, ultrasound training and certification is available to nurse practitioners and physician assistants, as well as physicians.[36] In sum, available information supports that mid-level healthcare providers as well as physicians can determine whether mifepristone is an appropriate treatment for a particular patient and dispense it.

You also assert that FDA should strengthen the requirement that providers accurately assess the duration of the pregnancy by mandating that gestational age be assessed by ultrasound (Petition at 5). We refer you to FDA's 2016 Response to the citizen petition submitted to Docket No. FDA-2002-P-0364 (the "2016 CP Response"), where FDA stated that the determination of gestational age does not always require an ultrasound. In the 2016 CP Response, FDA stated it had "determined that it was inappropriate for us to mandate how providers clinically assess women for duration of pregnancy and for ectopic pregnancy. These decisions should be left to the professional judgment of each provider, as no method (including TVS [transvaginal ultrasound]) provides complete accuracy. The approved labeling for Mifeprex recommended ultrasound evaluation as needed, leaving this decision to the judgment of the provider."[37]

In the Petition, you reference the Prescriber Agreement Form, in which the provider must attest they have the ability to: (1) accurately assess the duration of the pregnancy; (2) diagnose ectopic pregnancies; and (3) provide surgical intervention if needed (or have made plans to provide such care through others), and you state that a provider who does not physically meet with and examine a patient, but simply consults with the patient over the Internet, is not capable of fulfilling these requirements, or of ruling out additional

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[35] ACOG Practice Bulletin No. 225, supra n. 22.
[36] American Institute of Ultrasound in Medicine. Accessed November 26, 2021. https://www.aium.org/officialStatements/70.
[37] FDA's citizen petition response dated March 29, 2016, to the citizen petition submitted by the American Association of Pro-Life Obstetricians and Gynecologists, the Christian Medical and Dental Association, and Concerned Women for America on August 20, 2002, Docket No. FDA-2002-P-0364 at 18. See https://www.regulations.gov/document/FDA-2002-P-0364-0002.

contraindications (Petition at 5-6). You state that FDA should require certified prescribers to be physically present when Mifeprex is dispensed so that they can appropriately examine patients and rule out contraindications to the use of Mifeprex (Petition at 4).

Certified prescribers do not have to be physically present with the patient as long as they have confirmed the patient's gestational age and intrauterine pregnancy. As noted above, in the 2016 CP response, FDA "determined that it was inappropriate for us to mandate how providers clinically assess women for duration of pregnancy and for ectopic pregnancy."[38] Moreover, the evaluation of patients for contraindications to medical abortion does not necessarily require direct physical contact with the certified prescriber and can be done in different types of healthcare settings. A certified prescriber can also review the Patient Agreement Form[39] with the patient, fully explain the risks of the mifepristone treatment regimen, and answer any questions, as in any consent process, without physical proximity. See also section II.B.1.c (ETASU C – In-person Dispensing).

With respect to providing surgical intervention in cases of incomplete abortion or severe bleeding and assuring patient access to medical facilities equipped to provide blood transfusions and resuscitation (if necessary), the Prescriber Agreement Form does not reflect a requirement that the certified prescriber must provide such care personally; rather, the prescriber must agree that they have the ability to provide such care or that they have made plans to provide such care through others, and that they have the ability to assure the patient has access to appropriate medical facilities. It is common practice for healthcare providers to provide emergency care coverage for other healthcare providers' patients, and in many places, hospitals employ "hospitalists" to provide care to all hospitalized patients. We also note ACOG's statement that "[i]n rare cases, a patient who undergoes a medication abortion may need to obtain an additional intervention, such as uterine aspiration. If the prescribing clinician does not perform the intervention, it is medically appropriate to provide a referral."[40]

For these reasons, we deny your request that FDA limit the "ability" to prescribe and dispense mifepristone to licensed physicians, and we deny your request that FDA require certified providers to physically meet with and examine the patient.

b. Office Visits and Administration of Mifepristone/Misoprostol

In the Petition, you state that the use of mifepristone and misoprostol should require three office visits by the patient (Petition at 7). In support of this position, you state the following:

- Drug-induced abortion is contraindicated for patients who are not available for follow-up contact or evaluation (Petition at 10).

[38] Id.
[39] See https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390.
[40] ACOG Practice Bulletin Number 225 supra n. 22.

- Abortion complications are more frequent when women abort at home and more healthcare oversight is needed (Petition at 8).

- Home administration of misoprostol does not permit healthcare providers to control when their patients take misoprostol and without monitoring:

    - a patient may take buccal misoprostol before the minimum 24-hour period after taking Mifeprex, which leads to a significantly increased failure rate (Petition at 7).

    - a patient may swallow misoprostol rather than administer it buccally, and oral administration is not as effective as buccal administration in ending the pregnancy (Petition at 7).

- Because providers may now "confirm" that a patient's drug-induced abortion was successful without a clinic visit, this increases the threat that Rh-negative patients will not receive Rhogam, which is necessary to prevent serious risks in subsequent pregnancies (Petition at 7 and 9).

We address each of these points below.

i. Follow-up Care

The safe use of mifepristone when used in the approved regimen with misoprostol is not contingent on a specific number of office visits being made by the patient undergoing a medical termination of pregnancy. The 2016 labeling change for Mifeprex regarding post-treatment assessment, including the change to the approved regimen to reduce the number of offices visits from three to one, was based on evidence reviewed in the S-020 efficacy supplement. We concluded, upon reviewing the data, that three office visits were not necessary to assure the safe use of Mifeprex.[41]

In your Petition, you point to statements by ACOG that medical abortion is contraindicated for patients who are not available for follow-up contact or evaluation (Petition at 8, 10). The ACOG statements you point to are from ACOG Practice Bulletin No. 143, which has been withdrawn and replaced by Practice Bulletin No. 225.[42] Neither of the statements from the withdrawn Practice Bulletin nor Practice Bulletin No. 225 contraindicate medical abortion in women who are not available for an in-clinic follow-up visit. The current ACOG recommendations indicate that for medical abortion, "[f]ollow-up can be performed by telephone at 1 week, with subsequent at-home urine pregnancy testing at 4 weeks after treatment, which avoids the need for the patient to go to a facility."[43] The patient and their healthcare provider should determine the best option for follow-up as part of the consultation and consent process.[44] As reflected in ACOG's guidance, appropriate follow-

[41] See 2016 Clinical Review, supra n. 13, at 44 and 64-67.
[42] ACOG Practice Bulletin Number 225, supra n. 22.
[43] Id.
[44] Id.

up after medical termination of a pregnancy may be accomplished in multiple ways and not all require an in-clinic visit.

You also question findings in multiple studies that evaluated the effectiveness of semiquantitative urine pregnancy tests (multi-level pregnancy tests, or MLPT) and low sensitivity urine pregnancy tests (LSPT) to rule out on-going pregnancies and assessed the ability of patients to self-administer these tests and interpret the test results (Petition at 9-10). Overall, these studies concluded that in the majority of women, it is feasible to use a simplified test to determine if further follow-up is necessary. A recent systematic review and meta-analysis by Baiju assessed the effectiveness and safety of self-assessment of the outcome of medical abortion completed at home versus routine clinic follow-up after medical abortion, concluding self-assessment was not inferior to routine clinic follow-up.[45] We note that this is consistent with current ACOG recommendations, which state that "follow-up can be performed by telephone at 1 week, with subsequent at-home urine pregnancy testing at 4 weeks after treatment, which avoids the need for the patient to go to a facility."[46]

You also assert that it is important for a patient to be under observation after taking misoprostol to ensure that they are appropriately monitored and provided sufficient pain medication (Petition at 8). You cite the World Health Organization (WHO)'s statement in guidance that up to 90 percent of women will abort within 4-6 hours after taking misoprostol; you further state that the 2000 regimen permitted patients to be in the clinic during this time period (Petition at 8). Your reference to the WHO guidance document[47] appears to be out of context. The WHO guidance takes no position on whether women should return to and remain in the clinic during a follow-up visit for purposes of taking misoprostol; in fact, it explicitly recognizes that post-abortion care may not require a follow-up visit if the patient is adequately counseled.[48] In the United States, and as reflected in the approved labeling, medical termination of pregnancy usually involves patients terminating the pregnancy at home, with appropriate follow-up that may not include a return visit.

ii. At Home Medical Abortion and Healthcare Oversight

In addition, you cite a 2018 study to support your statement that abortion complications are more frequent when women abort at home (Petition at 8). The study evaluated complications following medical abortion (both less than 12 weeks and more than 12 weeks gestation) as well as following surgical abortion, at one hospital in Sweden between 2008 and 2015.[49] For the years 2008 to 2010, data were collected retrospectively; for the years

[45] Baiju, N, Acharya, G, D'Antonio, F, et al. 2019. Effectiveness, safety and acceptability of self-assessment of the outcome of first-trimester medical abortion: a systematic review and meta-analysis. BJOG; 126:1536-1544.
[46] ACOG Practice Bulletin Number 225, supra n. 22.
[47] World Health Organization, Safe Abortion: technical and policy guidance for health systems – 2nd edition. 2012. Page 45 and Section 2.2.2.1 Medication for pain.
[48] Id. at Section 2.3 Post-abortion care and follow-up, at 52.
[49] Carlsson I, Breding K, Larsson PG, 2018, Complications Related to Induced Abortion: A Combined Retrospective and Longitudinal Follow-up Study, BMC Women's Health 18:158.

2011 to 2015, data were collected prospectively. In this study, medical abortions after 12 gestational weeks all occurred at the hospital. The authors report that, among medical abortions less than 12 weeks, the complication frequency increased from 5.4 percent (2008 to 2010) to 8.2 percent (2015). However, the authors also compared the complications related to medical abortions that occurred at less than 12 gestational weeks between "at home" abortions (managed as an outpatient) and "at the hospital" abortions, in 2015 and found no statistically significant difference (8.2 percent "at home" versus 8.0 percent at the hospital). For pregnancies less than or equal to 9 gestational weeks, the rates are similar for the "at home" group (10.0 percent) and the "at the hospital" group (9.3 percent). Notably, as part of our review and approval of the S-020 efficacy supplement in 2016, we assessed serious adverse events by gestational age, including hospitalizations, serious infection requiring hospitalization or intravenous antibiotics, bleeding requiring transfusion, and ectopic pregnancy, as reported in the literature submitted by the Applicant. We concluded that these serious adverse events are rarely reported in the literature and that the regimen of mifepristone 200 mg followed by buccal misoprostol 800 mcg in 24-48 hours is safe to approve for use through 70 days gestation.[50]

You also state that medical abortion is a longer process than surgical abortion and that it requires more attention and care from healthcare providers (Petition at 10). We agree that medical abortion can be a longer process than surgical abortion,[51] but we disagree that medical abortion always requires in-person follow-up with a healthcare provider. Not all of the complications associated with medical abortion necessarily require more intensive management from healthcare providers during a follow-up visit. The question of whether to include an in-person follow-up visit should be discussed by the healthcare provider and the patient. We have concluded that medical abortions are safe and effective for patients who are appropriate candidates and reducing the number of clinic visits does not compromise patient safety.

The current approved labeling for mifepristone for medical termination of pregnancy states that complete pregnancy termination "can be confirmed by medical history, clinical examination, human Chorionic Gonadotropin (hCG) testing, or ultrasonographic scan." Not all these modalities require an in-clinic assessment during a follow-up visit. Our review of the S-020 efficacy supplement concluded that "available data support … that there are a variety of follow-up modalities that can adequately identify the need for additional intervention."[52] We note that these findings are also consistent with ACOG guidelines, which state that "[r]outine in-person follow-up is not necessary after uncomplicated medication abortion" and recommend several methods for post-treatment follow-up, as appropriate, including serial serum hCG testing alone or telephone follow-up at one week after treatment followed by urine pregnancy testing at four weeks after treatment.[53] Because there is more than one effective method to detect an on-going pregnancy, we conclude that the way in which post-treatment follow-up is performed may be determined by the healthcare provider and the patient.

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[50] 2016 Clinical Review, supra n. 13, at 51-57.
[51] See ACOG Practice Bulletin Number 225, supra note 22.
[52] 2016 Cross Discipline Team Leader Review, supra n. 19, at 17.
[53] ACOG Practice Bulletin Number 225, supra note 22.

iii. Misoprostol

In the Petition, you make a number of assertions regarding the use of misoprostol. We address each in turn.

First, you assert that a patient may take misoprostol before the prescribed minimum 24-hour period after taking Mifeprex, thereby rendering the regimen ineffective, and that home administration of misoprostol does not permit health providers to control when their patients take misoprostol (Petition at 7). You similarly assert that the use of buccal misoprostol sooner than 24 hours after administering mifepristone leads to significantly increased failure rates (Petition at 7).

As an initial matter, our review of the S-020 efficacy supplement in 2016 included data that evaluated the home use of misoprostol in over 30,000 women. The data showed that Mifeprex was safe and effective in a regimen with misoprostol when misoprostol was self-administered at home.[54] Therefore, any incorrect administration resulting in a failed abortion was infrequent and did not significantly affect the safety and efficacy of medical abortion. Furthermore, because the process of expelling the pregnancy may begin as soon as 2 hours after taking misoprostol, there is a benefit in allowing patients to choose when and where to start this process, to maximize the possibility of their being at a safe place at a convenient time to experience cramping and bleeding.[55]

In support of your assertion of significantly increased failure rates, you cite a pilot study by Lohr et al.[56] Lohr et al. assessed the complete abortion rate using simultaneous oral mifepristone and buccal misoprostol in three gestational age groupings (less than or equal to 49 days, 50-56 days, 57-63 days) and compared the rates with those published in previous pilot investigations[57] using simultaneous oral mifepristone and vaginal misoprostol in the same three gestational age groupings. The complete abortion rates reported by Lohr at 24 hours for oral mifepristone and buccal misoprostol were 72.5 percent, 69.2 percent, and 72.5 percent, respectively; the complete abortion rates at two weeks, however, were 97.5 percent, 100 percent, and 94.9 percent, respectively (and are consistent with the completion rates as described in the approved labeling).[58] The published complete abortion rates at 24 hours for simultaneous oral mifepristone and vaginal misoprostol administration were 90 percent, 88 percent, and 83 percent, respectively, for the gestational age groupings and the complete abortion rates at 2 weeks were 98 percent, 93 percent, 90 percent, respectively. Based on the data presented in Lohr,

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[54] See 2016 Clinical Review, supra n. 13, at 41 and 48.
[55] Id. at 38.
[56] Petition at 7 (referencing Lohr PA, Reeves MF, Hayes JL, et al., 2007, Oral Mifepristone and Buccal Misoprostol Administered Simultaneously for Abortion: A Pilot Study, Contraception, 76:215-220).
[57] Schreiber CA, Creinin MD, Harwood B, Murthy AS. A pilot study of mifepristone and misoprostol administered at the same time for abortion in women with gestation from 50 to 63 days. Contraception 2005;71:447–50; Murthy AS, Creinin MD, Harwood B, Schreiber C. A pilot study of mifepristone and misoprostol administered at the same time for abortion up to 49 days gestation. Contraception 2005;71:333–6.
[58] See https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020687s022lbl.pdf.

the use of buccal misoprostol at the same time as oral mifepristone does not adversely affect efficacy, although expulsion may be delayed. As recommended in Section 2.3 of the approved labeling, follow-up at 7-14 days after administration of mifepristone is more appropriate to evaluate efficacy.[59] It is misleading to only reference the abortion completion rates observed at the 24-hour timepoint from Lohr. Therefore, we do not agree that data from Lohr indicate higher failure rate with misoprostol taken before the prescribed minimum 24-hour period after taking mifepristone.

Although we disagree that Lohr demonstrates a higher failure rate with misoprostol taken before 24-hours after taking mifepristone, we note that our 2016 review of the S-020 efficacy supplement referenced a 2013 systematic review by Raymond, which concluded that if the interval between mifepristone and misoprostol interval is less than or equal to 24 hours, the procedure is less effective compared to an interval of 24-48 hours.[60] As explained above, the data reviewed in 2016 showed that Mifeprex, in a regimen with misoprostol administered at home, was safe and effective. Therefore, incorrect administration, if it occurred, was infrequent and did not significantly affect the safety and efficacy of medical abortion. However, in light of the data reviewed, section 2.1 of the labeling approved in 2016 (as well as the currently approved labeling and Medication Guide) states that there should be a "minimum 24-hour interval between" mifepristone and misoprostol (emphasis included in the labeling).[61] The approved dosing regimen also states that misoprostol is taken within 24 to 48 hours after taking mifepristone and acknowledges that the effectiveness of the regimen may be lower if misoprostol is administered less than 24 hours after mifepristone administration.

In addition to your concerns that a woman may take misoprostol too soon after administering mifepristone, you also state that waiting until 24 hours after administering mifepristone does not guarantee success (Petition at 7-8). In support of this concern, you cite a 2015 review by Chen and Creinin. You state that this review found "women taking misoprostol earlier than 48 hours after Mifeprex are more likely to fail the regimen" (Petition at 8). Chen and Creinin included studies in which the intervals between mifepristone and buccal misoprostol were 24 hours or 24-48 hours and stated that "based on the available literature, the overall efficacy of regimens with a 24-hour interval between mifepristone and buccal misoprostol is significantly lower than those with a 24- to 48-hour interval (94.2 percent compared with 96.8 percent)."[62] The rate differences were statistically significant, but both regimens were more effective than the 92 percent efficacy rate of the original regimen approved in 2000 (administering misoprostol 48 hours after taking mifepristone).

Finally, you also express concern that if misoprostol is self-administered, a woman may swallow it rather than keep the pill between her cheek and gum, and oral administration of

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[59] See https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020687s022lbl.pdf.
[60] 2016 Clinical Review, supra n. 13, at 31 (citing 8 Raymond EG, et al. First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review. Contraception 2013;87(1):26-37.)
[61] See https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020687s022lbl.pdf.
[62] See Chen MJ and Creinin MD. Mifepristone with buccal misoprostol for medical abortion. Obstet Gynecol. 2015;126(1):12-21; see also 2016 Clinical Review, supra n. 13, at 21.

misoprostol (i.e., swallowing the pill) following the lower dose of mifepristone in the current regimen is not as effective in ending the pregnancy (Petition at 7). Winikoff et al. specifically studied the use of oral compared to buccal misoprostol 24-36 hours after mifepristone 200 mg with overall success rates of 91.3 percent and 96.2 percent, respectively.[63] Both regimens resulted in a greater than 91 percent successful medical abortion. Although the study showed decreased efficacy with oral versus buccal administration in 57-63 days gestational age, there were no statistical differences in other gestational age groupings. Even assuming there is a small proportion of women who are 57-63 days gestational age and use oral administration of misoprostol (rather than buccal as labeled), a small decrease in the reported efficacy in that population would not justify requiring a clinic visit for all women undergoing medical abortion.

Overall, studies support the efficacy of the mifepristone, in a regimen with misoprostol when taken by the patient at home, Therefore, we do not agree that an in-person visit is necessary to manage administration of misoprostol.

iii. Rh-Negative Patients

In the Petition, you state that a follow-up examination is particularly critical for Rh-negative patients and that without that follow-up examination, women will not receive Rhogam after the abortion, increasing their risk of subsequent Rh isoimmunization, which can endanger future pregnancies (Petition at 9). You suggest that a clinic visit after the administration of Mifeprex is important for Rh-negative women to receive Rhogam and that removing the required follow-up visit puts Rh-negative women at risk for isoimmunization. We do not agree.

Rh testing is standard of care in the United States and RhD immunoglobulin (such as Rhogam) should be administered if indicated. Further, administration of RhD immunoglobulin should be given within 72 hours of a sensitizing event (e.g., medical abortion).[64] However, the facility where the RhD immunoglobulin injection occurs (clinic, hospital or laboratory) is not critical. A shift from medical clinics to hospitals for administration of injections has occurred over the years due to shortages of RhD immunoglobulin and poor reimbursement for RhD immunoglobulin injection from third-party payers.[65] This has resulted in pregnant women frequently obtaining routine 28-week RhD immunoglobulin injections at hospitals/laboratories with a prescription provided by their healthcare providers. This same process of obtaining RhD immunoglobulin via prescription is available to patients after medical termination of pregnancy and does not require a follow-up clinic visit.

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[63] Winikoff B, Dzuba, IG, Creinin MD, et al, 2008, Two Distinct Oral Routes of Misoprostol in Mifepristone Medical Abortion, Obstet Gynecol 112(6):1303-1310.

[64] ACOG Practice Bulletin No. 181. Prevention of Rh D Alloimmunization. August 2017.

[65] See https://www.mdedge.com/obgyn/article/61083/practice-management/rhogam-injections-payment-levels-vary-among-insurers.

In summary, the totality of data on the efficacy and safety of medical abortion at less than 70 days gestation, derived from numerous studies, has characterized the complications and rates of complications for completing medical abortion at home, and the findings show medical abortion at home is both safe and effective without three office visits. We therefore deny your request that the use of mifepristone in a regimen with misoprostol require three office visits by the patient.

c. Contraindications

In the Petition, you assert that critical language contraindicating Mifeprex for patients without access to appropriate emergency medical care was excluded from the 2016 Mifeprex labeling. You cite to a study[66] and ACOG statements as evidence that medical abortions have greater risks and more need for emergency "operation" than a surgical abortion, particularly for patients in rural areas with limited access to emergency medical care (Petition at 11).

Although inadequate access to medical facilities for appropriate care was removed from the list of contraindications in section 4 of the approved labeling when we approved the S-020 efficacy supplement, the 2016 Mifeprex labeling and the currently approved mifepristone labeling, as well as the Mifepristone REMS Program, continue to include appropriate instructions for providers regarding patient access to appropriate medical care.[67] For example, the Boxed Warning includes language directing healthcare providers to ensure that the patient knows whom to call and what to do, including potentially going to an emergency room, if the patient experiences serious events associated with the use of mifepristone. The labeling also directs healthcare providers, as part of the dosing regimen, to give the patient the name and phone number of a healthcare provider who will be handling emergencies.[68] In addition, one of the required qualifications listed in the Prescriber Agreement Form is the "[a]bility to provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made plans to provide such care through others, and ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary."[69] Therefore, although certain language about access to medical facilities was removed from the approved labeling in 2016, we disagree that critical language about access to appropriate emergency medical care is lacking from the approved labeling.

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[66] See Petition Reference Document No. 17 (Harrison Affidavit: Donna Harrison, M.D., Aff. *Okla. Coalition for Reproductive Justice v. Cline*, Case No. CV-2014-1886 (Feb. 24, 2015), ¶115 (referencing M. Niinimaki et al., Immediate Complications after Medical compared with Surgical Termination of Pregnancy, Obstet. Gynecol. 114:795 (Oct. 2009)).

[67] See Mifeprex labeling, approved 2016. https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf. See also current labeling at https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020687s022lbl.pdf.

[68] Id.

[69] Mifepristone REMS Program, https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390. Emphasis added.

You also cite information in Box 1, Features of Medical and Surgical Abortion (page 3) in the ACOG Practice Bulletin No. 143.[70] As mentioned above, the ACOG Practice Bulletin No. 143 has been withdrawn and the language you cite is not included in the current Practice Bulletin No. 225.

d. Adverse Event Reporting

In the Petition, you assert that even under the regimen approved in 2000, it was difficult to collect accurate and complete adverse event information for Mifeprex, and that collecting such information is virtually impossible under the regimen approved in 2016 because prescribers only are required to report deaths associated with Mifeprex (Petition at 12). You also assert that FDA cannot adequately assess the safety of the current Mifeprex regimen without comprehensive information on adverse events (Petition at 12). You state that certified prescribers should at a minimum be required to report the following to FDA's MedWatch reporting system and to the sponsor: deaths, hospitalizations, blood transfusions, emergency room visits, failures requiring surgical completion, ongoing pregnancy, or other major complications, including detailed information on these events (Petition at 13).

We acknowledge that there is always a possibility with any drug that some adverse events are not being reported, because reporting to the Agency's MedWatch program by health care professionals and patients is voluntary. We do not agree, however, that the 2016 changes to the prescriber reporting requirements limit our ability to adequately monitor the safety of mifepristone for medical termination of pregnancy. Prior to the 2016 approval of the S-20 efficacy supplement, we assessed approximately 15 years of adverse event reports both from the Applicant and through the MedWatch program and determined that certain ongoing additional reporting requirements under the Mifeprex REMS, such as hospitalization and blood transfusions, were not warranted. This assessment was based on the well-characterized safety profile of Mifeprex, with known risks occurring rarely, along with the essentially unchanged safety profile of Mifeprex during this 15-year period of surveillance. Accordingly, the Prescriber Agreement Form was amended as part of our 2016 approval of the S-20 efficacy supplement to require, with respect to adverse event reporting, only that prescribers report any cases of death to the Applicant.

We also note that the reporting changes to the Prescriber Agreement Form as part of our 2016 approval do not change the adverse event reporting requirements for the Applicants. Like all other holders of approved NDAs and ANDAs, the Applicants are required to report all adverse events, including serious adverse events, to FDA in accordance with the requirements set forth in FDA's regulations (see 21 CFR 314.98, 21 CFR 314.80, and 21 CFR 314.81). FDA also routinely reviews the safety information provided by the Applicants in the Annual Reports. As with all drugs, FDA continues to closely monitor the postmarketing safety data on mifepristone for the medical termination of pregnancy.

[70] Petition at 11. Medical Management of First-Trimester Abortion. ACOG Practice Bulletin Number 143. March 2014 (Reaffirmed 2016. Replaces Practice Bulletin Number 67, October 2005); Obstet Gynecol. 2014 Mar;123(3):676-692 at 680.

You state that FDA should provide guidance to emergency healthcare providers and physicians so that they know how to distinguish complications following drug-induced abortion from complications following spontaneous miscarriage (Petition at 13). We disagree that specific guidance is needed at this time. In the past, when appropriate, FDA has worked with the NDA Applicant to issue communications to healthcare providers and emergency department providers concerning certain serious adverse events.[71] Furthermore, the approved Medication Guide advises patients to take the Medication Guide with them if they need to go to the emergency room or seek care from a healthcare provider other than the one who dispensed the medication to them, so the emergency room or healthcare provider understands the patient is having a medical abortion. We have not identified a change in the safety profile of mifepristone that would warrant additional communications to healthcare providers and emergency department providers concerning complications following medical abortion. If we become aware of safety information that merits further communications with emergency department providers or healthcare providers, or that warrants revisions to the approved labeling, we will act as appropriate.

You also assert that many Mifeprex prescribers "violate FDA protocol," instructing their patients to lie to emergency medical personnel, and that this prevents emergency healthcare providers from appropriately caring for their patients and further decreases the likelihood that adverse events will be reported (Petition at 12). Your only support for this claim is a reference to instructions from the organization Aid Access[72] to patients that they can tell emergency room staff that they had a miscarriage and do not need to tell medical staff that they had a medical abortion. The Petition does not provide any data or additional information establishing "many Mifeprex prescribers violate FDA protocol, instructing their patients to lie," or that these providers thereby prevented appropriate care and decreased the number of adverse events reported.

B. REMS

1. Request to Retain Mifeprex REMS

In your Petition, you request that FDA retain the Mifeprex REMS (Petition at 14). We agree that a REMS is necessary to ensure that the benefits of mifepristone in a regimen with misoprostol outweigh the risks. FDA's determination as to whether a REMS is necessary

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[71] See Historical Information on Mifepristone (Marketed as Mifeprex), available at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111334.htm. For example, the NDA applicant and FDA agreed that there was a need to issue a Dear Health Care Provider letter in April 2002 and a Dear Emergency Room Director letter in September 2004. The fact that these letters were issued does not imply that the approved mifepristone regimen is unsafe; it is not uncommon for drug sponsors to issue "Dear Health Care Provider" letters, and, as noted in the Mifepristone Q&A document posted on our Web site in April 2002, "[w]hen FDA receives and reviews new information, the agency provides appropriate updates to doctors and their patients so that they have essential information on how to use a drug safely."

[72] We note that Aid Access facilitated the sale of unapproved mifepristone and misoprostol to U.S. consumers and that FDA sent Aid Access a warning letter asking it to promptly cease causing the sale of unapproved and misbranded drugs to U.S. consumers. US FDA Warning Letter to Aidaccess.org, dated March 8, 2019. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/aidaccessorg-575658-03082019.

to ensure that the benefits of a drug outweigh its risks is a complex, drug-specific inquiry, reflecting an analysis of multiple, interrelated factors and of how those factors apply in a particular case.[73] In conducting this analysis, FDA considers whether (based on premarketing or postmarketing risk assessments) there is a particular risk or risks associated with the use of the drug that, on balance, outweigh its benefits and whether additional interventions beyond FDA-approved labeling are necessary to ensure that the drug's benefits outweigh its risks.[74]

As described in the background section of this response (see section I.A.), FDA determined that interventions in addition to the FDA-approved labeling were necessary to ensure that the benefits of Mifeprex outweighed its risks when the drug was initially approved in 2000, and periodic re-evaluations of the REMS since that time have reached the same conclusion. As further described in the background section of this response (see section I.E.), FDA recently undertook a review of the Mifepristone REMS Program. As explained below, the Mifepristone REMS Program continues to be necessary to ensure the benefits outweigh the risks.

After review of multiple different sources of information, including published literature, safety information submitted to the Agency during the COVID-19 PHE, FAERS reports, the first REMS assessment report for the Mifepristone REMS Program, and information provided by advocacy groups, individuals, and the Plaintiffs in ongoing litigation,[75] as well as information submitted by the Applicants, we have concluded that the REMS can be modified to reduce the burden on the health care delivery system without compromising patient safety. As explained below, we agree that the healthcare provider certification (ETASU A) and dispensing of mifepristone to patients with evidence or other documentation of safe use conditions (ETASU D) continue to be necessary components of the REMS to ensure the benefits outweigh the risks. However, we have concluded that the Mifepristone REMS Program must be modified to remove the requirement under ETASU C that mifepristone be dispensed only in certain healthcare settings, specifically clinics, medical offices, and hospitals.

Below, we discuss each of these elements of the Mifepristone REMS Program.

a. ETASU A – Prescriber Certification/Qualifications

ETASU A under the Mifepristone REMS Program requires healthcare providers who prescribe mifepristone to be certified. In order to become certified, prescribers must: 1) review the prescribing information for mifepristone and 2) complete the Prescriber Agreement Form. In signing the Prescriber Agreement Form, prescribers agree they meet the qualifications listed below:

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[73] See FDA Guidance for Industry, *REMS: FDA's Application of Statutory Factors in Determining When a REMS Is Necessary* (Apr. 2019).
[74] Id.
[75] See supra n. 10.

- Ability to assess the duration of pregnancy accurately
- Ability to diagnose ectopic pregnancies
- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made plans to provide such care through others, and ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
- Has read and understood the Prescribing Information of mifepristone (which the provider can access by phone or online).

In addition to meeting these qualifications, as a condition of certification the healthcare provider also agrees to follow the guidelines for use below:

- Review the Patient Agreement Form with the patient and fully explain the risks of the mifepristone treatment regimen. Answer any questions the patient may have prior to receiving mifepristone.
- Sign and obtain the patient's signature on the Patient Agreement Form.
- Provide the patient with a copy of the Patient Agreement Form and the Medication Guide.
- Place the signed Patient Agreement Form in the patient's medical record.
- Record the serial number from each package of mifepristone in each patient's record.
- Report deaths to the Applicant, identifying the patient by a non-identifiable patient reference and the serial number from each package of mifepristone.

Our review of the published literature did not identify any studies comparing healthcare providers who met these qualifications with healthcare providers who did not. In the absence of such studies, there is no evidence to contradict our previous finding that prescribers' ability to accurately date pregnancies, diagnose ectopic pregnancies, and provide surgical intervention either personally or through others, is necessary to mitigate the serious risks associated with the use of mifepristone in a regimen with misoprostol. Therefore, our conclusion continues to be that a healthcare provider who prescribes mifepristone in a regimen with misoprostol should meet the above qualifications. Absent these provider qualifications, we are concerned that serious and potentially fatal complications associated with medical abortion, including missed ectopic pregnancy and heavy bleeding from incomplete abortion, may not be detected or appropriately managed.

Accordingly, we have determined that ETASU A must remain an element of the Mifepristone REMS Program to ensure the benefits outweigh the risks. Maintaining the requirement for prescriber certification ensures that providers meet the necessary qualifications and adhere to the guidelines for use listed above. The burden of prescriber certification has been minimized to the extent possible by requiring prescribers to certify only one-time for each applicant.

Although we agree with your request to retain the REMS for mifepristone (now the Mifepristone REMS Program) insofar as it pertains to ETASU A, as discussed in section II.A.2.a of this response, we do not agree with your request that the healthcare provider needs to be a licensed physician to meet this requirement.

b. ETASU D – Requirement For The Drug To Be Dispensed With Evidence Or Other Documentation Of Safe-Use Conditions

ETASU D under the Mifepristone REMS Program requires mifepristone to be dispensed with evidence or other documentation of safe-use conditions. To receive mifepristone for medical termination of intrauterine pregnancy through 70 days gestation, the patient must sign a Patient Agreement Form indicating that the patient has received, read, and been provided a copy of the Patient Agreement Form and received counseling from the prescriber regarding the risk of serious complications associated with mifepristone for this indication. The Patient Agreement Form ensures that patients are informed of the risks of serious complications associated with mifepristone for this indication. In a number of approved REMS, Patient Agreement Forms or Patient Enrollment Forms ensure that patients are counseled about the risks of the product and/or informed of appropriate safe use conditions.[76]

As a condition of certification under the Mifepristone REMS Program, healthcare providers must follow the guidelines for use of mifepristone, including reviewing the Patient Agreement Form with the patient, fully explaining the risks of the treatment regimen and answering any questions the patient may have before receiving the medication. With this form, the patient acknowledges that they have received and read the form, and that they have received the counseling regarding when to take mifepristone, the risk of serious complications associated with mifepristone and what to do if they experience adverse events (e.g., fever, heavy bleeding). Both the healthcare provider and patient must sign the document and the patient must receive a copy of the signed form. In addition to the counseling described in the Patient Agreement Form, patients also receive a copy of the Medication Guide for mifepristone. Ultimately, the Patient Agreement Form serves as an important counseling component, and documentation that the safe use conditions of the Mifepristone REMS Program have been satisfied, as the prescriber is required to place the signed Patient Agreement Form in the patient's medical record.

In addition, we conducted an updated review of published literature since 2016 to assess the utility of maintaining the Patient Agreement Form as part of the Mifepristone REMS Program, and these studies do not provide evidence that would support removing ETASU D. For these reasons, we have determined that ETASU D must remain an element of the Mifepristone REMS Program to ensure the benefits outweigh the risks.

[76] REMS@FDA, https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm, Accessed November 15, 2021.

c. ETASU C – In-Person Dispensing

ETASU C under the Mifepristone REMS Program currently requires mifepristone to be dispensed to patients only in certain healthcare settings, specifically clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber. This creates what we refer to in this response as an in-person dispensing requirement under the REMS; i.e., the patient must be present in person in the clinic, medical office, or hospital when the drug is dispensed. The mifepristone REMS document currently states that mifepristone may not be distributed to or dispensed through retail pharmacies or settings other than a clinic, medical office, or hospital. As explained below, based on a recent review of the REMS, we believe that the Mifepristone REMS Program must be modified to remove the requirement that mifepristone be dispensed only in certain healthcare settings, specifically clinics, medical offices, and hospitals, because this requirement is no longer necessary to ensure that the benefits of the drug outweigh the risks. This conclusion is based on our review of information from the Mifepristone REMS Program one-year (1st) REMS[77] assessment data and postmarketing safety information, and supported by our review of the published literature.

i. Assessment Data

As part of our review of the REMS, we evaluated information included in the 1st REMS assessment report for the Mifepristone REMS Program, which included healthcare provider certification data, program utilization data, and non-compliance data. This 1st REMS assessment report covers a reporting period between April 11, 2019 through February 29, 2020. During this reporting period, a small number of non-compliance events were reported.

As described in section I.C. of this response, during the timeframe from January 27, 2020 through September 30, 2021, there were periods when the in-person dispensing requirement was not enforced. To better understand whether there was any impact on safety or non-compliance during the periods when the in-person dispensing requirement was not enforced, we requested additional information from the Applicants to provide for more comprehensive assessment of the REMS for the time period from January 27, 2020 (the effective date of the COVID-19 PHE) to September 30, 2021. We requested the Applicants provide a summary and analysis of any program deviation or non-compliance events from the REMS requirements and any adverse events that occurred during this time period that had not already been submitted to FDA. The NDA and the ANDA Applicants reported a total of eight cases reporting adverse events between January 27, 2020 and September 30, 2021. These eight cases were also identified in the FAERS database and are described below.

The number of adverse events reported to FDA during the COVID-19 PHE with mifepristone use for medical termination of pregnancy is small, and the data provide no

[77] This REMS assessment report was the first submitted following the approval of the single, shared system REMS for mifepristone.

indication that any program deviation or noncompliance with the Mifepristone REMS Program contributed to these reported adverse events.

ii. FAERS/Postmarketing Safety Data

FDA routinely monitors postmarketing safety data for approved drugs through adverse events reported to our FAERS database,[78] through our review of published medical literature, and when appropriate, by requesting applicants submit summarized postmarketing data. For our recent review of the REMS, we searched our FAERS database, reviewed the published medical literature for postmarketing adverse event reports for mifepristone for medical termination of pregnancy, and requested that the Applicants submit a summary and analysis of certain adverse events. Our review of this postmarketing data indicates there have not been any new safety concerns with the use of mifepristone for medical termination of pregnancy through 70 days gestation, including during the time when in-person dispensing was not enforced.

In order to evaluate the periods when in-person dispensing was and was not enforced, we conducted a search of the FAERS database and the published medical literature to identify U.S. postmarketing adverse events that reportedly occurred from January 27, 2020 through September 30, 2021 with mifepristone use for medical termination of pregnancy. The data for this time period were then further divided into the date ranges when in-person dispensing was enforced per the REMS (January 27, 2020 - July 12, 2020 and January 13, 2021 - April 12, 2021) versus when in-person dispensing was not enforced: July 13, 2020 - January 12, 2021 (in-person dispensing enforcement was temporarily enjoined) and April 13, 2021 - September 30, 2021 (enforcement discretion for in-person dispensing because of the COVID-19 PHE).

Based on the above search, a total of eight cases were identified in FAERS and no additional case reports were identified in the medical literature. Two of the eight cases reported adverse events that occurred when in-person dispensing was being enforced (i.e., January 27, 2020-July 12, 2020 and January 13, 2021-April 12, 2021). These two cases reported the occurrence of uterine/vaginal bleeding (case 1) and uterine/vaginal bleeding and sepsis (case 2). Of note, uterine/vaginal bleeding and sepsis are labeled adverse events. Five of the eight cases reported adverse events that occurred when in-person dispensing was not enforced (i.e., July 13, 2020-January 12, 2021 and April 13, 2021-September 30, 2021); however, the narratives provided in the FAERS reports for three of the five cases explicitly stated that mifepristone was dispensed in-person. These five cases reported the occurrence of ongoing pregnancy (case 3), drug intoxication and death approximately 5 months after ingestion of mifepristone (case 4), death [cause of death is currently unknown] (case 5), sepsis and death (case 6), and pulmonary embolism (case 7). Of note, ongoing pregnancy and sepsis, including the possibility of fatal septic shock, are labeled adverse events. The remaining case reported the occurrence of oral pain/soreness (case 8) in July

[78] FAERS is a database that contains adverse event reports, medication error reports and product quality complaints resulting in adverse events that were submitted to FDA. The database is designed to support FDA's post-marketing safety surveillance program for drug and therapeutic biologic products.

2021, but did not provide sufficient information to determine the exact date of the adverse event.

As discussed in section II.A.2.d., the Applicants report adverse events, including serious adverse events, to FDA in accordance with applicable regulations.[79] To enable additional review of adverse events, Applicants were requested to provide a summary and analysis for adverse events reported with incomplete medical abortion requiring surgical intervention to complete abortion, blood transfusion following heavy bleeding or hemorrhage, ectopic pregnancies, sepsis, infection without sepsis, hospitalization related to medical abortion, and emergency department/urgent care encounter related to medical abortion. The Applicant for Mifeprex provided the requested summary of postmarketing safety information from March 29, 2016, when S-020 was approved, through September 30, 2021. The Applicant for the generic provided the requested summary of postmarketing safety information from April 11, 2019 (date of initial approval) through September 30, 2021. The information provided by the Applicants included the same cases identified in FAERS, as discussed above.

We analyzed the FAERS data referenced above to determine if there was a difference in adverse events when in-person dispensing was and was not enforced. Based on FDA's review of this data, we concluded that there does not appear to be a difference in adverse events when in-person dispensing was and was not enforced and that mifepristone may be safely used without in-person dispensing. FDA's review of the summary and analysis data submitted by the Applicants (which, as noted above, included the same cases identified from FAERS) did not change this conclusion.

iii. Published Literature

As noted above, we also conducted an extensive review of the published literature since March 29, 2016 (the date the S-020 efficacy supplement for Mifeprex was approved) through September 30, 2021.[80] Published studies have described alternatives in location and method for dispensing mifepristone by a certified prescriber (or equivalent healthcare provider in countries other than the United States). Some studies have examined replacing in-person dispensing in certain healthcare settings with dispensing at retail pharmacies[81]

[79] See 21 CFR 314.98, 21 CFR 314.80, and 21 CFR 314.81.

[80] In support of your request that we retain the REMS and continue limiting the dispensing of Mifeprex to patients in clinics, medical offices, and hospitals by or under the supervision of a certified prescriber, you reference two studies that you assert do not comply with the REMS (Petition at 19-22). Outcomes from both of the studies you reference have been reported in the published literature and are addressed in the discussion that follows. We note that as a general matter, a clinical investigation of an approved drug that is subject to a REMS can take place in healthcare settings outside those provided for in the REMS. When an approved drug that is subject to a REMS is studied in a clinical trial, the REMS does not apply to the use of the drug in that clinical trial. However, FDA reviews the protocol to ensure that it will be conducted in a manner that adequately addresses the risks that the REMS is intended to mitigate, such that the trial participants will not be exposed to an unreasonable and significant risk of illness or injury. See 21 CFR 312.42(b)(1)(i) and (b)(2)(i).

[81] Grossman D, Baba CF, Kaller S, et al. Medication Abortion With Pharmacist Dispensing of Mifepristone. Obstet Gynecol 2021;137:613–22; Rocca CH, Puri M, et al. Effectiveness and safety of early medication

and dispensing mifepristone from pharmacies by mail.[82] Other studies have evaluated two modes of dispensing by prescribers: (1) prescribers mailing the medications to patients,[83] and (2) prescribers using couriered delivery of medications.[84] Different studies have evaluated dispensing mifepristone by mail by an entity described as "a partner organization."[85]

We note that the ability to generalize the results of these studies to the United States population is hampered by differences between the studies with regard to pre-abortion care (e.g., telemedicine versus in-person). In addition, the usefulness of the studies is limited in some instances by small sample sizes and lack of follow-up information on outcomes with regard to both safety and efficacy. There are also factors which complicate the analysis of the dispensing element alone. Some of these factors are: (1) only a few studies have evaluated alternatives for in-person dispensing of mifepristone in isolation (for example, most studies on mail dispensing of mifepristone also include telemedicine consultation); and (2) because most serious adverse events with medical abortion are infrequent, further evaluation of changes in dispensing would require studies with larger numbers of participants. We did not find any large clinical studies that were designed to collect safety outcomes in healthcare systems similar to the United States. Despite the limitations of the studies we reviewed, we have concluded that overall the outcomes of these studies are not inconsistent with our conclusion that, based on the 1st year REMS assessment report and postmarketing safety data, mifepristone will remain safe and efficacy will be maintained if the in-person dispensing requirement is removed from the Mifepristone REMS Program.

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abortion provided in pharmacies by auxiliary nurse-midwives: A non-inferiority study in Nepal. PLoS ONE 13(1): e0191174. https://doi.org/10.1371/journal.pone.019117; Wiebe ER, Campbell M, et al. Comparing telemedicine to in-clinic medication abortions induced with mifepristone and misoprostol. Contracept X. 2020; 2: 100023.

[82] Grossman D, Raifman S, Morris N, et.al. Mail-order pharmacy dispensing of mifepristone for medication abortion after in-person clinical assessment. Contraception 2021, ISSN 0010-7824, https://doi.org/10.1016/j.contraception.2021.09.008, Available online 20 September 2021; Upadhyay UD, Koenig LR, Meckstroth KR. Safety and Efficacy of Telehealth Medication Abortion in the US During the COVID-19 Pandemic. JAMA Network Open. 2021;4(8):e2122320, doi:10.1001/jamanetworkopen.2021.22320; Hyland P, Raymond EG, Chong E. A direct-to-patient telemedicine abortion service in Australia: Retrospective analysis of the first 18 months. Aust N Z J Obstet Gynaecol 2018;58: 335-340.

[83] See Anger HA, Raymond EG, et al. Clinical and service delivery implications of omitting ultrasound before medication abortion provided via direct-to-patient telemedicine and mail. Contraception 2021 Jul 28;S0010-7824(21)00342-5. doi: 10.1016/j.contraception.2021.07.108. Published online. Raymond E, Chong E, et al. TelAbortion: evaluation of a direct to patient telemedicine abortion service in the United States. Contraception 2019; 100:173-177. See also Chong et al., infra n. 103 Kerestes et al., infra n. 105, and Aiken et al., infra n. 106.

[84] Reynolds-Wright JJ, et al. BMJ Sex Reprod Health 2021;0:1–6. doi:10.1136/bmjsrh-2020-200976.

[85] Endler M, Beets L, Gemzell Danielsson K, Gomperts R. Safety and acceptability of medical abortion through telemedicine after 9 weeks of gestation: a population-based cohort study. BJOG 2019;126;609-618. Norten H, Ilozumba O, Wilkinson J, Gemzell Danielsson K, Gomperts R. 10-year evaluation of the use of medical abortion through telemedicine: a retrospective cohort study. BJOG 2021; https://doi.org/10.1111/1471-0528.16765; Aiken ARA, Digol I, Trussell J, Gomperts R. Self-reported outcomes and adverse events after medical abortion through online telemedicine: population based study in the Republic of Ireland and Northern Ireland. BMJ 2017;357:j2011 http://dx.doi.org/10.1136/bmj.j2011.

Below is a summary of our review of the literature, organized by the methods of dispensing mifepristone that were studied.

(a) Retail pharmacy dispensing

Three studies reported medical abortion outcomes for retail pharmacy dispensing of mifepristone after clinical evaluation (Grossman,[86] Rocca,[87] Wiebe[88]). Grossman conducted a US-based study in which mifepristone and misoprostol were dispensed from a pharmacy partnered with the clinic. Complete abortion without additional procedures occurred in 93.5 percent of participants with known outcomes. The reported proportion of complete abortion is within the range described in the approved mifepristone labeling. No participants experienced a serious adverse event, were hospitalized or required transfusion. Three participants had emergency department (ED) visits with treatment (intravenous hydration, pain medication, pelvic infection after uterine aspiration for incomplete abortion). The study safety and efficacy outcomes are consistent with labeled outcome frequencies. The study has limited generalizability because it was conducted in two US states and involved partnered pharmacies, some of which were in the same building as the clinic. Additionally, all participating pharmacies in this study were required to have a pharmacist on duty during clinic hours who had been trained in the study protocol and was willing to dispense mifepristone. The study conditions may not be generalizable to United States retail pharmacies; there is insufficient information to assess this.

Rocca[89] conducted an observational study evaluating participants who obtained medical abortions in Nepal by comparing the provision of medical abortion service by newly trained nurse midwives in pharmacies to medical abortion provided in government-certified clinics. The authors reported that, with respect to complete abortion (greater than 97 percent) and complications (no hospitalizations or transfusions), evaluation and dispensing in pharmacy was non-inferior to in-clinic evaluation and dispensing.

Wiebe,[90] in a retrospective, chart review study conducted in Canada, compared abortion outcomes of women who underwent medical abortion with telemedicine consult, and either received medications by courier or picked them up at a local pharmacy, with outcomes of a matched control cohort of women who received the medications at a pharmacy after an in-clinic visit. The groups had similar documented complete medical abortion outcomes (equal to or greater than 95 percent participants with known outcomes). The telemedicine group had one case of hemorrhage (0.5 percent) and one case of infection requiring antibiotics (0.5 percent) compared with no cases of hemorrhage or infection requiring antibiotics in the in-clinic cohort. The telemedicine group had more ED visits (3.3 percent compared to 1.5 percent in-clinic cohort). Both models of dispensing mifepristone resulted in efficacy and safety outcomes within labeled frequency.

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[86] Grossman et al., supra n. 81.
[87] Rocca et al., supra n. 81.
[88] Wiebe et al., supra n. 81.
[89] Rocca et al., supra n. 81.
[90] Wiebe et al., supra n. 81.

None of the three studies allow a determination regarding differences in safety between in-person dispensing by a certified prescriber in a health care setting and dispensing through a retail pharmacy, due to limitations on the generalizability of the results of the studies to the current retail pharmacy environment in the United States. The outcome findings from the one United States study (Grossman)[91], in which the pharmacies were partnered with prescribers, are unlikely to be broadly generalizable to the current retail pharmacy environment and do not reflect typical prescription medication availability with use of retail pharmacy dispensing. For the retail pharmacy dispensing study in Canada (Wiebe),[92] timely provision of medication from the retail pharmacy was accomplished by either courier to the woman or faxed prescription to the woman's pharmacy. It is unknown whether conditions that would allow timely access to medications for medical abortion would occur in retail pharmacies throughout the United States, suggesting the findings from that study may not be broadly generalizable. The third study (Rocca)[93] evaluated medical abortion provided in Nepali pharmacies and essentially moved the abortion provider and clinical examination into the pharmacy, a scenario that is not, at this time, applicable to the United States retail setting.

(b) Mail order pharmacy

Three studies evaluated mail order pharmacy dispensing (Grossman,[94] Upadhyay,[95] Hyland[96]). Grossman published an interim analysis of an ongoing prospective cohort study evaluating medical abortion with mifepristone and misoprostol dispensed by mail-order pharmacy after in-person clinical assessment. Complete abortion without additional procedures occurred in 96.9 percent of participants with known outcomes. Two (0.9 percent) participants experienced serious adverse events; one received a blood transfusion and one was hospitalized overnight. Nine (4 percent) participants attended 10 ED visits. In this interim analysis, the outcomes are consistent with labeled frequencies.

Upadhyay[97] reports findings from a retrospective cohort study of women undergoing medical abortion in the United States without a consultation or visit. Eligibility was assessed based on a participant-completed online form collecting pregnancy and medical history. Participants who were considered eligible received medication delivered by a mail-order pharmacy. Abortion outcome was determined by either an assessment on day 3 or a 4-week pregnancy test. The investigators reported a complete abortion rate without additional procedures of 95 percent for participants with known outcomes and stated that no participants had any major adverse events. The proportion of abortion outcomes assessed at 3 days versus 4 weeks is not reported. Regardless, determining outcomes at 3 days is insufficient to determine outcome rates or safety findings because a 3-day follow-up period is too short. As recommended in Section 2.3 of the approved labeling, follow-up at

[91] Grossman et al., supra n. 81.
[92] Wiebe et al., supra n. 81.
[93] Rocca et al., supra n. 81.
[94] Grossman et al, supra n. 82.
[95] Upadhyay et al., supra n. 82.
[96] Hyland et al., supra n. 82.
[97] Upadhyay et al., supra n. 82.

7-14 days after administration of mifepristone is more appropriate to evaluate safety and efficacy. This study used a model with numerous deviations from standard provision of medical abortion in the United States, such as no synchronous interaction with the prescriber during informed consent or prior to prescribing medication and no confirmation of self-reported medical, surgical, and menstrual history. These deviations, limited follow-up information, and small sample size limit the usefulness of this study.

Hyland[98] describes findings from a cohort study in Australia evaluating medical abortion outcomes utilizing telemedicine and a central mail order pharmacy. Complete abortions without additional procedures occurred in 96 percent of participants with documented outcomes and is consistent with labeled efficacy. Of the participants included in the analysis, 95 percent had no face-to-face clinical encounters after medications were mailed while 3 percent were admitted to the hospital and 2 percent had an outpatient encounter. One participant who was hospitalized and underwent a surgical uterine evacuation received a transfusion. Not included in the findings are 7 hospitalizations occurring in 7 participants who did not have "full follow up." The authors do not report any other adverse events and conclude use of the telemedicine medical abortion service is safe. However, the reasons for hospitalization are not discussed by the authors; therefore, it is unknown why the patients were hospitalized. Although the reported frequency of hospitalizations (3 percent) is higher than the less than 1 percent in the FDA-approved mifepristone labeling, conclusions on the safety findings cannot be made in the absence of information about the reasons for hospitalization. Other limitations of this study include incomplete information about outcomes with face-to-face encounters.

Overall, the three studies evaluating mail order pharmacy dispensing suggest that efficacy of medical abortion is maintained with mail order pharmacy dispensing. With respect to safety, in the Grossman study[99] the interim analysis, although small, does not raise serious safety concerns. Safety findings from the Hyland[100] study are difficult to interpret. Although only one transfusion is reported and the authors state the findings demonstrate safety, a higher hospitalization rate and lack of information on the reasons for hospitalization preclude reaching any conclusions about the safety findings. Lastly, the Upadhyay[101] study had no reported adverse events, but the findings are less useful because of the limited follow-up, and because medical abortions were provided using a model with numerous deviations from standard provision of medical abortion in the United States.

(c) Clinic dispensing by mail

A total of five studies evaluated clinic dispensing by mail. Gynuity Health Projects conducted a prospective cohort study (the "TelAbortion" study) evaluating use of telemedicine for remote visits and mifepristone being dispensed from clinics via overnight or regular tracked mail. Three publications reviewed have reported outcomes for the Gynuity population exclusively: Raymond (outcomes from May 2016 to December

[98] Hyland et al., supra n. 82.
[99] Grossman et al., supra n. 82.
[100] Upadhyay et al., supra n. 82.
[101] Hyland et al., supra n. 82.

2018),[102] Chong (outcomes from May 2016 to September 2020)[103] and Anger (outcomes from March 2020 to September 2020).[104] A fourth study, Kerestes,[105] reports outcomes of medical abortion at the University of Hawai'i from April 2020 to November 2020 and a fifth study, Aiken (2021)[106] reports outcomes of medical abortion up to 70 days gestational age in the United Kingdom before and during the COVID-19 PHE in a retrospective cohort study.

In Raymond,[107] complete abortion without additional procedures occurred in 93 percent of participants with known outcomes. There were two hospitalizations (one participant received a transfusion for severe anemia despite having had a complete abortion) and 7 percent of participants had clinical encounters in ED/urgent care centers. The reported outcomes are similar to outcomes described in approved labeling except the combined ED/urgent care center encounters (7 percent) exceeded the ED visits in approved labeling (2.9-4.6 percent).[108] Of note, the authors state that half of the ED/urgent care visits did not entail any medical treatment. In Chong,[109] approximately 50 percent of the medical abortions occurred during the period of the COVID-19 PHE. Complete abortion without an additional procedure occurred in 95 percent of those with known outcomes. Transfusions were 0.4 percent and hospitalizations were 0.7 percent; 6 percent of participants had unplanned clinical encounters in ED/urgent care. Surgical interventions were required in 4.1 percent to complete abortion. The reported outcomes in Chong (which updated the findings described in Raymond) are similar to outcomes described in approved labeling except that (as with the Raymond study it updated) the combined ED/urgent care center encounters (6 percent) exceeded the ED visits in approved labeling (2.9-4.6 percent).

Anger,[110] which compared outcomes among participants enrolled in the Gynuity study who did ("test medical abortion cohort") versus did not ("no-test medical abortion cohort")[111]

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[102] Raymond et al., supra n. 83.
[103] Chong E, Shochet T, et al. Expansion of a direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic. Contraception 2021;104:43-48.
[104] Anger et al., supra n. 83.
[105] Kerestes C, Murayama S, et al. Provision of medication abortion in Hawai'i during COVID-19: Practical experience with multiple care delivery models. Contraception 2021 Jul;104(1):49-53. doi:10.1016/j.contraception.2021.03.025. Epub 2021 Mar 28.
[106] Aiken ARA, Lohr PA, et al. Effectiveness, safety and acceptability of no-test medical abortion (termination of pregnancy) provided via telemedicine: a national cohort study. BJOG 2021;128:1464–1474.
[107] Raymond, supra n. 83.
[108] The authors reported the combined frequency of emergency department/urgent care visits, whereas the approved labeling includes the frequency for emergency department (emergency room) visits. Therefore it is unknown whether the frequency of emergency department visits in the trial, as distinct from the combined frequency of emergency department/urgent care visits, is comparable to the frequency of emergency department visits reflected in approved labeling.
[109] Chong et al., supra n. 103.
[110] Anger et al., supra n. 83.
[111] "No-test medication abortion" refers to medical abortion provided without a pretreatment ultrasound, pelvic examination or laboratory tests when, in the judgment of the provider, doing so is medically appropriate (appropriateness based on history and symptoms); "no-test medication abortion" does include post-abortion follow up. A sample protocol is described by Raymond et al." (Raymond EG, Grossman D, Mark A, et.al. Commentary: No-test medication abortion: A sample protocol for increasing access during a pandemic and beyond. Contraception 2020;101:361-366)

have confirmation of gestational age/intrauterine location with an examination or ultrasound, found that those without an examination or ultrasound prior to medical abortion were more likely to require procedural interventions and had more unplanned clinical encounters.[112] There were no reported ectopic pregnancies in either group. The number of ED/urgent care visits and the proportion of unplanned clinical encounters that led to medical treatment were not reported. In the "test" group, complete medical abortion was confirmed in 98 percent of participants with known outcomes; one participant was "hospitalized and/or blood transfusion" and 8 percent had an unplanned clinic encounter (participant sought in-person medical care related to abortion and the visit was not planned prior to abortion). In the "no-test" group, complete medical abortion was confirmed in 94 percent of participants with known outcomes; two participants were "hospitalized and/or blood transfusion" and 12.5 percent had an unplanned clinical encounter.

Kerestes[113] included three different delivery models: traditional in-person visits, telemedicine consultation with in-person pick-up of medications, and telemedicine consultation with delivery of medications by mail (most of the latter were enrolled through Gynuity's TelAbortion study). Among participants with follow-up data, the rates of successful medical abortion without surgery were consistent with outcomes in approved labeling. Blood transfusion was given to two participants (both in the telemedicine plus in-person pickup group). Although ED visits occurred the most frequently in the telemedicine plus mail group (four participants or 5.8 percent) and the least in the in-person group (two participants or 2.1 percent), the study reported no increases in other serious adverse events. Aiken (2021)[114] reported outcomes before and during the pandemic in a retrospective cohort study in the United Kingdom. The study compared the two cohorts: one before the pandemic with in-person visits and dispensing (traditional model) and one during the pandemic with either an in-person visit and in-person dispensing or a telemedicine visit and dispensing by mail or picked up from the clinic (hybrid model). Complete abortion occurred in greater than 98 percent in both cohorts; the rate was slightly higher in the telemedicine group than in the in-person group. There were no significant differences in the rates of reported serious adverse events. The investigators' analysis determined that the efficacy and safety were comparable between both cohorts and concluded the hybrid model for medical abortion is effective and safe.

Taken together, data from the three Gynuity study reports (Raymond, Chong, and Anger), Kerestes, and Aiken (2021) support that efficacy of medical abortion was maintained when mifepristone was dispensed by mail from the clinic. Study reports of Raymond, Chong, and Kerestes all suggest there may be an increase in ED/urgent care visits with telemedicine visits and dispensing by mail from the clinic, but without increases in other serious adverse events. Anger's comparative analysis suggests a pre-abortion examination may decrease the occurrence of procedural intervention and decrease the number of unplanned visits for postabortion care. The Aiken (2021) study appears to be of sufficient

[112] We note that the two cohorts were not randomized in the Anger study; they had different baseline characteristics. Consequently, findings based on the comparisons between the two cohorts should be interpreted carefully.
[113] Kerestes et al., supra n. 105.
[114] Aiken et al., supra n. 106.

sample size to determine whether safety outcomes with mail dispensing differ from in-person dispensing; however, significant limitations include that the analysis was based on deidentified information and the investigators were unable to verify the outcomes extracted. Further, the study's design did not capture all serious safety outcomes, thus limiting the certainty of the findings.

Notwithstanding the limitations discussed above, these studies overall support that dispensing by mail from the clinic is safe and effective. Although the literature suggests there may be more frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail from the clinic, there are no apparent increases in other serious adverse events related to mifepristone use.

(d) Clinic dispensing by courier

Reynolds-Wright[115] reported findings from a prospective cohort study of participants at less than 12 weeks gestational age in Scotland undergoing medical abortion at home that provided mifepristone for pick up at the service or by couriered delivery to woman's home. The outcomes from this study in Scotland are consistent with the outcomes in the approved mifepristone labeling. However, the number of couriered deliveries was not reported. Thus this study does not provide abortion outcomes separately for couriered delivery of mifepristone and misoprostol. The study shares the same limitations as the Aiken (2021) study; the study's design did not capture all serious safety outcomes, thus limiting the certainty of the findings.

(e) Partner organization dispensing by mail

Women on Web (WoW), an internet group, connects patients and providers outside of the US and provides medical abortion globally, dispensing mifepristone through "a partner organization" by mail. WoW uses a model with numerous deviations from the standard provision of medical abortion in the United States. For example, this model has no synchronous interaction with the prescriber during informed consent or prior to prescribing medication and no confirmation of self-reported medical, surgical, and menstrual history or confirmed pregnancy testing. Three studies (Endler, Norten, and Aiken (2017))[116] reported outcomes based on dispensing through this model. Endler and Norten reported outcomes from WoW cohorts but do not provide relevant information on mifepristone dispensing by mail because neither provide meaningful outcomes data for consideration. Although Aiken (2017) is a large cohort study, the outcomes are self-reported and an unusually high rate of outcomes are unaccounted for; these limitations result in the data being insufficient to determine the safety of dispensing mifepristone by mail though a partner organization.

In sum, there are insufficient data from the literature we have reviewed to determine the safety and efficacy of dispensing from a retail pharmacy, by courier, or by a partner organization. With respect to dispensing mifepristone by mail, our review of the literature indicates that dispensing mifepristone by mail from the clinic or from a mail order

[115] Reynolds-Wright JJ, et al. BMJ Sex Reprod Health 2021;0:1–6. doi:10.1136/bmjsrh-2020-200976.
[116] Endler et al., Norten et al., and Aiken et al., supra n. 85.

pharmacy does not appear to jeopardize the efficacy of mifepristone for medical abortion. While the studies we reviewed are not adequate on their own to establish the safety of the model of dispensing mifepristone by mail, the safety and efficacy outcomes reported in these studies remain within the ranges labeled for the approved mifepristone products. Although the literature suggests there may be more frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail from the clinic, there are no apparent increases in other significant adverse events related to mifepristone use.

Based on the REMS assessment data, FAERS data from the time period when the in-person dispensing requirement was not being enforced, and our review of the literature, we conclude that mifepristone will remain safe and effective if the in-person dispensing requirement is removed, provided all the other requirements of the REMS are met and pharmacy certification is added. Removing the in-person dispensing requirement will render the REMS less burdensome to healthcare providers and patients, and provided all other requirements of the REMS are met, including the additional requirement for pharmacy certification, the REMS will continue to ensure that the benefits of mifepristone for medical abortion outweigh the risks. Therefore, to reduce the burden imposed by the Mifepristone REMS Program, the REMS must be modified to remove the in-person dispensing requirement, which would allow, for example, dispensing of mifepristone by mail via certified prescribers or pharmacies, in addition to in-person dispensing in clinics, medical offices and hospitals as currently outlined in ETASU C.

In your Petition, you state that "[e]liminating or relaxing the REMS to facilitate Internet or telephone prescriptions would be dangerous to women and adolescent girls" and that "health care providers prescribing abortion-inducing drugs over the Internet or phone or before a patient is even pregnant cannot adequately evaluate patients for contraindications to the drugs" (Petition at 18-19).

We do not agree that eliminating the REMS requirement for the dispensing of Mifeprex in certain healthcare settings will be dangerous to patients, nor do we agree that doing so will affect the ability of healthcare providers to evaluate women for contraindications to mifepristone in a regimen with misoprostol for medical termination of intrauterine pregnancy through 70 days gestation. There are many factors that contribute to patient safety, including evaluation of a patient, informed consent, development of a follow-up plan, and provision of a contact for emergency care. All of these can occur in many types of healthcare settings. The evaluation of patients for contraindications to medical abortion does not necessarily require direct physical contact with the certified prescriber.

You also assert that telemedicine abortion absolves abortion providers of responsibility for the well-being of their patients (Petition at 19). We do not agree. Healthcare providers who prescribe mifepristone are responsible for the well-being of their patients regardless of mode of evaluation or dispensing of medication. The Agency agrees with the American Medical Association that a healthcare provider-patient relationship is entered when the "physician serves a patient's medical needs;"[117] in the context of medical abortion, this

[117] See www.ama-assn.org/delivering-care/ethics/patient-physician-relationships.

healthcare provider-patient relationship continues until resolution of the pregnancy or transfer of care to another healthcare provider.[118]

We also note that patients who are not pregnant at the time of evaluation would not be appropriate candidates for being prescribed mifepristone for medical termination of pregnancy because they do not fulfill the approved indication of having an intrauterine pregnancy of up to 70 days gestation.

2. Other Safety Issues and Additional Studies

In support of your request that we retain the Mifeprex REMS, you cite the Council for International Organizations of Medical Sciences' (CIOMS) definition of "rare" to assert that because "about 1 out of 100 women" using Mifeprex and misoprostol require surgery, serious complications are common, not rare (Petition at 15-16).[119] Although we agree that certain elements of the Mifepristone REMS Program are necessary to assure the safe use of mifepristone, we do not agree with your assertion.

In the Petition, you state that the Medication Guide improperly downplays the risks of the use of Mifeprex in a regimen with misoprostol and you cite the Medication Guide as stating "'*rarely*, serious and potentially life-threatening bleeding, infections, and other problems can occur following . . . medical abortion.' Specifically, 'in about 1 out of 100 women [administered Mifeprex and misoprostol] bleeding can be so heavy that it requires a surgical procedure." (Petition at 15). Using these two separate statements in the Medication Guide, you argue that the CIOMS's definition of rare ("1 out of 1000") means that if 1 out of 100 women using Mifeprex in a regimen with misoprostol require surgery, serious complications are common, not rare. (Petition at 16). However, your reference to the two sentences in the Medication Guide conflates two different clinical scenarios: (1) the adverse event of serious and potentially life-threatening bleeding, and (2) treatment failure.

The first sentence you reference states: "Although cramping and bleeding are an expected part of ending a pregnancy, rarely, serious and potentially life-threatening bleeding, infections, or other problems can occur following a miscarriage, surgical abortion, medical abortion, or childbirth." This statement refers to life-threatening adverse events that can occur during termination regardless of gestational age or during miscarriage or childbirth regardless of the mode of delivery (e.g., vaginal delivery or cesarean section). At the time of our review of the clinical studies submitted to support the S-020 efficacy supplement, the reported rate of death in the studies reviewed, based on one death, was 0.007 percent (very rare under the CIOMS definition).[120] The rate of infections requiring hospitalization or

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[118] See https://www.ama-assn.org/delivering-care/ethics/ethical-practice-telemedicine.

[119] Council for International Organizations of Medical Sciences. Guidelines for Preparing Core Clinical Safety Information on Drugs Second Edition. 1999. https://cioms.ch/wp-content/uploads/2018/03/Guidelines-for-Preparing-Core-Clinical-Safety-Info-Drugs-Report-of-CIOMS-Working-Group-III-and-V.pdf. Accessed December 13, 2021 (CIOMS).

[120] Id. at 36 (defining the "very rare" standard category of frequency as less than 0.01 percent).

intravenous antibiotics was less than 0.1 percent (rare under the CIOMS definition),[121] and rates of transfusion were 0.03-0.7 percent (rare to uncommon under the CIOMS definition).[122] Therefore, "rarely" accurately refers to the frequency of the adverse events referenced in this statement.

The second sentence you reference from the Medication Guide states: "In about 1 out of 100 women, bleeding can be so heavy that it requires a surgical procedure (surgical aspiration or D&C)." This statement refers to the rate of surgical procedures for bleeding following treatment with mifepristone. Heavy bleeding or hemorrhage after medical abortion is a small subset of bleeding and can require a surgical procedure due to ongoing pregnancy or incomplete expulsion; these are considered failed treatment rather than adverse events and are not characterized using the CIOMS definitions. Even if heavy, bleeding after medical abortion may not be considered a serious adverse event unless clinically diagnosed as hemorrhage or requiring a transfusion. Furthermore, in the vast majority of medical abortions, surgical intervention is not necessary.

You also cite a 2009 study and a 2018 study to assert that medical abortions carry greater risks than surgical abortions (Petition at 16). The 2009 Niinimaki, et al.[123] study reported overall incidences of immediate adverse events (up to 42 days) in medical and surgical abortions performed in women undergoing induced abortion from 2000-2006 based on data from the Finnish national registries. We agree that the overall incidence of adverse events for medical abortion was fourfold higher when compared with surgical abortion (20.0 percent versus 5.6 percent). Specifically, the incidence of hemorrhage, incomplete abortion, and surgical (re)evacuation were higher for medical abortion. However, the authors specifically noted that because medical abortion is associated with longer uterine bleeding, the high rate of events, which were pulled from a national registry reflecting both inpatient and outpatient visits, is not surprising. They opined that uterine bleeding requiring surgical evacuation probably better reflects the severity of bleeding after termination of pregnancy; the incidence of such bleeding was relatively low, although it was more common with medical abortion. In addition, the authors acknowledged there are inherent weaknesses in registry-based studies; there is variable reliability both of diagnoses and of severity of diagnoses. Nevertheless, the authors concluded that both methods are generally safe and recommended discussing the adverse event profiles of different methods when counseling women seeking pregnancy termination.

We note that Ireland, et al.[124] reported findings from a more recent retrospective cohort study of 30,146 United States women undergoing pregnancy termination before 64 days of gestation from November 2010 to August 2013. Efficacy of pregnancy termination was 99.6 percent and 99.8 percent for medical and surgical abortion, respectively.

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[121] Id. at 36 (defining the "rare" standard category of frequency as greater than or equal to 0.01 percent and less than 0.1 percent).
[122] Id. at 36 (defining the "uncommon" standard category of frequency as greater than or equal to 0.1 percent and less than 1 percent); see also 2016 Clinical Review, supra n. 13, at 47 and 51.
[123] Niinimaki M, Pouta A, Bloigu A, et al. Immediate complications after medical compared with surgical termination of pregnancy. Obstet Gynecol. 2009;114(4):795-804.
[124] Ireland LD, Gatter, M, Chen, A. 2015. Medical Compared with Surgical Abortion for Effective Pregnancy Termination in the Frist Trimester. Obstetrics & Gynecology 126;22-28.

Unanticipated aspiration for persistent pain, bleeding or both were 1.8 percent and 0.4 percent for medical and surgical abortion respectively. These findings are compatible with the Niinimaki study findings. There was no difference in major adverse events as defined by the authors (emergency department visit, hospitalization, uterine perforation, infection, hemorrhage requiring transfusion) between the groups. The authors conclude medical and surgical abortion before 64 days of gestation are both highly effective with low complication rates.

The 2018 Carlsson study is addressed above in section II.A.2.b.ii. of this response; as discussed above, that study showed no statistically significant difference between the overall complication rates between an "at home" and "at the hospital" abortion.[125]

We acknowledge that medical abortion is known to have more days of bleeding and increased rates of incomplete abortion compared to surgical abortion. However, as noted above, in the vast majority of medical abortions, surgical intervention is not necessary. Thus, medical abortion and surgical abortion are two options; both have benefits, side effects, and potential complications. Patients and their healthcare providers should discuss which method is preferable and safer according to each woman's unique situation.

You state that the Mifeprex REMS should require a formal study for at-risk populations, including: patients under the age of 18; patients with repeat Mifeprex abortions; patients with limited access to emergency room services; and patients who self-administer misoprostol (Petition at 13-14). As we explain below, additional studies are not needed at this time.

In justifying your assertion that a formal study is required in patients under the age of 18, you state that Mifeprex was approved for use in the pediatric population in 2000 after the requirement for studies in the pediatric population was waived (Petition at 13-14). The approved indication for mifepristone does not limit its use by age. Although patients age 17 and under were not included in the clinical trials supporting the initial approval of Mifeprex in 2000, we stated at the time that the safety and efficacy were expected to be the same for postpubertal (i.e., post-menarchal) adolescents. Our conclusion in 2000 that pediatric studies of Mifeprex were not needed for approval was consistent with FDA's implementation of the regulations in effect at that time. Because we determined that there were sufficient data from studies of mifepristone, the original Mifeprex approval should have reflected the Agency's conclusion that the pediatric study requirements were waived for pre-menarchal females and that the pediatric study requirements were met for post-menarchal adolescents, rather than stating that the Agency was waiving the requirements for all pediatric age groups.

As currently required by the Pediatric Research Equity Act (PREA),[126] certain applications or supplemental applications must include pediatric assessments of the safety and effectiveness of the drug for the claimed indication(s) in all relevant pediatric

[125] Carlsson et al., supra n. 49.
[126] Section 505B of the FD&C Act (21 U.S.C. 355c).

subpopulations, unless that requirement is waived or deferred.[127] In accordance with PREA, when FDA reviewed the S-020 efficacy supplement, a partial waiver was granted for pediatric studies in pre-menarchal females because pregnancy does not occur in premenarchal females. We also determined that the applicant had fulfilled the pediatric study requirement in post-menarchal adolescents. This determination was based on data extrapolated from adults and information in literature. Review of these findings found the safety and efficacy in this population to be similar to the safety and efficacy in the adult population.[128] Therefore, we do not agree that a formal study is required in patients under 18.

With regard to your concerns about repeat abortions and your assertion that a study is necessary in this population, we acknowledge that published data concerning adverse reproductive health outcomes in U.S. women who undergo repeat medical abortions are limited. We concluded in our 2016 review of the S-020 efficacy supplement that there is no evidence that repeated medical or surgical abortion is unsafe or that there is a tolerance effect. We also noted that return to fertility after the use of mifepristone is well documented. [129] This is reflected both in Section 17 of the approved labeling, Patient Counseling Information, which states that the provider should "inform the patient that another pregnancy can occur following medical abortion and before resumption of normal menses," and in the Medication Guide, which states "You can become pregnant again right after your pregnancy ends." Although you state that more than one out of every three abortions in the United Sates is a repeat abortion (Petition at 14),[130] we are not aware of reports suggesting greater safety concerns in repeat abortions than a first-time abortion. Therefore, we do not agree that a study is necessary in this population. You also cite a published study, using a mouse model, of repeated medical termination of pregnancy that showed repeat medical abortion impaired the reproductive function of female mice (Petition at 14).[131] Per our 2016 review, there is no evidence in available clinical data that repeated medical or surgical abortion is unsafe, or that fertility is impaired by the use of mifepristone; therefore, data from a single non-clinical study in mice are not persuasive.[132]

With respect to your request for a formal study of mifepristone for medical abortion in women without access to emergency care, we disagree that such a study is necessary. In order to become a certified prescriber, a healthcare provider must agree 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 that they have the ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary. These prescriber qualifications ensure that mifepristone is prescribed to women for whom emergency care is available.

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[127] Section 505B(a)(2) of the FD&C Act (21 U.S.C. 355c(a)(2)).
[128] 2016 Clinical Review, supra n. 13, at 74-76.
[129] Id. at 47.
[130] In support of this assertion, you cite Jones R, Jerman J, Ingerick M. Which abortion patients have had a prior abortion? Findings from the 2014 U.S. Abortion Patient Survey. J Womens Health.
[131] Lv F, Xu X, Zhang S, et al. Repeated abortion affects subsequent pregnancy outcomes in BALB/c mice. PLoS One. 2012;7(10):e48384. doi:10.1371/journal.pone.0048384.
[132] 2016 Clinical Review, supra n. 13, at 47.

Finally, you assert that FDA should require a formal study in patients who self-administer misoprostol. As explained in section II.A.2.b.ii of this response, FDA conducted a literature review of self-administration of misoprostol at home as part of its review of the S-020 efficacy supplement and found no safety or efficacy concerns with home self-administration of misoprostol. Therefore, we disagree that a formal study is required in this population.

With regard to safety generally, in addition to the FAERS data provided above (see section II.B.1.c.ii. in this response), FDA routinely monitors adverse events reported to FAERS and published in the medical literature for mifepristone for medical termination of pregnancy through 70 days gestation. We have not identified any new safety concerns with the use of mifepristone for this indication.

3. Other Articles

In your Petition, you reference several documents that discuss alternative models of providing abortion medications and advocate for the lifting of the REMS on mifepristone (Petition at 23-24). You assert that these recent publications demonstrate how abortion advocates will continue to pressure FDA to eliminate the REMS and move towards over-the-counter access for Mifeprex.[133]
We agree that the overarching message in the publications you reference appears to be advocating self-management of medical abortion. Nonetheless, as discussed in this response, we have determined that the Mifepristone REMS Program continues to be necessary for the safe use of this drug product, with some modifications.

III. CONCLUSION

For the reasons set forth above, we deny your request that FDA restore and strengthen elements of the Mifeprex regimen and prescriber requirements approved in 2000; and we grant in part and deny in part your request to retain the Mifepristone REMS Program. As with all approved drug products, we will continue to monitor the safety of mifepristone for the approved indication and take any appropriate actions.

Sincerely,

Patrizia A. Cavazzoni -S

Digitally signed by Patrizia A. Cavazzoni -S
Date: 2021.12.16 15:05:41 -05'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research

[133] You also reference clinical trials relating to the use of mifepristone for spontaneous miscarriage management and question the results of studies related to this use (Petition at 16-18). The use of mifepristone for the management of early miscarriage is not an approved indication for this drug product and is outside the scope of the Mifepristone REMS Program. Therefore, we do not address it in this response.

EXHIBIT 35

FDA, Questions and Answers on FDA's Adverse Event Reporting System (FAERS)

Questions and Answers on FDA's Adverse Event Reporting System (FAERS)

What is FAERS?

The FDA Adverse Event Reporting System (FAERS) is a database that contains adverse event reports, medication error reports and product quality complaints resulting in adverse events that were submitted to FDA. The database is designed to support the FDA's post-marketing safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation (ICH E2B (/drugs/guidances-drugs/international-council-harmonisation-efficacy)). Adverse events and medication errors are coded using terms in the Medical Dictionary for Regulatory Activities (MedDRA) (http://www.meddra.org/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) terminology.

How does FDA use the information in FAERS?

FAERS is a useful tool for FDA for activities such as looking for new safety concerns that might be related to a marketed product, evaluating a manufacturer's compliance to reporting regulations and responding to outside requests for information. The reports in FAERS are evaluated by clinical reviewers, in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), to monitor the safety of products after they are approved by FDA.

If a potential safety concern is identified in FAERS, further evaluation is performed. Further evaluation might include conducting studies using other large databases, such as those available in the Sentinel System. (/sentinel-initiative-transforming-how-we-monitor-product-safety) Based on an evaluation of the potential safety concern, FDA may take regulatory action(s) to improve product safety and protect the public health, such as updating a product's labeling information, restricting the use of the drug, communicating new safety information to the public, or, in rare cases, removing a product from the market.

Who sends reports to FAERS?

Healthcare professionals, consumers, and manufacturers submit reports to FAERS. FDA receives voluntary reports directly from healthcare professionals (such as physicians, pharmacists, nurses and others) and consumers (such as patients, family members, lawyers and others). Healthcare professionals and consumers may also report to the products' manufacturers. If a manufacturer receives a report from a healthcare professional or consumer, it is required to send the report to FDA as specified by regulations.

How can I report an adverse event or medication error to FDA?

The MedWatch (https://www.fda.gov/Safety/MedWatch/default.htm) website provides information about voluntary and mandatory reporting (https://www.fda.gov/Safety/MedWatch/HowToReport/default.htm).

Can mandatory reporters submit adverse events electronically?

Yes, the FDA Adverse Events Reporting System (FAERS) Electronic Submissions (/drugs/fda-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-electronic-submissions) website provides drug and therapeutic biological product manufacturers, distributors, packers, and other interested parties with information about FDA Adverse Event Reporting System (FAERS) electronic submissions and instructions on how to electronically submit post-marketing individual case safety reports (ICSRs), with and without attachments.

Yes, FAERS data does have limitations. First, there is no certainty that the reported event (adverse event or medication error) was due to the product. FDA does not require that a causal relationship between a product and event be proven, and reports do not always contain enough detail to properly evaluate an event. Furthermore, FDA does not receive reports for every adverse event or medication error that occurs with a product. Many factors can influence whether an event will be reported, such as the time a product has been marketed and publicity about an event. There are also duplicate reports where the same report was submitted by a consumer and by the sponsor. Therefore, FAERS data cannot be used to calculate the incidence of an adverse event or medication error in the U.S. population. For more information, please refer to the question " What points should I consider while viewing the dashboard content? (https://fis.fda.gov/extensions/fpdwidgets/2e01da82-13fe-40e0-8c38-4da505737e36.html#_Toc493751926)"

Is FAERS data available to the public?

FAERS data is available to the public in the following ways:

- FAERS dashboard (/drugs/fda-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard): a highly interactive web-based tool that allows for the querying of FAERS data in a user friendly fashion.
- FAERS data files (/drugs/fda-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-latest-quarterly-data-files): provides raw data consisting of individual case safety reports extracted from the FAERS database. A simple search of FAERS data cannot be performed with these files by persons who are not familiar with the creation of relational databases.
- Individual case safety reports from the FAERS database can also be obtained by sending a Freedom of Information (FOI) request to FDA (/how-make-foia-request).

How do I find or confirm my report is in FAERS?

To confirm that your report is in FAERS, please send a Freedom of Information (FOI) request to FDA (/how-make-foia-request).

What are the benefits of the FAERS public dashboard?

This tool makes the data easier to query and produces user-friendly information and charts. For example, users can view a summary of adverse event reports received from 1968 to the present or for a specific timeframe. In addition, users can search on a product of interest within a specific timeframe.

Will there be a tutorial so I can learn how to use this database?

Yes, a recorded webinar (/about-fda/pharmacy-student-experiential-program/fda-drug-topics-fda-adverse-events-reporting-system-faers-public-dashboard-january-30-2018) is available which reviews the capabilities, and limitations, of the FAERS public dashboard.

Is the FAERS public dashboard accessible on an Android™ or iPhone®?

Yes, but the user interface layout may not be very user friendly. FDA will continue to work on the dashboard to make the user interface Android and iPhone friendly.

Can I download my search results from the dashboard?

Yes, you will be able to export a limited set of search data to an Excel® spreadsheet and then download it. FDA will still continue to provide the FAERS Latest Quarterly Data Files (/drugs/fda-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-latest-quarterly-data-files) online.

Note: The data fields listed on the FAERS Dashboard currently is a subset of the data fields available in the FAERS Quarterly Data files. Future release of the FAERS Dashboard plans to make the other data fields available. Also the data displayed in the FAERS Dashboard may not be identical to the data in the FAERS Quarterly Data files due to different data extraction dates.

Where else can I find safety information?

- Potential Signals of Serious Risks/New Safety Information Identified from the FDA Adverse Event Reporting System (FAERS): quarterly reports on potential serious side effects identified by FAERS. (/drugs/fda-adverse-event-reporting-system-faers/potential-signals-serious-risksnew-safety-information-identified-fda-adverse-event-reporting-system)
- Post-marketing Drug and Biologic Safety Evaluations (/drugs/surveillance/postmarket-drug-and-biologic-safety-evaluations): provides summary information about ongoing and completed post-marketing safety evaluations of adverse experience reports made to FDA for New Drug Applications (NDAs) and Biologic License Applications (BLAs) approved since September 27, 2007.
- Center for Drug Evaluation and Research (CDER): Drug Safety and Availability (https://www.fda.gov/Drugs/DrugSafety/default.htm)
- Post-market Drug Safety Information for Patients and Providers (https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/default.htm)
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.fda.gov/Safety/MedWatch/default.htm)

How are versions of a case in FAERS handled?

Each unique submission of a case received is assigned a version number (for example, Case #1234567, version 1). The initial version received will be version 1. If a follow up is received on a previously submitted case, then that version of the case will be version 2, and so on. The latest version of a case represents the most current information about that case.

The data is updated quarterly.

What points should I consider while viewing the dashboard content?

When you view the website output of reported reactions (side effects or adverse drug reactions) for a drug product, it is important to consider the following points:

- **Data Quality:** There are many instances of duplicative reports and some reports do not contain all the necessary information. Duplicate reporting occurs when the same report is submitted by the consumer and the sponsor. The information in FAERS evolves daily and the number of individual cases may increase or decrease. It is therefore possible that the information on this website may change over time.
- **Existence of a report does not establish causation:** For any given report, there is no certainty that a suspected drug caused the reaction. While consumers and healthcare professionals are encouraged to report adverse events, the reaction may have been related to the underlying disease being treated, or caused by some

only the reporter's observations and opinions.

- **Information in reports has not been verified:** Submission of a report does not mean that the information included in it has been medically confirmed nor it is an admission from the reporter that the drug caused or contributed the event.
- **Rates of occurrence cannot be established with reports:** The number of suspected reactions in FAERS should not be used to determine the likelihood of a side effect occurring. The FDA does not receive reports for every adverse event or medication error that occurs with a product. Many factors can influence whether an event will be reported, such as the time a product has been marketed and publicity about an event. Therefore, information in these reports cannot be used to estimate the incidence (occurrence rates) of the reactions reported.
- **Patients should talk to their doctor** before stopping or changing how they take their medications.
- **Patient Outcomes received in FAERS**: These data describe the outcome of the patient as defined in U.S. reporting regulations (21 CFR 310.305, 314.80, 314.98, 600.80). Serious means that one or more of the following outcomes were documented in the report: death, hospitalization, life-threatening, disability, congenital anomaly, and/or other serious outcome. Documenting one or more of these outcomes in a report does not necessarily mean that the suspect product(s) named in the report was the cause of the outcomes.

Importantly, the FAERS data by themselves are not an indicator of the safety profile of the drug.

EXHIBIT 36

Kathi A. Aultman et al., D*eaths and Severe Adverse Events after the Use of Mifepristone as an Abortifacient from September 2000 to February 2019*, 26 Law & Medicine 3 (2021)

Deaths and Severe Adverse Events after the use of Mifepristone as an Abortifacient from September 2000 to February 2019

Kathi A. Aultman M.D.,[*] Christina A. Cirucci M.D., Donna J. Harrison M.D.,[**] Benjamin D. Beran M.D.,[***] Michael D. Lockwood D.O.,[****] Sigmund Seiler M.D.[*****]

ABSTRACT: *Objectives:* Primary: Analyze the Adverse Events (AEs) reported to the Food and Drug Administration (FDA) after use of mifepristone as an abortifacient. Secondary: Analyze maternal intent after ongoing pregnancy and investigate hemorrhage after mifepristone alone.

***Methods*: Adverse Event Reports (AERs) for mifepristone used as an abortifacient, submitted to the FDA from September 2000 to February 2019, were analyzed using the National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAEv3).**

***Results*: The FDA provided 6158 pages of AERs. Duplicates, non-US, or AERs previously published (Gary, 2006) were excluded. Of the remaining, there were 3197 unique, US-only AERs of which there were 537 (16.80%) with insufficient information to determine clinical severity, leaving 2660 (83.20%) Codable US AERs (Figure 1). Of these, 20 were Deaths, 529 were Life-threatening, 1957 were Severe, 151 were Moderate, and 3 were Mild.**

[*] Associate Scholar with the Charlotte Lozier Institute.

[**] Executive Director, American Association of Pro-Life Obstetricians and Gynecologists, PO Box 395 Eau Claire, Michigan 49111-0395. Ph 202 230-0997. donna@aaplog.org.

[***] Department of Obstetrics and Gynecology, Medical College of Wisconsin, Milwaukee, WI.

[****] Department of Osteopathic Manipulative Medicine, Liberty University College of Osteopathic Medicine.

[*****] Associate Professor of Family Medicine, Liberty University College of Osteopathic Medicine.

The deaths included: 9 (45.00%) sepsis, 4 (20.00%) drug toxicity/ overdose, 1 (5.00%) ruptured ectopic pregnancy, 1 (5.00%) hemorrhage, 3 (15.00%) possible homicides, 1 (5.00%) suicide, 1 (5.00%) unknown (Table 1).

Retained products of conception and hemorrhage caused most morbidity. There were 75 ectopic pregnancies, including 26 ruptured ectopics (includes one death).

There were 2243 surgeries including 2146 (95.68%) D&Cs of which only 853 (39.75%) were performed by abortion providers.

Of 452 patients with ongoing pregnancies, 102 (22.57%) chose to keep their baby, 148 (32.74%) had terminations, 1 (0.22%) miscarried, and 201 (44.47%) had unknown outcomes.

Hemorrhage occurred more often in those who took mifepristone and misoprostol (51.44%) than in those who took mifepristone alone (22.41%).

***Conclusions*: Significant morbidity and mortality have occurred following the use of mifepristone as an abortifacient. A pre-abortion ultrasound should be required to rule out ectopic pregnancy and confirm gestational age. The FDA AER system is inadequate and significantly underestimates the adverse events from mifepristone.**

A mandatory registry of ongoing pregnancies is essential considering the number of ongoing pregnancies especially considering the known teratogenicity of misoprostol.

At the very least, the FDA should reinstate the original 2011 REMS and strengthen the reporting requirements.

***Conflict of Interest Statement*: The authors did not report any potential conflicts of interest. Authors note that although Dr. Harrison is an associate editor for Issues in Law and Medicine, she recused herself from any involvement in the peer review process for this manuscript.**

***Keywords*: Mifepristone, Mifeprex, RU-486, Misoprostol, Abortifacient, Medical Abortion, Abortion Pill, Medical Abortion Complications, No touch abortion, DIY Abortion, Self-Administered Abortion, Adverse Events, Adverse Event Reports, Post-marketing Surveillance, FAERS, Drug Safety, Emergency Medicine, FDA, REMS, Risk Evaluation Mitigation Strategy.**

Introduction

The application for mifepristone (RU-486, RU-38486, Mifeprex) as an abortifacient was submitted to the Food and Drug Administration (FDA) in 1996 by the Population Council, which was given the manufacturing and distribution rights from Roussel Uclaf. [1] The Population Council partnered with Danco Laboratories, newly created in 1995, and gave them the manufacturing, marketing, and distribution rights. The FDA approved mifepristone in September 2000 under restricted distribution regulations (Subpart H) due to the FDA's conclusion that restrictions "on the distribution and use of mifepristone are needed to ensure safe use of this product."[2]

Included in these restrictions was the requirement that all serious Adverse Events (AEs), after the use of mifepristone as an abortifacient, be reported to the FDA by Danco as part of post-marketing surveillance. According to the FDA,[3] the purpose of such post-marketing surveillance includes identification of potential risks recognized after the time of approval, identification of unexpected deaths, causal attribution of AEs based on the product's known pharmacological action, and AEs for which a Risk Evaluation Mitigation Strategy (REMS) is intended to mitigate the risk.

In 2006, in response to the deaths of 4 women from a rare bacterial sepsis from *Clostridium sordellii (C. sordellii)*, the FDA and CDC convened a workshop, during which mifepristone alteration of the immune system was detailed, and they concluded that such alteration could lead to impaired ability to respond to *C. sordellii* toxin.[4]

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[1] Citizen petition re: Request for Stay and Repeal of the Approval of Mifeprex (mifepristone) for the Medical Termination of Intrauterine Pregnancy through 49 Day's Gestation Final. Before the Department of Health and Human Services: Food and Drug Administration. AAPLOG. 2002. 7-10. Accessed November 13, 2020. https://aaplog.wildapricot.org/resources/Documents/2002%20Aug%2020%20Citizen%20Petition_Mifeprex.pdf

[2] Center for Drug Evaluation and Research. Approval Letter for Mifeprex NDA 20-687. February 18, 2000. Food and Drug Administration. p 5. Accessed November 16, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687approvable00.pdf

[3] US Department of Health and Human Services, Food and Drug Administration Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research. Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff. November 2019. p 7-8. Accessed Jan 16 2021. https://www.fda.gov/media/130216/download p7-8

[4] Emerging Clostridial Disease Workshop: May 11, 2006, Atlanta, GA. Department of Health and Human Services, Centers for Disease Control and Prevention, Food and Drug Administration, National Institutes of Health. 2006. p. 109,110. Accessed November 13, 2020. https://aaplog.wildapricot.org/resources/2006%20CDC%20FDA%20Clostridial%20Disease%20Transcript.pdf

There is evidence that both mifepristone[5,6,7] and misoprostol[8] can suppress immune response to *C. sordellii* in animal models.

In response to the septic deaths, Planned Parenthood changed their off-label protocol from vaginal administration of misoprostol to buccal in 2006.[9,10] Yet, as we found in our analysis, sepsis deaths from *C. sordellii* and other bacteria continued to occur after 2007. All sepsis deaths occurred with either vaginal or buccal misoprostol, which were both off label routes of administration until the buccal route was authorized in 2016.[11]

In 2011, the FDA approved a Risk Evaluation and Mitigation Strategy (REMS) for Mifepristone incorporating the original restrictions.[12] In May 2015, Mifepristone's sponsor submitted a supplemental new drug application to the FDA to obtain approval to revise the drug's labeling, which the FDA approved in 2016.[13,14] The 2016 changes in the Regimen and Prescriber Agreement extended the original gestational age limit from 49 days to 70 days, changed the mifepristone dose from 600 mg to 200 mg orally, changed the misoprostol dose from 400 mcg orally on Day 3 to 800 mcg buccally on Day 2 or 3, allowed non-physicians to become prescribers, reduced the number of required office visits from 3 to just one initial office visit, and allowed a repeat dose of misoprostol if complete expulsion did not occur.[15] The prescriber agreement was changed so

[5] Emerging Clostridial Disease Workshop: May 11, 2006, Atlanta, GA. Department of Health and Human Services, Centers for Disease Control and Prevention, Food and Drug Administration, National Institutes of Health. 2006. p. 109, 110 Accessed November 13, 2020. https://aaplog.wildapricot.org/resources/2006%20CDC%20FDA%20Clostridial%20Disease%20Transcript.pdf

[6] Webster JI, Sternberg EM. Role of the hypothalamic-pituitary-adrenal axis, glucocorticoids and glucocorticoid receptors in toxic sequelae of exposure to bacterial and viral products. J Endocrinol. 2004;181(2):212, 213, 216, 217. doi.org/10.1677/joe.0.1810207

[7] Hawes AS, Rock CS, Keogh CV, Lowry SF, Calvano SE. In vivo effects of the antiglucocorticoid RU 486 on glucocorticoid and cytokine responses to Escherichia coli endotoxin. Infect Immun. 1992;60(7):2645, 2646. doi:10.1128/IAI.60.7.2641-2647.1992

[8] Aronoff DM, Hao Y, Chung J, et al. Misoprostol impairs female reproductive tract innate immunity against Clostridium sordellii. J Immunol. 2008;180(12):8227-8229. https://doi.org/10.4049/jimmunol.180.12.8222

[9] Trussell, J, Nucatola, D, Fjerstad, M, Lichtenberg, ES. Reduction in infection-related mortality since modifications in the regimen of medical abortion. Contraception, 2014;89(3):193-196. https://doi.org/10.1016/j.contraception.2013.11.020

[10] Fjerstad M, Trussell, J, Sivin, I, Lichtenberg, ES, Rates of Serious Infection after Changes in Regimens for Medical Abortion. N Engl J Med. 2009 July 9;361(2):148-149. July 9, 2009 N Engl J Med 2009; 361:145-151. doi:10.1056/NEJMoa0809146

[11] GAO-18-292 Revised Mifeprex Labeling: Food and Drug Administration Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts. Report to Congressional Requesters. Food and Drug Administration. 2018. p. 7. Published March 2018. Accessed November 13, 2020. https://www.gao.gov/assets/700/690914.pdf

[12] NDA 20-687 MIFEPREX (mifepristone) Tablets, 200 mg: Risk Evaluation and Mitigation Strategy (REMS). Food and Drug Administration. 2011. 1-11. Reference ID: 2957855. Published June 8, 2011. Accessed November 13, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2011-06-08_Full.pdf

[13] GAO-18-292 Revised Mifeprex Labeling: Food and Drug Administration Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts. Report to Congressional Requesters. Food and Drug Administration. 2018. p. 1. Published March 2018. Accessed November 13, 2020. https://www.gao.gov/assets/700/690914.pdf

[14] NDA 20-687 MIFEPREX (mifepristone) Tablets, 200 mg: Risk Evaluation and Mitigation Strategy (REMS). Food and Drug Administration. 2016. 1-8. Reference ID: 3909592. Published March 29, 2016. Accessed November 13, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020RemsR.pdf

[15] GAO-18-292 Revised Mifeprex Labeling: Food and Drug Administration Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts. Report to Congressional Requesters. Food and Drug Administration. 2018. p.7. Published March 2018. Accessed November 13, 2020. https://www.gao.gov/assets/700/690914.pdf

that instead of being required to "report any hospitalization, transfusion or other serious event to Danco Laboratories,"[16] providers were only required to report deaths.[17] The requirement to report ongoing pregnancies that are not terminated was also eliminated. "The FDA approved GenBioPro, Inc.'s abbreviated new drug application (ANDA) for generic Mifeprex on April 11, 2019" and "established a single, shared system REMS for mifepristone products" without substantially changing the REMS.[18]

During the COVID-19 pandemic the Maryland District Court issued a preliminary injunction prohibiting the FDA from enforcing the in-person dispensing and signature requirements contained in the mifepristone REMS.[19] This decision eliminated the need for an initial office visit for dispensing the medication and opened the door for dispensing of the drug via telehealth with no actual clinician contact. On January 12, 2021, the Supreme Court enabled the FDA to enforce the mifepristone REMS.[20] These requirements are essential for the safety of women and must be kept in place.

The first systematic analysis of these Adverse Event Reports (AERs) obtained by the Freedom of Information Act (FOIA), was published by Gary and Harrison in 2006.[21] This paper extends that analysis to AERs not previously published and augments the scant published literature on mifepristone safety.

Objectives

Primary: To analyze and codify the significant adverse events and their treatment after the use of mifepristone as an abortifacient, extending the previously published analysis by Gary in 2006.[22] Secondary: To examine maternal decisions in the case of ongoing pregnancy after attempted mifepristone termination, and to determine if failing to take misoprostol after mifepristone increased the risk of hemorrhage.

[16] NDA 20-687 MIFEPREX (mifepristone) Tablets, 200 mg: Risk Evaluation and Mitigation Strategy (REMS). Food and Drug Administration. 2011. p. 7. Reference ID: 2957855. Published June 8, 2011. Accessed November 13, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2011-06-08_Full.pdf

[17] NDA 20-687 MIFEPREX (mifepristone) Tablets, 200 mg: Risk Evaluation and Mitigation Strategy (REMS). Food and Drug Administration. 2016. p. 6. Reference ID: 3909592. Published March 29, 2016. Accessed November 13, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020RemsR.pdf

[18] Questions and Answers on Mifeprex. Food and Drug Administration. March 28, 2018. Updated 4-12-2019. Accessed November 13, 2020. https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex

[19] American College of Obstetricians and Gynecologists, et al., v. Food and Drug Administration, et al., No. 20-1320, 2020 WL 3960625 (D. Md. July 13, 2020). Accessed November 16th, 2020. https://www.courthousenews.com/wp-content/uploads/2020/07/093111166803.pdf

[20] FDA v ACOG. SCOTUS. 20a34_3f14. Accessed January 20, 2021. https://www.supremecourt.gov/opinions/20pdf/20a34_3f14.pdf

[21] Gary M, Harrison D. Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient. Ann Pharmacother. 2006 Feb 40(2):191-7. https://doi.org/10.1345/aph.1G481

[22] Gary M, Harrison D. Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient. Ann Pharmacother. 2006 Feb 40(2):191-7. https://doi.org/10.1345/aph.1G481

Materials and Methods

FDA AERs related to the use of mifepristone from September 2000 to February 2019 were obtained through the Freedom of Information Act (FOIA) from the FDA, and a comparison was made with FDA reports available online on the FDA Adverse Events Reporting System (FAERS) Dashboard.[23] Duplicate AERs were identified by comparing FDA case identification numbers, manufacturer identification numbers, dates of treatment, patient age, and descriptions of case scenarios to ensure that each case was included only once in this analysis. The authors excluded duplicates, cases originating outside of the United States, and cases previously published in the Gary analysis[24] (Figure 1).

One of the concerns in looking at AEs is the risk of falsely assigning causality. The FDA does not give guidance for determining causality for AEs in the AERs but does give guidance for selecting AEs for inclusion in the Adverse Reaction section of the Drug Label.[25] They recommend that, "Decisions on whether there is some basis to believe there is a causal relationship are a matter of judgment and are based on factors such as" the "frequency of reporting," "the extent to which the adverse event is consistent with the pharmacology of the drug," "the timing of the event relative to the time of drug exposure," and other factors. Although a causal relationship cannot be attributed with certainty to all reported AEs for a drug, a causal relationship seems probable for each of the categories of AEs we chose to analyze based on these factors, except for ectopic pregnancies and some of the deaths. Ectopic pregnancies were included in our analysis not because there is a causal relationship, but because ectopic pregnancy is a contraindication to the use of mifepristone and the diagnosis was missed, putting women's lives at risk. The deaths must be evaluated individually to determine causality.

Because reporting is often voluntary and sporadic, there is no denominator for how many mifepristone abortions are performed in the U.S. It was therefore impossible to calculate complication rates for mifepristone and misoprostol abortions based on AER data. For clarity, we specified the denominator used in each case. Coding for severity was done using the National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAEv3),[26] since this was

[23] FDA Adverse Events Reporting System (FAERS) Public Dashboard. Food and Drug Administration. Accessed November 13, 2020. https://fis.fda.gov/sense/app/d10be6bb-494e-4cd2-82e4-0135608ddc13/sheet/33a0f68e-845c-48e2-bc81-8141c6aaf772/state/analysis

[24] Gary M, Harrison D. Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient. Ann Pharmacother. 2006 Feb 40(2):191-7. https://doi.org/10.1345/aph.1G481

[25] Guidance for Industry Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products — Content and Format. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER); January 2006. P. 8. Accessed January 8, 2021. https://www.fda.gov/media/72139/download

[26] Common Terminology Criteria for Adverse Events v3.0 (CTCAE). Cancer Center Therapy Evaluation Program (CTEP); 2003. 1-77. Published December 12, 2003. Accessed November 13, 2020. https://aaplog.wildapricot.org/resources/CTCAEv3.pdf

the methodology used in the original analysis of the first 607 Adverse Events.[27] The five levels of coding are: Mild, Moderate, Severe, Life-threatening, and Death.

Overall severity (Figure 1) for each unique AER was determined independently by two board-certified physicians (Obstetrics and Gynecology or Family Medicine). Since within each AER, a patient may have experienced several Adverse Events (AEs), the overall severity of the AER was based on the highest severity of its AEs. For the diagnoses we analyzed (Table 1), each AE was coded in the same manner and stratified according to type, severity, and treatment. Disagreements were resolved by discussion or review by a third board-certified Obstetrician-Gynecologist who also reviewed coding for uniformity. Surgeries, transfusions, providers, and location of treatment were analyzed and tabulated.

Ruptured ectopic pregnancies were coded as Life-threatening and unruptured ectopic pregnancies as Severe.

Infections were coded as Life-threatening when evidence of sepsis was present, or ICU-level treatment was required. They were coded as Severe if parenteral/IV antibiotics were given and Moderate if oral antibiotics were prescribed.

Life-threatening hemorrhage was defined, as in the previous analysis, to be transfusion of two or more units of packed red blood cells (PRBCs), hemoglobin less than 7, or documented large volume, rapid blood loss with clinical symptomatology of acute blood loss anemia (e.g., syncope, tachycardia, hypotension). Severe hemorrhage was defined as requiring surgical intervention and/or less than 2 U PRBCs. Moderate hemorrhage was defined as management with fluids/medication alone.

Retained Products of Conception (RPOC) was coded as Severe if a dilatation and curettage/evacuation (D&C) was performed. Ongoing viable intrauterine pregnancy was considered equivalent in severity to RPOC requiring curettage and thus Severe. When the ultimate outcome was unknown, the pregnancy was considered ongoing if "ongoing pregnancy" was noted or ultrasound showed cardiac motion or significant growth.

AEs which did not contain sufficient information to assign an accurate severity code were deemed "Uncodable." AERs lacking any codable information were deemed overall Uncodable.

The percent of women with significant hemorrhage after mifepristone alone was compared to those who took both mifepristone and misoprostol, to investigate the validity of the assertion that lack of subsequent misoprostol administration was a causative factor in hemorrhage after mifepristone use.[28]

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[27] Gary M, Harrison D. Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient. Ann Pharmacother. 2006 Feb 40(2):191-7. https://doi.org/10.1345/aph.1G481

[28] Creinin MD, Hou MY, Dalton L, Steward R, Chen MJ. Mifepristone Antagonization With Progester-one to Prevent Medical Abortion: A Randomized Controlled Trial. Obstet Gynecol. 2020;135(1):158-165. doi:10.1097/AOG.0000000000003620

Results

Adverse Event Report Overall Severity

Figure 1 summarizes the handling of the AERs provided by the FDA and their severity coding. The FDA provided 6158 pages of AERs. Of these, any duplicates, non-US, or AERs previously published in the Gary paper were excluded from the analysis. There were 3197 unique, US-only AERs of which 537 had insufficient information to determine clinical severity, leaving 2660 Codable US-only AERs. Of these, 20 were Deaths, 529 were Life-threatening, 1957 were Severe, 151 were Moderate, and 3 were Mild.

Deaths (Table 1)

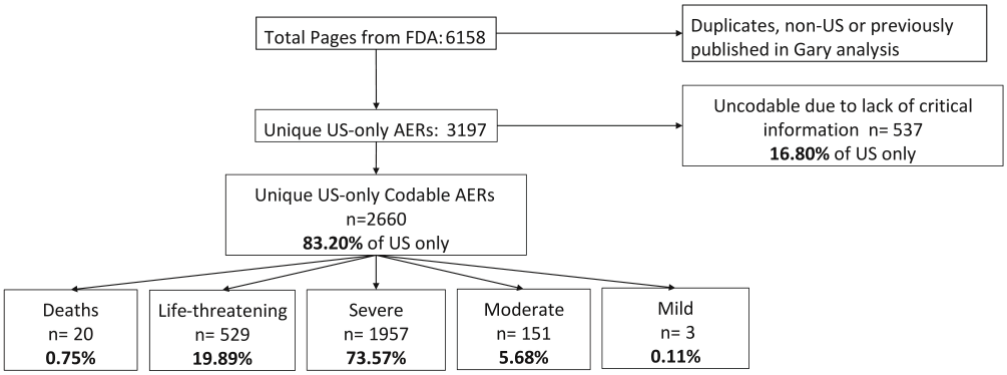
Our analysis identified 23 of the 24 deaths reported by the FDA as of 2018.[29] Three of those deaths were previously published in the Gary paper[30] leaving 20 deaths (Table 1). Our analysis yielded a total of 7 sepsis deaths. These included five cases of *C. sordellii* and one case of *Clostridium perfringens*, all consistent with those reported by the FDA. There was an additional death which we categorized as a sepsis death whereas the FDA labeled this case as "delayed onset toxic shock-like syndrome" but did not include it as a sepsis death. The patient had an exploratory laparotomy revealing green pus, which was culture positive for *prevotella* and *peptostreptococcus,* and she died intraoperatively.[31]

[29] RCM # 2007-525 NDA 20-687 Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018. FDA. 1-2. Reference ID: 4401215. Accessed November 13, 2020. https://www.fda.gov/media/112118/download

[30] Gary M, Harrison D. Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient. Ann Pharmacother. 2006 Feb 40(2):191-7. https://doi.org/10.1345/aph.1G481

[31] Individual Case Safety Report number 4734082-4-00-01. Danco Laboratories, LLC. Office of Post-marketing Drug Risk Assessment, Food and Drug Administration. Received August 4, 2005. Accessed November 13, 2020. https://aaplog.wildapricot.org/resources/Peptostreptococcus%20death%209.10277-8.pdf

Figure 1. AER Distribution



Note: From 2000 to 2016 FDA only required the manufacturer to report AEs which were severe, life-threatening or had fatal outcomes. Since 2016, FDA only requires the manufacturer to report fatal outcomes.

We categorized two deaths as suspicious for infectious death. One case was labeled by the FDA as "undetermined natural causes," however, the AER reported the cause of death as "acute visceral and pulmonary (1420 grams) congestion and edema," [32] which is consistent with the clinical findings for sepsis/Acute Respiratory Distress Syndrome (ARDS). This patient had autopsy-proven retained products of conception and blood cultures which grew *Strep viridans* isolated at less than 24 hours incubation. One additional case which the FDA labeled "methadone overdose"[33,34] we considered suspicious for sepsis. Prior to her death, this patient had fever and chills and was treated by an outside physician with cephalexin, which would have been ineffective against infections from *C. sordellii* or anaerobic gram-negative bacilli. There was no autopsy report or toxicology report in the AER.

Non-infectious deaths include one death that the FDA listed as "natural," caused by "pulmonary emphysema."[35] This patient was a 40-year-old chronic smoker who died within hours of misoprostol ingestion and had a contusion on her head consistent with a fall, a scenario possibly related to a cardiac event or acute respiratory reaction to misoprostol. She had an intact fetus at the time of

[32] Individual Case Safety Report number 9587011-03-00-01. Danco Laboratories, LLC. Office of Post-marketing Drug Risk Assessment, Food and Drug Administration. Received May 21, 2014. Accessed November 13, 2020. https://aaplog.wildapricot.org/resources/death%20Visc%20pul%20cong.pdf

[33] Individual Case Safety Report number 4970303-0-00-01. Danco Laboratories, LLC. Office of Post-marketing Drug Risk Assessment, Food and Drug Administration. Received April 21, 2014. Accessed November 13, 2020. https://aaplog.wildapricot.org/resources/death%2023%20yo%20meth%20overdose%20fever%20and%20chills.pdf

[34] Individual Case Safety Report number 5063156-8-00-01. Danco Laboratories, LLC. Office of Post-marketing Drug Risk Assessment, Food and Drug Administration. Received July 27, 2006. Accessed November 13, 2020. https://aaplog.wildapricot.org/resources/methadone%20AER%20(1).pdf

[35] Individual Case Safety Report number 11283049-02-00-01. Danco Laboratories, LLC. Office of Post-marketing Drug Risk Assessment, Food and Drug Administration. Received December 8, 2015. Accessed November 13, 2020. https://aaplog.wildapricot.org/resources/emphysema.pdf

autopsy. Other non-infectious deaths included one death from a ruptured ectopic pregnancy, one from hemorrhage, 3 possible homicides, one suicide, and 4 deaths from drug toxicity/overdose. It is unknown whether the 8 women who died by homicide, suicide, or drug toxicity/overdose were screened for domestic violence, drug addiction, or depression prior to the abortion.

Infection (Table 1)

Infection was the leading cause of mortality. There were 502 cases of infection, which included 9 Deaths, 39 had Life-threatening sepsis, 249 were Severe infections, 132 Moderate infections, and 73 infections which were Uncodable.

Ectopic Pregnancy (Table 1)

There were 75 ectopic pregnancies. Of these, 26 were ruptured, including 1 death. Twenty-four were unruptured, and there were 25 for which the rupture status was not given. Fifty-six ectopic pregnancies were treated surgically and 11 were treated with methotrexate. The management was not documented in 7 cases. The patient who died received no treatment as she died on the way to the hospital.

Retained Products of Conception (RPOC) (Tables 1 and 2)

RPOC was the leading cause of morbidity. There were 977 confirmed cases of RPOC, including 2 molar pregnancies, and 1506 likely cases of RPOC (documentation was inadequate for confirmation). Of the 2146 total D&Cs, most were for RPOC, including 897 for confirmed RPOC, 1058 for bleeding or presumed RPOC, but no pathology was provided, and 2 for molar pregnancy. A small percentage of RPOC had medical treatment or no treatment.

Hemorrhage/Bleeding (Table 1)

There were 1639 bleeding events including one death. These included 466 Life-threatening and 642 Severe events. There were also 106 events coded as Moderate, while 424 reports of bleeding were Uncodable given the information in the database.

Ongoing Pregnancy (Table 1)

There were 452 ongoing pregnancies. Of these 102 chose to keep their baby, 148 chose termination, 1 miscarried, and 201 had an unknown outcome. Of those with an unknown outcome, there were 44 patients referred or scheduled for termination, who did not follow through (39 no-showed, 3 canceled, 2 did not schedule).

Surgeries (Table 2)

There were 2243 surgeries including 2146 D&Cs, 76 laparoscopies/laparotomies without hysterectomy, 7 hysterectomies, and 14 other surgeries. Of the hysterectomies, 3 were performed for sepsis, 2 for hemorrhage, 1 for a cervical ectopic, and 1 for placenta accreta. There were 1291 surgeries performed in the hospital or ER and 952 in an outpatient setting. Of the 2146 D&Cs, 1194 were performed in the hospital or ER, and 952 in an outpatient setting. Of the 2146 D&Cs, 1194 were provided by the Hospital or ER, 853 by the abortion provider, and 99 by another outpatient provider.

Transfusions (Table 2)

Four hundred and eighty-one patients required blood transfusion following medical abortions. Of these, 365 received 1 to 10 units packed red blood cells (PRBCs) alone, 1 received fresh frozen plasma (FFP) alone, 8 received a combination of PRBCs and FFP, and 107 received an unknown amount of blood product.

Relationship of Misoprostol Use to Hemorrhage (Table 3)

The use of mifepristone with misoprostol was associated with a higher incidence of hemorrhage than the use of mifepristone alone. Of the 3056 women who took both mifepristone and misoprostol, 1572 (51.44%) hemorrhaged, whereas, among the 58 women who did not take misoprostol, only 13 (22.41%) hemorrhaged. It was unclear whether 84 patients took misoprostol or not. Fifty-four (64.29%) of them hemorrhaged. The hemorrhage rate was higher for the mifepristone with misoprostol group as compared to the mifepristone alone group even if all the unknowns were assigned to the mifepristone alone group or vice versa.

Table 1 - Diagnoses[a]

Deaths	Deaths (n)	Deaths (%)	Deaths: % of (3197) Unique US AERs (%)	Organism (%)
Sepsis	9	45.00%	0.28%	
Sepsis confirmed	7	35.00%	0.22%	100%
Clostridium sordellii	*5*	*25.00%*	*0.16%*	*71.43%*
Clostridium perfringens / Peptostreptococcus	*1*	*5.00%*	*0.03%*	*14.29%*
Peptostreptococcus	*1*	*5.00%*	*0.03%*	*14.29%*
Sepsis Likely, Unknown Organism	2	10.00%	0.06%	
Visceral and Pulmonary Congestion consistent with ARDS / sepsis	1	5.00%	0.03%	
Fever / chills treated with cephalexin, found dead[b]	1	5.00%	0.03%	
Ruptured Ectopic Pregnancy	1	5.00%	0.03%	
Hemorrhage	1	5.00%	0.03%	
Possible Homicide	3	15.00%	0.09%	
Suicide	1	5.00%	0.03%	
Drug Toxicity/Overdose	4	20.00%	0.13%	
Unknown[c]	1	5.00%	0.03%	
Total Deaths	**20**	**100%**	**0.63%**	
Infections, Level of Severity	**Infections (n)**	**Infections (%)**	**Infections: % of (3197) Unique US AERs (%)**	
Death	9	1.79%	0.28%	
Life threatening infection/sepsis	39	7.77%	1.22%	
Severe infection (IV anitbiotics)	249	49.60%	7.79%	
Moderate infection (oral antibiotics)	132	26.29%	4.13%	
Uncodable[d]	73	14.54%	2.28%	
Total Infections	**502**	**100%**	**15.70%**	

Table 1 – Diagnoses (Continued)

Ectopic Pregnancies, Rupture Status	Ectopic Pregnancies (n)	Ectopic Pregnancies (%)	Ectopic Pregnancies: % of (3197) Unique US AERs (%)
Ruptured[e]	26	34.67%	0.81%
Unruptured[f]	24	32.00%	0.75%
Surgical Treatment	13	17.33%	0.41%
Methotrexate Treatment	11	14.67%	0.34%
Unknown Rupture Status[g]	25	33.33%	0.78%
Surgical Treatment	18	24.00%	0.56%
Unknown Treatment	7	9.33%	0.22%
Total Ectopic Pregnancies	**75**	**100%**	**2.35%**
Ectopic Pregnancies, Level of Severity	**Ectopic Pregnancies (n)**	**Ectopic Pregnancies (%)**	**Ectopic Pregnancies: % of (3197) Unique US AERs**
Death	1	1.33%	0.03%
Life Threatening (Ruptured, survived)	25	33.33%	0.78%
Severe (Not Ruptured)	24	32.00%	0.75%
Uncodable	25	33.33%	0.78%
Total Ectopic Pregnancies	**75**	**100%**	**2.35%**

Table 1 – Diagnoses (Continued)

Retained Products of Conception (RPOC)	RPOC (n)	RPOC (%)	RPOC: % of (3197) Unique US AERs (%)
RPOC confirmed	977	39.35%	30.56%
RPOC confirmed (by pathology or ultrasound); Had D&C	891	35.88%	27.87%
RPOC confirmed by U/S but D&C not documented	29	1.17%	0.91%
RPOC treated medically	27	1.09%	0.84%
Tissue at os (no D&C)[h]	27	1.09%	0.84%
Molar Pregnancy	2	0.08%	0.06%
No Treatment, RPOC on autopsy	1	0.04%	0.03%
RPOC Likely	1506	60.65%	47.11%
Had D&C, no pathology provided	1056	42.53%	33.03%
Unknown[i]	450	18.12%	14.08%
Total RPOCs	**2483**	**100%**	**77.67%**
Bleeding Events, Level of Severity	**Bleeding Events (n)**	**Bleeding Events (%)**	**Bleeding Events: % of (3197) Unique US AERs**
Death	1	0.06%	0.03%
Life threatening or Disabling: 2U or more transfusion or Hgb<7 or witnessed massive blood loss	466	28.43%	14.58%
Severe: surgical intervention and/or 1 U transfusion	642	39.17%	20.08%
Moderate: medical intervention	106	6.47%	3.32%
Uncodable[j]	424	25.87%	13.26%
Total Bleeding Events	**1639**	**100%**	**51.27%**

Table 1 – Diagnoses (Continued)

Ongoing Pregnancies, Outcome	Ongoing Pregnancies (n)	Ongoing Pregnancies	Ongoing Pregnancies: % of (3197) Unique US AERs (%)	Ongoing Pregnancies with Unknown Outcome (%)
Desired to Keep Pregnancy	102	22.57%	3.19%	
Kept Pregnancy	101	22.35%	3.16%	
Kept Pregnancy but baby died in-utero	1	0.22%	0.03%	
Terminated Pregnancy	148	32.74%	4.63%	
Surgical Termination[k]	139	30.75%	4.35%	
Medical Termination	9	1.99%	0.28%	
Unknown Intent, miscarried[l]	1	0.22%	0.03%	
Unknown Outcome	201	44.47%	6.29%	100%
Referred D&C but did not show	39	8.63%	1.22%	19.40%
Referred D&C but cancelled	3	0.66%	0.09%	1.49%
Told to schedule/referred D&C did not go	2	0.44%	0.06%	1.00%
Unknown outcome, no other information[m]	157	34.73%	4.91%	78.11%
Total	**452**	**100%**	**14.14%**	

[a] Because of rounding, percentages may not appear to add up exactly.
[b] FDA attributed to methadone overdose.
[c] 40 year old smoker died within hours of misoprostol ingestion. Per FDA, "natural causes due to severe pulmonary emphysema."
[d] Patients with documented infection but inadequate information to determine severity.
[e] One of the ruptured ectopics died on the way to the hospital. The other 25 were treated surgically.
[f] The unruptured ectopics include two cornual ectopics, one treated surgically and one treated medically.
[g] Includes two cervical ectopics, one treated with D&C/Hysterectomy/massive transfusion and one with unknown treatment.
[h] Either with path provided, or described as RPOC, placental fragments, fetus, or tissue.
[i] Suspected RPOC indicating D&C needed, but not documented as being done.
[j] Patients with documented bleeding but inadequate information to determine severity.
[k] Includes one hysterotomy for pregnancy in non-communicating horn.
[l] After no show for surgical termination.
[m] Includes 10 with known gestational age 20-29 weeks.

Table 2 – Treatment[a]

Type of Surgery	Type of surgery (n)	Type of surgery (%)	Surgery: % of (3197) Unique US AERs (%)
D&C[b]	**2146**	**95.68%**	**67.13%**
Hysterectomy	**7**	**0.31%**	**0.22%**
Sepsis (includes 2 deaths)	3	0.13%	0.09%
Hemorrhage after uterine perforation	2	0.09%	0.06%
Hemorrhage - Cervical Ectopic	1	0.04%	0.03%
Placenta accreta	1	0.04%	0.03%
Laparoscopy/Laparotomy without hysterectomy	**76**	**3.39%**	**2.38%**
Ectopic (Actual or Suspected)	66	2.94%	2.06%
Infection	7	0.31%	0.22%
Uterine Perforation	1	0.04%	0.03%
Salpingo oophorectomy for Torsion	1	0.04%	0.03%
Hysterotomy for pregnancy in non-communicating horn	1	0.04%	0.03%
Other Surgeries	**14**	**0.62%**	**0.44%**
Uterine Artery Embolization	1	0.04%	0.03%
Vaginal sutures (after 15 week surgical termination for ongoing pregnancy)	1	0.04%	0.03%
Paracenteses (multiple, same patient, death)	1	0.04%	0.03%
Necrotozing fasciitis debridement and below knee amputation	1	0.04%	0.03%
Upper and lower endoscopy for bright red bleeding	1	0.04%	0.03%
Unknown surgery for deep venous thrombosis	1	0.04%	0.03%
Angioplasty	1	0.04%	0.03%
Cholecystectomy	2	0.09%	0.06%
Appendectomy	1	0.04%	0.03%
Laceration repair (scalp, chin)	2	0.09%	0.06%
Unknown Surgery	2	0.09%	0.06%
Total	**2243**	**100%**	**70.16%**

Table 2 – Treatment (Continued)

Location of Surgery	Location of Surgery (n)	Location of Surgery (%)
All Surgeries	**2243**	**100.00%**
Hospital or ER	1291	57.56%
Outpatient	952	42.44%
D&C	**2146**	**100.00%**
Hospital or ER	1194	55.64%
Outpatient	952	44.36%
Surgical Provider for D&C	**Surgical Provider (n)**	**Surgical Provider (%)**
Hospital/ER	1194	55.64%
Abortion Provider	853	39.75%
Other Provider	99	4.61%
Total	**2146**	**100%**
Indication for D&Cs	**Indication for D&C (n)**	**Indication for D&C (%)**
Confirmed D&C[c]	**2146**	**100%**
RPOC (confirmed by pathology or ultrasound)	897	41.80%
RPOC/Bleeding (no pathology provided)	1058	49.30%
Ongoing pregnancy, surgical termination by D&C	139	6.48%
RPOC ruled out	34	1.58%
Ectopic evaluation	12	0.56%
Molar pregnancy	2	0.09%
Not able to take misoprostol	4	0.19%
Possible D&C	**680**	
Possible RPOC, unknown treatment, possible D&C	450	
RPOC confirmed by U/S but D&C not documented	29	
Ongoing pregnancy Unknown outcome, possible D&C	201	
TOTAL (Confirmed and Possible)	**2826**	

Table 2 – Treatment (Continued)

Transfusions	Transfusions (n)	Transfusions (%)	Transfusion: % of (3197) Unique US AERs (%)
PRBC alone	**365**	**75.88%**	**11.42%**
1U	32	6.65%	1.00%
1-2U	1	0.21%	0.03%
2U	246	51.14%	7.69%
2.5U	1	0.21%	0.03%
3U	45	9.36%	1.41%
4U	27	5.61%	0.84%
5U	5	1.04%	0.16%
6U	5	1.04%	0.16%
7U	2	0.42%	0.06%
10U	1	0.21%	0.03%
Other Blood products	**9**	**1.87%**	**0.28%**
1 U FFP	1	0.21%	0.03%
2 U PRBC/1 U FFP	1	0.21%	0.03%
2 U PRBC/ 4 U FFP	1	0.21%	0.03%
3 U PRBC/ 1 U FFP	1	0.21%	0.03%
4 U PRBC/ 1 U FFP	1	0.21%	0.03%
4 U PRBC/ 2 U FFP	1	0.21%	0.03%
5 U PRBC/ 4 U FFP	1	0.21%	0.03%
6 U PRBC/ 2 U FFP	1	0.21%	0.03%
7 U PRBC/ FFP and Platelets unknown amount	1	0.21%	0.03%
Unknown amount (documented as given, units not recorded)	**107**	**22.25%**	**3.35%**
Total[d]	**481**	**100%**	**15.05%**

[a] Because of rounding, percentages may not appear to add up exactly.
[b] With or without suction, one with hysteroscopy.
[c] There were 8 patients who had 2 D&Cs and one who required uterine artery embolization. There were 4 perforations: two had resultant hysterectomies, one had a laparoscopy, and one received 2 U PRBCs but no documented surgery.
[d] Additionally there were 7 patients who likely received transfusion, but was not recorded, 3 patients who refused transfusion, and 1 patient for whom transfusion was considered but not given.

Table 3 – Relationship of Misoprostol to Hemorrhage[a]

	Mifepristone + Misoprostol		Mifepristone alone		Unknown		Mifepristone + Misoprostol + unknown [b]		Mifepristone alone + unknown [c]	
	n	%	n	%	n	%	n	%	n	%
No Hemorrhage	**1484**	**48.56%**	**45**	**77.59%**	**30**	**35.71%**	**1514**	**48.23%**	**75**	**52.82%**
Hemorrhage	**1572**	**51.44%**	**13**	**22.41%**	**54**	**64.29%**	**1625**	**51.77%**	**67**	**47.18%**
Death	1	0.03%	0	0.00%	0	0.00%	1	0.03%	0	0.00%
Life threatening	441	14.43%	5	8.62%	20	23.81%	461	14.69%	25	17.61%
Severe	633	20.71%	3	5.17%	6	7.14%	639	20.36%	9	6.34%
Moderate	101	3.30%	1	1.72%	4	4.76%	105	3.35%	5	3.52%
Uncodable	396	12.96%	4	6.90%	24	28.57%	420	13.38%	28	19.72%
Total US AERs	**3056**	**100%**	**58**	**100%**	**84**	**100%**	**3139**	**100%**	**142**	**100%**

[a] Because of rounding, percentages may not appear to add up exactly.
[b] Assumes all unknowns took both mifepristone and misoprostol.
[c] Assumes all unknowns took mifepristone, but not misoprostol.

Discussion

This article is critically important considering the paucity of published literature on mifepristone safety and the minimal analysis done on the AERs by the FDA.

Ectopic Pregnancies

Although reported as AEs, ectopic pregnancies are not a direct adverse event from the medication, but rather a contraindication to its administration. They were reported as adverse events because the ectopic pregnancies were missed.

The American College of Obstetricians and Gynecologists (ACOG) notes that "According to the Centers for Disease Control and Prevention, ectopic pregnancy accounts for approximately 2% of all reported pregnancies. However, the true current incidence of ectopic pregnancy is difficult to estimate because many patients are treated in an outpatient setting where events are not tracked, and national surveillance data on ectopic pregnancy have not been updated since 1992. Despite improvements in diagnosis and management, ruptured ectopic pregnancy continues to be a significant cause of pregnancy-related mortality and morbidity. In 2011–2013, ruptured ectopic pregnancy accounted for 2.7% of all pregnancy-related deaths and was the leading cause of hemorrhage-related mortality."[36]

[36] ACOG Practice Bulletin No. 193: Tubal Ectopic Pregnancy, Obstet Gynecol: March 2018; 131(3): e91-e103. doi:10.1097/AOG.0000000000002560

Confirmed/suspected ectopic pregnancy and undiagnosed adnexal mass are contraindications to mifepristone use under current prescribing requirements. The label warnings state: "Ectopic pregnancy: exclude before treatment."[37] Unfortunately, it is difficult to rule out ectopic pregnancy by history alone because, "half of all women who receive a diagnosis of an ectopic pregnancy do not have any known risk factors."[38] According to ACOG Practice Bulletin No. 193, "The minimum diagnostic evaluation of a suspected ectopic pregnancy is a transvaginal ultrasound evaluation and confirmation of pregnancy." Of the 75 reported ectopic pregnancies in the FDA AERs we analyzed, over a third were known to be ruptured including one death. Clearly, an ultrasound should be required prior to the administration of mifepristone to document that the pregnancy is located within the uterus. Although not 100% effective, this will screen for ectopic pregnancy, confirm gestational age, which can be inaccurate based on menstrual history alone,[39] and screen for adnexal masses, another contraindication to mifepristone use.[40]

Ongoing pregnancies

Of the women with an ongoing pregnancy, less than a third were known to have proceeded with termination of the pregnancy, and almost a quarter were known to have kept their pregnancy; in almost half, the outcome was unknown. The significant percentage of women with ongoing pregnancy who changed their mind and chose to keep their pregnancy, after initially choosing termination, raises concerns regarding the pre-abortion counseling and informed consent they received. Women undergoing abortion should receive the same quality of informed consent and pre-procedural counseling that is standard of care prior to other medical treatment or surgery. It is imperative that women considering abortion be provided adequate and complete information and counseling on risks, advantages, disadvantages, and alternative options.

Additionally, the high percentage of women with ongoing pregnancies for whom there is no follow up or known outcome is concerning. As health care providers we are to continue to care for our patients and manage any complications, yet in the AERs we reviewed this was not typically the case for the abortion provider. Furthermore, a federal registry of known outcomes and birth defects is imperative. One of the initial FDA post-marketing requirements for

[37] MIFEPREX. Package insert. Danco; 2016. Approved March 2016. p. 1. Accessed November 13, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf

[38] ACOG Practice Bulletin No. 193: Tubal Ectopic Pregnancy, Obstet Gynecol: March 2018; 131(3): e91-e103. doi: 10.1097/AOG.0000000000002560

[39] Shipp, Thomas D. 2020. Overview of ultrasound examination in obstetrics and gynecology. Lit Rev current through Dec 2020. UpToDate. Edited by Barss A Vanessa. Wolters Kluwer. June 10, 2020. Accessed January 11, 2021. https://www.uptodate.com/contents/ectopic-pregnancy-clinical-manifestations-and-diagnosis/print?source=history_widget.

[40] MIFEPREX. Package insert. Danco; 2016. Approved March 2016. Accessed November 13, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf

Danco was a surveillance study of outcomes of ongoing pregnancies.[41] The FDA released them from this post-marketing commitment in January 2008 because Danco reported that only one or two ongoing pregnancies per year were followed for final outcomes in part because of consent requirements.[42] This is disturbing in light of the percentage of women in our analysis who kept their pregnancies, as well as those with ongoing pregnancy and unknown outcomes, all of whom could have been followed for final outcomes. The significant lack of follow-up of ongoing pregnancies (44.47% with unknown outcomes) and the very minimal information on those who chose to keep the pregnancy, highlights the need for a national registry especially considering the teratogenicity of misoprostol.[43]

Relationship of Misoprostol to Hemorrhage

The Creinin study of abortion pill reversal was stopped for safety concerns due to hemorrhage in 3 of the 12 study participants.[44] One of the conclusions of that study was that "Patients who use mifepristone for a medical abortion should be advised that not using misoprostol could result in severe hemorrhage, even with progesterone treatment."[45] The authors hypothesized that the absence of misoprostol caused these women to hemorrhage. The women who had documented use of misoprostol in our database hemorrhaged at a higher rate than those documented not to have taken misoprostol.

Reporting of Adverse Events

Although not the initial goal of this study, the analysis of the AERs revealed glaring deficiencies in the AE reporting system making it difficult to properly evaluate adverse events. When mifepristone was approved in 2000, FDA required that providers "must report any hospitalization, transfusion or other serious event to Danco Laboratories."[46] This created an inherent conflict of interest as it is not in the best interest of the entities or providers to report adverse events to those regulating them. Because only severe events were reportable, this requirement likely resulted in an underestimation of moderate and mild AEs. It

[41] Center for Drug Evaluation and Research. NDA 20-687. Approval Letter for MIFEPREX (mifepristone) Tablets, 200 mg to Population Council. Food and Drug Administration. Written September 28, 2000. Accessed November 13, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.htm

[42] 2016 03 20 FDA resp to Cit Pet.pdf. Docket No. FDA-2002-P-0364. FDA. March 29, 2016. p. 31. Accessed November 13, 2020. https://aaplog.wildapricot.org/resources/2016%2003%2020%20%20FDA%20resp%20to%20Cit%20Pet.pdf

[43] Cytotec (misoprostol tablets). Package insert. G.D. Searle; Revised November 2012. Accessed November 13, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/019268s047lbl.pdf

[44] Creinin MD, Hou MY, Dalton L, Steward R, Chen MJ. Mifepristone Antagonization With Progesterone to Prevent Medical Abortion: A Randomized Controlled Trial. Obstet Gynecol. 2020;135(1):158-165. doi:10.1097/AOG.0000000000003620

[45] Creinin MD, Hou MY, Dalton L, Steward R, Chen MJ. Mifepristone Antagonization With Progesterone to Prevent Medical Abortion: A Randomized Controlled Trial. Obstet Gynecol. 2020;135(1):5. doi:10.1097/AOG.0000000000003620

[46] M I F E P R E X™(Mifepristone) Tablets, 200 mg Prescriber's agreement. Food and Drug Administration. September 28, 2000, 1-2. Accessed November 16, 2020. http://wayback.archive-it.org/7993/20170113112742/http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111364.pdf

is also likely that some of the AEs that we coded as Mild or Moderate were actually Severe but there was not enough information in the AER for us to justify coding them as Severe. In March 2016, the FDA substantially reduced the prescribing requirements and changed the drug protocol [47] and yet at the same time eliminated reporting requirements except for deaths.[48] With the relaxation of reporting requirements, the ability to perform any relevant post-marketing evaluation of mifepristone was lost. It is imperative for the safety of women that the FDA restore and strengthen the 2011 REMS requirements.

The information in the AERs is almost exclusively obtained from abortion providers, rather than the physician treating the complication, yet in this analysis, abortion providers managed only 39.75% of surgical complications (a number which is likely much lower since these are only the cases which are known to the abortion provider). Throughout the reports, there was also a lack of detail and many patients who were simply "lost to follow-up." This resulted in 16.80% of the AERs being Uncodable as to severity and likely under-coding of many AERs and AEs, as coding could only be assigned based on the scant information provided. Many of the AEs experienced by women were unknown to the abortion provider until the follow-up examination, which is troubling considering the poor follow-up rate and elimination of the requirement for an in-office follow up visit. Some of the patient deaths were not known to the abortion provider until they saw the death in an obituary or were contacted by an outside source. Because of this, in addition to abortion providers, hospitals, emergency departments, and private practitioners should be required to report AEs.

Complications occur in the best of hands in all areas of medicine, but as physicians, we are responsible to manage those complications and follow our patients through to resolution. The findings that: 1. the most common outcome of ongoing pregnancy was unknown outcome, 2. abortion providers performed less than half the D&Cs done for complications, and 3. a third of ectopic pregnancies (missed prior to administering the abortifacient) had unknown rupture status, leave us deeply concerned regarding the care these women received. A post-marketing requirement was that there be a "cohort-based study of safety outcomes of patients having medical abortion under the care of physicians with surgical intervention skills compared to physicians who refer their patients for surgical intervention."[49] The applicant was released from this requirement because they stated that because there were so few providers

[47] GAO-18-292 Revised Mifeprex Labeling: Food and Drug Administration Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts. Report to Congressional Requesters. Food and Drug Administration. 2018. p. 7. Published March 2018. Accessed November 13, 2020. https://www.gao.gov/assets/700/690914.pdf

[48] NDA 20-687 MIFEPREX (mifepristone) Tablets, 200 mg: Risk Evaluation and Mitigation Strategy (REMS). Food and Drug Administration. 2016. p. 3, 6. Reference ID: 3909592. Published March 29, 2016. Accessed November 13, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020RemsR.pdf

[49] Center for Drug Evaluation and Research. NDA 20-687. Approval Letter for MIFEPREX (mifepristone) Tablets, 200 mg to Population Council. Food and Drug Administration. Written September 28, 2000. Accessed November 13, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687apltr.htm

without surgical intervention skills, no meaningful study could be done.[50] Yet, that same year the FDA changed the provider agreement to allow non-physicians to become prescribers.[51] These findings highlight the importance of follow-up and management of complications by the abortion provider. Allowing any further relaxation of mifepristone prescribing requirements will put women at an even higher risk of adverse events

Limitations and Strengths

It was not possible to calculate complication rates for mifepristone and misoprostol abortions based on AER data because there is no denominator for how many mifepristone abortions are performed in the U.S. since reporting is often voluntary and sporadic. For clarity, we specified the denominators we used.

Our analysis was limited by the fact that the number of AEs for which we received reports is likely a gross underestimation of the actual number of AEs that occurred. In our analysis, the surgical management of over half the complications was performed by someone other than the abortion provider, yet treating physicians are not required to report complications. Few reports were generated by those in Emergency Departments and hospitals who treated the complications.

Our analysis was also limited by the lack of information in the AERs, including redaction of critical dates, a paucity of diagnosis and treatment information, and lack of follow up.

Our study has several strengths. Our data comes from information provided to the FDA and is the largest analysis of AERs for mifepristone abortions. This data is publicly available under the Freedom of Information Act so that anyone can verify the data for themselves. This analysis reviews all AERs not reported in the first study by Gary.[52] Although heavily redacted, there was sufficient information in over 80% of the AERs to evaluate severity. An objective standardized system, CTCAEv3, was used to code for severity, and each AER was coded by at least two board-certified obstetrician-gynecologists or family medicine physicians.

Conclusions and Relevance

This article is important because it augments the scant published literature on mifepristone safety.

Due to the lack of adequate reporting of adverse events, especially by those treating them, these unique AERs represent a fraction of the actual adverse events occurring in American women.

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[50] 2016 03 20 FDA resp to Cit Pet.pdf. Docket No. FDA-2002-P-0364. FDA. March 29, 2016. p. 31. Accessed November 13, 2020. https://aaplog.wildapricot.org/resources/2016%2003%2020%20%20FDA%20resp%20to%20Cit%20Pet.pdf

[51] GAO-18-292 Revised Mifeprex Labeling: Food and Drug Administration Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts. Report to Congressional Requesters. Food and Drug Administration. 2018. p. 7. Published March 2018. Accessed November 13, 2020. https://www.gao.gov/assets/700/690914.pdf

[52] Gary M, Harrison D. Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient. Ann Pharmacother. 2006 Feb 40(2):191-7. https://doi.org/10.1345/aph.1G481

Significant morbidity and mortality have occurred with the use of mifepristone as an abortifacient, including at least 24 US deaths reported by the FDA from September 2000 to December 2018. Because of this and the significant morbidity associated with this drug, the FDA should consider at a minimum reinstating the original 2011 REMS and strengthening the reporting requirements. The reporting of transfusions, hospitalizations, and other serious adverse events are essential.

Given the morbidity and mortality of undiagnosed ectopic pregnancy, a clear contraindication to the use of mifepristone, an ultrasound to confirm pregnancy location is essential before mifepristone is dispensed.

Considering the significant percentage of women with ongoing pregnancies who chose to continue their pregnancy, there must be reasonable waiting periods, parental involvement, and adequate pre-abortion counseling on all pregnancy options. It is also critical that a pregnancy registry be established.

In our analysis, the patients who used mifepristone alone had a lower rate of hemorrhage than those using mifepristone followed by misoprostol.

The FDA Adverse Event Reporting System is woefully inadequate to determine the post-marketing safety of mifepristone due to its inability to adequately assess the frequency or severity of adverse events. The reliance solely on interested parties to report, the large percentage of uncodable events, the redaction of critical clinical information unrelated to personally identifiable information, and the inadequacy of the reports highlight the need to overhaul the current AER System.

This analysis evaluated 3197 adverse events resulting from the use of mifepristone as an abortifacient and brought to light serious concerns about the safety requirements and care of women undergoing mifepristone abortion. Although complications may occur in the best of hands, and no medical procedure is without risks, safety measures must be employed to minimize these adverse outcomes. Women undergoing abortion should receive the same quality of informed consent and pre-procedural counseling that is standard of care prior to other medical treatment or surgery. It is imperative that women considering abortion be provided adequate and complete information and counseling on risks, advantages, disadvantages, and alternative options. Although there may be disagreements about the ethics of abortion, there must be total agreement that our patients—whether undergoing a medical abortion or otherwise—deserve the highest standard of medical care.

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EXHIBIT 37

Christiana A. Cirucci 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*, 8 Health Servs. Rsch & Managerial Epidemiology 1 (2021)

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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

Christina A. Cirucci[1], Kathi A. Aultman[2], and Donna J. Harrison[3]

Abstract

Background: As part of the accelerated approval of mifepristone as an abortifacient in 2000, the Food and Drug Administration (FDA) required prescribers to report all serious adverse events (AEs) to the manufacturer who was required to report them to the FDA. This information is included in the FDA Adverse Event Reporting System (FAERS) and is available to the public online. The actual Adverse Event Reports (AERs) can be obtained through the Freedom of Information Act (FOIA).

Methods: We compared the number of specific AEs and total AERs for mifepristone abortions from January 1, 2009 to December 31, 2010 from 1. Planned Parenthood abortion data published by Cleland et al. 2. FAERS online dashboard, and 3. AERs provided through FOIA and analyzed by Aultman et al.

Results: Cleland identified 1530 Planned Parenthood mifepristone cases with specific AEs for 2009 and 2010. For this period, FAERS online dashboard includes a total (from all providers) of only 664, and the FDA released only 330 AERs through FOIA. Cleland identified 1158 ongoing pregnancies in 2009 and 2010. FAERs dashboard contains only 95, and only 39 were released via FOIA.

Conclusions: There are significant discrepancies in the total number of AERs and specific AEs for 2009 and 2010 mifepristone abortions reported in 1. Cleland's documentation of Planned Parenthood AEs, 2. FAERS dashboard, and 3. AERs provided through FOIA. These discrepancies render the FAERS inadequate to evaluate the safety of mifepristone abortions.

Keywords

mifepristone, misoprostol, adverse drug reaction reporting systems, drug-related side effects and adverse reactions, postmarketing product surveillance, induced abortion, steroidal abortifacient agents, United States food and drug administration

Introduction

The accelerated approval of mifepristone in the United States (US) in 2000 included post-marketing restrictions to monitor safety. Prescribers were required to report any ongoing pregnancies, hospitalizations, transfusions, and other serious events to the manufacturer, who was required to submit them to the Food and Drug Administration (FDA).[1] Adverse events (AEs) are documented in the FDA Adverse Event Reporting System (FAERS), available online.[2] Copies of the actual Adverse Event Reports (AERs) can be obtained via the Freedom of Information Act (FOIA).[3]

A paper published by Cleland et al. analyzed eight adverse events/outcomes (AEs) from mifepristone abortions at 63 days and less performed by Planned Parenthood in 2009 and 2010. They analyzed hospital admissions, blood transfusions, emergency department (ED) treatments, intravenous (IV)

[1] Sewickley, PA
[2] Charlotte Lozier Institute
[3] American Association of Pro-Life Obstetricians and Gynecologists, USA

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Corresponding Author:
Christina A. Cirucci, Sewickley, Pennsylvania, United States.
Email: chris@aaplog.org

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antibiotics, infections requiring IV antibiotics or hospitalization, deaths, ongoing pregnancies, and ectopic pregnancies. Cleland explained that Planned Parenthood reports all significant AEs to Danco Laboratories, which submits them to the FDA, per the mifepristone prescribing information. Their analysis for these specific AEs led them to conclude that, "Among the 233 805 medical abortions provided at Planned Parenthood health centers in 2009 and 2010, significant adverse events or outcomes were reported in 1530 (0.65%) cases."[4] Unless associated with another AE, they did not include data on incomplete abortion managed at Planned Parenthood or hemorrhage without transfusion, two of the most common AEs resulting from mifepristone abortion. They also admit that "we cannot exclude the possibility that some clinically significant adverse events or outcomes were not included. Some patients may have experienced a significant adverse event or outcome but did not follow up after their medical abortion."[4] Cleland did not provide the loss to follow-up rate.

In 2021, Aultman et al. published an analysis of the AERs for mifepristone abortion from September 2000 to February 2019 (excluding those published by Gary in 2006) utilizing AERs obtained through FOIA.[5,6]

The objective of this paper was to compare the total number of AERs/cases (which may include more than one AE) and the individual AEs identified by Cleland for 2009 and 2010 mifepristone abortions from three sources: those identified by Planned Parenthood as published by Cleland, those currently posted on the FAERS dashboard, and those provided by the FDA in response to FOIA and analyzed by Aultman.

Methods

We searched the FAERS dashboard for any US AERs related to mifepristone abortion occurring from January 1, 2009 through December 31, 2010 and tabulated the total number of AERs, hospital admissions, deaths, ongoing pregnancies, and ectopic pregnancies. The FAERS did not have enough information to evaluate for transfusion, ED visits, IV antibiotics, or infections requiring IV antibiotics or hospital admission. Since FAERS does not provide the "abortion date," we used the "event date"; in cases where there was no "event date," we used the "latest manufacturer received date." We evaluated Aultman's AERs for the events in Cleland and confirmed any missing reports by searching the 6158 pages of AERs related to mifepristone abortion obtained by FOIA. In analyzing FOIA data, Aultman accounted for duplicates. In the FAERS data, we accounted for duplicates for deaths and ectopic pregnancies, but FAERS did not provide sufficient detail to do so for hospital admissions and ongoing pregnancies. We then compared the total number of reports, as well as hospitalizations, ongoing pregnancies, ectopic pregnancies, and deaths from Cleland, FAERS, and FOIA AERs for 2009 and 2010. Adverse events not reported by Cleland were not evaluated. The FAERS and FOIA total AERs include reports from all sources, not just from Planned Parenthood, and include all reports for those years, not just those with the eight AEs evaluated by Cleland.

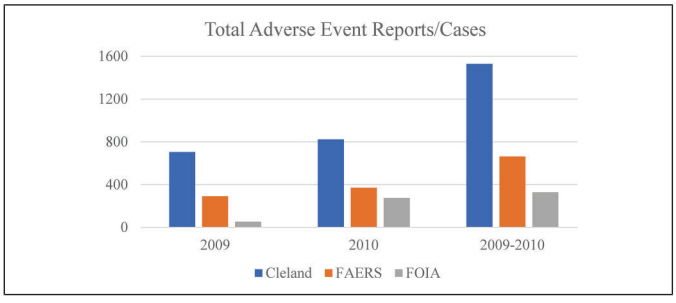


Figure 1. Comparison of total adverse event reports from three sources.

Results

Our analysis shows significant discrepancies between the number of AERs identified by Planned Parenthood as reported in Cleland, the number in the FAERS database, and the number received under FOIA. There are also discrepancies in the number of hospitalizations, ectopic pregnancies, and ongoing pregnancies.

Total Reports (Figure 1)

Cleland identified 1530 cases involving eight specific AEs after Planned Parenthood mifepristone abortion in 2009 and 2010. The FAERS dashboard contains only 664 AERs for this period, and only 330 were provided through FOIA. Both include AERS with other types of adverse events not included by Cleland and include reports from all sources, not just Planned Parenthood.

Specific Adverse Events/Outcomes (Table 1)

Cleland identified 548 ongoing pregnancies after mifepristone abortion in 2009, the FAERS dashboard includes just 56, and only seven were received via FOIA. For 2010, Cleland identified 610 ongoing pregnancies, FAERS contains just 39, and only 32 were obtained via FOIA. Cleland identified 70 hospital admissions in 2009 and 65 in 2010. FAERS includes 87 and 125, respectively, but the FDA only provided 14 and 94 via FOIA. Ectopic pregnancy, although not caused by mifepristone, is a contraindication to its use. Cleland reported eight ectopic pregnancies in 2009 and eight in 2010. FAERS includes eight for 2009 and nine for 2010. The FOIA AERs have only one ectopic for 2009 and eight for 2010. Cleland reported no deaths in 2009 and one in 2010. FAERS and FOIA were consistent with one death in 2009 and two in 2010.

Discussion

The total number of AEs published in Cleland is significantly higher than the number in the FAERs database, even though Cleland did not evaluate all AEs, including

Table 1. Comparison of Number of Specific Adverse Events[a] from Three Sources.

	2009			2010			Total 2009 to 2010		
	Cleland	FAERS[b]	FOIA	Cleland	FAERS[b]	FOIA	Cleland	FAERS[b]	FOIA
Hospital Admission	70	87	14	65	125	94	135	212	108
Transfusion	42		10	72		59	114		69
ED Treatment	87		27	151		105	238		132
IV Antibiotics	23		5	34		27	57		32
Infection requiring IV Antibiotics or Admission	14		4	23		21	37		25
Death	0	1	1	1	2	2	1	3	3
Ongoing Pregnancy	548	56	7	610	39	32	1158	95	39
Ectopic Pregnancy	8	8	1	8	9	8	16	17	9

[a]Events are not mutually exclusive.
[b]If blank, FAERS dashboard does not provide this detail.

failed abortions treated at Planned Parenthood.[4] The discrepancy is particularly concerning because the total number of AEs and AERs in the FAERS should be significantly higher than Cleland since Planned Parenthood performs only 37% of US abortions.[7] It is unclear why so many cases identified by Planned Parenthood in Cleland do not appear in FAERS. Cleland states, "In accordance with the mifepristone prescribing information, Planned Parenthood Federation of America reports all significant adverse events and outcomes to Danco Laboratories, the US distributor of mifepristone, which in turn reports them to the FDA."[4] If this claim is true, then either Danco did not report a significant number of adverse events to the FDA, or the FDA did not include them in FAERS. It also raises the question of whether FAERS includes all complications reported by the other 63% of abortion providers.

We are concerned that FDA and others will continue to rely on Cleland's statement, "significant adverse events or outcomes were reported in 1530 (0.65%) cases"[4] to claim that the complication rate for the abortion pill regimen is low. Although Cleland's paper is a study of over 200 000 abortions and is cited extensively in support of the safety of medical abortion[8–11] the analysis excludes the most common adverse events (retained products of conception and hemorrhage not requiring transfusion). Additionally, Cleland's reported complication rate of 0.65% is only a report of the complications known to Planned Parenthood. Cleland does not report the percent of patients lost to follow-up.[4]

There is also concern that the FDA will continue to rely on the FAERS to make decisions about removing mifepristone REMS, despite the findings herein that FAERS does not include all the events even known to the abortion provider. To compound this problem, in 2016, the FDA eliminated the requirement to report adverse events resulting from mifepristone other than death.[12] Nevertheless, in her April 12, 2021 letter to the American College of Obstetricians and Gynecologists, FDA Commissioner Janet Woodcock stated that, based on a review of post-marketing AEs from January 27, 2020, to January 12, 2021, the in-person dispensing requirements in the mifepristone REMS would not be enforced.[13] It is alarming that policy decisions that affect women's safety are based on a lack of information in the FAERS. Whether the inaccuracy of FAERS extends to required reporting for other medications is unknown to us, but the findings in this paper have significant implications for drug safety evaluation in general.

The ability of the FAERS to accurately identify complications from mifepristone abortion depends on 1. the abortion provider being aware of the adverse event, 2. the provider reporting the adverse event to the manufacturer, 3. the manufacturer reporting to the FDA, and 4. the FDA including the event in the FAERS. One problem inherent in this system is that adverse events unknown to the abortion provider or occurring in patients lost to follow-up will be missed. In addition, ED physicians or treating physicians other than the abortion provider were never obligated to report and may not even be aware of the system. For those events known to Planned Parenthood, it is unclear whether the error occurred in the abortion provider reporting to the manufacturer, the manufacturer reporting to the FDA, or the FDA uploading to the database.

FDA compliance in response to FOIA requests is required by law.[3] The number of AERs supplied under FOIA is much lower than the number in the FAERS database and known to the FDA at the time. Although there may be extenuating circumstances requiring that some information be withheld, withholding information, especially to this extent, interferes with independent, scientific analysis necessary to validate claims of safety and efficacy.

Strengths and Limitations

One of the limitations of this study is that Cleland only reported on a limited number of possible AEs. Because of the scant information included in the FAERS, we could not even compare all AEs reported by Cleland. Since we do not have

access to the Planned Parenthood records, reports cannot be evaluated on a patient-by-patient basis but only as a composite.

One of the strengths of this study is that it is the first known study comparing FAERS data with an outside report of mifepristone complications.

Conclusions

There are significant discrepancies in the number of AEs and total AERs reported for 2009 and 2010 mifepristone abortions identified by Planned Parenthood as reported by Cleland, those in FAERS, and those provided by FOIA, impugning the reliability of FAERS to evaluate the safety or efficacy of mifepristone abortions at a time when the FDA is under pressure to eliminate REMS on mifepristone.[14,15] The FDA used their review of post-marketing adverse events that occurred in 2020 and 2021 as a rationale for removing the in-person dispensing requirements for mifepristone during COVID, even though reporting requirements (other than death) were eliminated in 2016.[13] Whether Planned Parenthood did not submit all the AEs to Danco, Danco did not submit all to the FDA, or the FDA did not include all is unknown. By withholding a significant number of AERs, the FDA did not adequately comply with the FOIA request by the authors of the Aultman paper, hampering their ability to analyze the data. These discrepancies, and the fact that since 2016, reporting AEs other than deaths is no longer required,[12] demonstrate that the FAERS is inadequate to evaluate the safety of mifepristone.

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ORCID iDs

Christina A. Cirucci https://orcid.org/0000-0002-4681-6529
Kathi A. Aultman https://orcid.org/0000-0002-9235-5049

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Author biographies

Christina A. Cirucci, MD received her Bachelor of Science in Mechanical Engineering from Virginia Tech in Blacksburg, VA and her MD from Thomas Jefferson University, Philadelphia, PA. She completed her residency in obstetrics and gynecology at the Medical College of Virginia in Richmond, VA. She is a diplomate of the American Board of Obstetrics and Gynecology and a life Fellow of the American College of Obstetricians and Gynecologists. She is a member of the Christian Medical and Dental Associations, the North American Menopause Society, the Pennsylvania Medical Society, and the Allegheny County Medical Society. She is a board member of the American Association of Pro-Life Obstetricians and Gynecologists. She worked in private practice for twenty years in Pittsburgh, PA.

Kathi A. Aultman, MD received her B.A. from Drew University in 1972, earned her MD at the University of Florida College of Medicine in 1977, and completed her OB/GYN Residency at the University of Florida affiliated Jacksonville Health Education Program in 1981. She is a diplomate of the American Board of Obstetrics and Gynecology and is currently an Associate Scholar with the Charlotte Lozier Institute. She is a member of the American Association of Prolife Obstetricians and Gynecologists, the Christian Medical and Dental Associations, the Florida Medical Association, and is a Life Fellow of the American College of Obstetricians and Gynecologists. She practiced medicine from 1981-2014 in Orange Park, Florida. Dr. Aultman was the co-founder and co-director of the first Rape Treatment Center in Jacksonville, Florida and performed sexual assault exams on women and children as a medical examiner for Duval and Clay Counties. She performed 1st trimester D&C with suction abortions and 2nd trimester D&Es. She also served as the Medical Director for Planned Parenthood of Northeast Florida, Inc. from 1981 to 1983.

Donna J. Harrison, MD received her MD from the University of Michigan and completed her OBGYN residency at a University of Michigan affiliate hospital (St. Joseph Mercy Hospital). She is a diplomate of the American Board of Obstetrics and Gynecology. She is currently CEO of the American Association of Pro-Life Obstetricians and Gynecologists.

EXHIBIT 38

FDA, Adverse Event Reporting System (FAERS) Electronic Submissions

FDA Adverse Event Reporting System (FAERS) Electronic Submissions

This page is intended to assist industry when making certain regulatory submissions in electronic format to the FDA's Adverse Event Reporting System (FAERS) database for the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

On January 16, 2024, FDA began accepting electronic submissions of both expedited and non-expedited postmarketing individual case safety reports (ICSRs) for human drugs, including biological products regulated by CDER, in electronic format using the E2B(R3) standard endorsed by the International Council for Harmonisation (ICH) and adopted by FDA.

In addition, on April 1, 2024, FDA began accepting electronic submissions of premarketing (IND study or IND-exempt BA/BE study) individual case safety reports (ICSRs) in electronic format using ICH E2B(R3) standard. The following timelines apply to companies submitting ICSRs electronically using database-to-database transmission (E2B).

Timelines

- **Postmarketing Safety Reporting for human drug and biological products using the E2B standard:**
  - On January 16, 2024, FDA implemented the E2B(R3) standard for electronic transmission of ICSRs and submitters have until April 1, 2026, to implement E2B(R3) standard for electronic transmission.
  - Submitters to FAERS may continue to submit using E2B(R2) data standards for two (2) years during the E2B(R3) implementation period.
  - Continue to submit postmarketing ICSRs in E2B(R2) format as you prepare to submit ICSRs using E2B(R3) data standards.
  - Once your company has begun submitting in the E2B(R3) standard, your company may not revert to legacy methods or standards
- **If you are submitting ICSRs via the Safety Reporting Portal (SRP) no action is required.**
- FDA issued a final rule on June 10, 2014, requiring industry to submit postmarketing safety reports in an electronic format.
- **Premarketing Reporting (IND safety reports) using the E2B standard:**
  - Submitters have until April 1, 2026, (24 months after publication of the final guidance for industry, *Providing Regulatory Submissions in Electronic Format: IND Safety Reports*) to comply with electronic submission requirements for IND safety reports under 21 CFR 312.32(c)(1)(i) for serious and unexpected suspected adverse reactions.
  - As you prepare to submit ICSRs electronically during the voluntary submission period, sponsors may continue to submit a PDF copy of the Form FDA-3500A MedWatch form using the eCTD standard until April 1, 2026.
- **Premarketing Reporting (IND-exempt BA/BE safety reports) using the E2B standard:**
  - The electronic submission of the ICSRs from IND-exempt BA/BE studies is a voluntary option for submission.

- As you prepare to submit ICSRs electronically, continue to submit IND-exempt BA/BE safety reports on Form FDA-3500A MedWatch to ogd-premarketsafetyreports@fda.hhs.gov (mailto:ogd-premarketsafetyreports@fda.hhs.gov)

Submitting Individual Case Safety Reports (ICSRs), Periodic Safety Reports (PSRs):

1. Submitting ICSRs

You have two options for submitting ICSRs electronically:

Option A: Database-to-Database Transmission ("E2B")

ICSRs should be submitted in XML format using the one of the standards below via Electronic Submission Gateway (ESG):

- E2B(R3) standard (/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-electronic-submissions-e2br3-standards): in accordance with the ICH E2B(R3) and FDA's regional technical specifications.
- E2B(R2) standard (/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-electronic-submissions-e2br2-standards): **only** for postmarketing ICSRs until April 1, 2026, during the E2B(R3) implementation period.

Option B: Safety Reporting Portal (SRP (https://www.safetyreporting.hhs.gov/SRP2/en/Home.aspx))

Applicants for human drug products, biological products, and responsible persons for companies with reporting requirements who do not have E2B capability may submit postmarketing ICSRs and respective attachments electronically via SRP (https://www.safetyreporting.hhs.gov/SRP2/en/Home.aspx) by manually entering the data into a web form. To submit via SRP, you must first establish an SRP account. A Gateway partner (i.e., a company that submits ICSRs electronically via the ESG) cannot use SRP to submit ICSRs, and respective attachments.

Steps for requesting an SRP account

Contact faersesub@fda.hhs.gov (mailto:faersesub@fda.hhs.gov) to advise FDA of your intent to begin submitting via the SRP and establish an account.

SRP account activation

- Your account will be activated in about 7 to 10 business days from the date of request.
- You will be notified via email with the subject line "SRP Account Activation" that will include the Web link to the SRP portal along with your account information.
- After receiving this email, your account will be considered active, and you may begin submitting your ICSR via SRP.

2. Submitting PSRs

Please note that a PSR submission is comprised of both a descriptive portion and the non-expedited ICSRs received during the reporting interval of the PSR (21 CFR 314.80(c)(2) and 600.80(c)(2)).

- **Descriptive Portion:**
  - Use Electronic Common Technical Document (eCTD) (/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd) specifications to submit electronically.
  - Indicate in the descriptive portion that the ICSRs have been submitted electronically as XML files to the ESG or via the SRP.
- **Non-expedited ICSRs:**
  - Must be submitted as described above for electronic submission of ICSRs and on or before the PSR due date. Please do NOT re-submit any ICSRs that were previously submitted.

Resources For You

- FAQ: CDER and CBER-Regulated Combination Products (/media/131508/download?attachment)
- FAQ: FAERS Submissions (/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/faers-submissions-frequently-asked-questions)
- Public Meeting: Electronic Submission of Adverse Event Reports to FDA Adverse Event Reporting System (FAERS) using International Council for Harmonisation (ICH) E2B(R3) Standards (/drugs/news-events-human-drugs/electronic-submission-adverse-event-reports-fda-adverse-event-reporting-system-faers-using)
- FAQs: Safety Reporting Portal (/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/faqs-safety-reporting-portal)
- FDA issues final rule on postmarketing safety report in electronic format (http://wayback.archive-it.org/7993/20170111002213/http:/www.fda.gov/Drugs/DrugSafety/ucm400526.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

EXHIBIT 39

FDA, Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments (Apr. 2021)

Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments

Technical Specifications Document

Associated Guidance Documents and Conformance Guide:

Draft Guidance for Industry: Providing Submissions in Electronic Format – Postmarketing Safety Reports (June 2014)

Guidance for Industry and FDA Staff: Postmarketing Safety Reporting for Combination Products (July 2019)

Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format: IND Safety Reports (October 2019)

Electronic Submissions of IND Safety Reports Technical Conformance Guide (October 2019)

For questions regarding this technical specifications document, contact the Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, Food and Drug Administration, at FAERSESUB@fda.hhs.gov; or Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, at CBERICSRSubmissions@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

April 2021

Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments

Revision History Table

Date	Version	Summary of Changes
2008-06-11	1.0	Initial Version
2008-08-06	1.1	Added Filename format information
2008-10-10	1.2	Updated UTF-8 to ISO-8859-1 encoding; indicated simultaneous acceptance of ICSR and ICSR attachments; provided another acceptable file extension for SGML files; and clarified use of abbreviations (NDA, ANDA, and STN)
2008-10-22	1.3	Provided clarification in Section II; updated footnote 3; and added new paragraph to Section V.C.
2013-07-05	1.4	Updated AERS to FAERS migration changes, removed references to SGML file formatting, incorporated updates from CBER
2018-02-06	1.5	Added a new section to highlight data fields for reporting ICSRs on Combination Products
2019-09-30	1.6	Added two new sections to provide regional data elements for electronic submissions of certain IND safety reports (section I) and IND-exempt Bioavailability (BA)/Bioequivalence (BE) studies (section J). Added an appendix (II) highlighting various case scenarios for electronic submissions of IND safety reports to FAERS.

2020-02-11	1.7	Added a new value to the data element B.4.k.1 for drug characterization to accommodate a similar device. Updated the data element B.4.k.18.2 to specify values. Updated the data element B.4.k.18.3 to use default value.
2020-12-18	1.8	Added a new regional data element A.1.FDA.16 (FDA Safety Report Type) in Table 2 Detailed Description of Administrative Tags Added section Submission Rules Added a new value to the data element B.4.k.1 and B.4.k.19 in section J. IND-exempt BA/BE Studies
2021-03-26	1.9	Updated section XML Header to include DTD 3.0 for premarketing reporting Updated the reference description to data element A.1.FDA.16 in Table 2 Detailed Description of Administrative Tags Updated section ICSR Message Header Information to include information in premarketing reporting Updated section AS2 Headers and Routing IDs for Premarketing Safety Report Submissions Updated section Submission Rules

Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments

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Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments

This document provides current specifications for submitting individual case safety reports (ICSRs) and ICSR attachments in electronic form. The specifications apply to electronic submission of ICSRs for drug and biological products studied under an investigational new drug application (IND) (including bioequivalence studies conducted under IND), ICSRs from IND-exempt bioavailability (BA)/bioequivalence (BE) studies, and ICSRs for marketed drug and biological products and combination products to the FDA Adverse Event Reporting System (FAERS). The specifications do not apply to the following marketed biological products: prophylactic vaccines, whole blood or components of whole blood, human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated by FDA.

This document discusses the technical specifications for electronic submission of ICSRs and ICSR attachments through the FDA Electronic Submissions Gateway (ESG).[1] ICSRs (and any ICSR attachments) are to be prepared in accordance with the International Council for Harmonisation (ICH) E2B(R2) data elements in extensible markup language (XML) file format for compatibility with the FAERS database. ICSRs for marketed products should not be submitted to the electronic Common Technical Document (eCTD).[2]

If you have not previously submitted an ICSR in electronic format to FAERS, you should contact the FAERS electronic submission coordinator at faersesub@fda.hhs.gov and they will assist you with submission of a test file.

I. ELECTRONIC SUBMISSIONS OF ICSRS AND ICSR ATTACHMENTS

Each initial ICSR or follow-up ICSR may consist of structured information and non-structured information, such as ICSR attachments.

For the FDA to process, review, and archive the ICSRs, prepare your ICSRs for electronic submission by following these steps:

- Provide a unique filename for the submission; see section II of this document.
- Add a file header and file extension; see section IV of this document.
- Populate the elements of the ICSR file; see section V of this document.

[1] For information on providing submissions using the ESG, refer to https://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm.

[2] See FAERS Electronic Submissions at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm115894.htm.

- If applicable, add ICSR attachments to ICSRs; see section VI of this document.

II. SUBMISSION FILE NAME

Each electronic submission of ICSRs or attachments to ICSRs must have a unique filename (e.g., your named file + date and time stamp down to the second: filenameYYYYMMDDHHMMSS). You may choose your own format to maintain uniqueness.

III. ICSR ACKNOWLEDGEMENTS

A. ESG Acknowledgement

After submitting an ICSR or ICSR attachment, you should receive an ESG message delivery notice (MDN) notifying the sender of the receipt of their submission, but not acknowledging the acceptance of the submission. If the MDN is not received within 2 hours, go to the ESG System Status web page. If the ESG web page is non-operational, go to the ESG Home Page for further information.

B. FAERS Acknowledgment

The MDN is then followed by a FAERS acknowledgment within 2 hours of the ESG acknowledgement. The FAERS acknowledgement notifies the sender whether their submission has been processed. If you do not receive the FAERS acknowledgement, resubmit the ICSRs without changing the filename.

If you receive a report acknowledgement code 02, indicating that your submission did not process due to file error/s that are specified in the acknowledgment, then proceed as follows:

- For submission with a single ICSR, resubmit the corrected ICSR with a new unique filename.
- For a submission consisting of multiple ICSRs, if one or more ICSRs in the submission failed to process, separate those ICSRs from the processed ICSRs, correct them and resubmit only the corrected ICSRs as a new submission with a unique filename. For example, if there were 50 ICSRs in an original submission and 15 of them failed to process, then only those 15 ICSRs must be separated, corrected appropriately, and resubmitted with a new unique filename. The resubmission should not contain any of the previously processed ICSRs.

IV. ELECTRONIC TRANSPORT FORMAT: XML FILES

FDA accepts the data elements defined in the "Guidance for Industry E2BM Data Elements for

Transmission of Individual Case Safety Reports (April 2002)."[3] The ICH E2B(R2) guidance provides additional information and clarification of the previously issued guidances.[4]

The electronic transport format also known as the Document Type Definition (DTD) for XML files is described in the associated document "XML Formatted DTD" (DTD Version 2.1, DTD Version 2.2 and DTD Version 3.0) (see links to the documents below in section C).

A. AS2 Headers and Routing IDs for Postmarketing Safety Report Submissions

For postmarketing safety report submissions, the sponsors should include the unique AS2 headers or routing IDs for safety reports and attachments in one of the two ways listed below.

- AS2 Headers
  - Destination: "CDER"
  - XML files: AERS
  - PDF's: AERS_ATTACHMENTS

or

- Routing IDs
  - XML files: FDA_AERS
  - PDF's: FDA_AERS_ATTACHMENTS

B. AS2 Headers and Routing IDs for Premarketing[5] Safety Report Submissions

For premarketing safety report submissions, the sponsors should include the unique AS2 headers or routing IDs for premarketing safety reports and attachments, as listed below, to differentiate these reports between CDER and CBER, and from postmarketing ICSRs.

[3] For information on Guidance for Industry on E2BM Data Elements for Transmission of Individual Case Safety Reports, please refer to the following:

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073092.pdf.

[4] See the guidance for industry entitled *E2B Data Elements for Transmission of Individual Case Safety Reports* (January 1998) (E2B). FDA currently supports use of E2B data elements in addition to the E2BM data elements. However, it is preferred that ICSRs be submitted with E2BM data elements to allow for the most efficient processing of the submissions. For those who wish to use E2B data elements and the corresponding electronic transport format (ICH M2 Electronic Transmission of Individual Case Safety Reports Message Specification Final Version 2.3 Document Revision February 1, 2001 (ICH ICSR DTD Version 2.1)), please refer to documentation provided at https://www.fda.gov/downloads/drugs/ucm149932.pdf

[5] The term premarketing safety report refers to IND safety reports and IND-exempt BA/BE studies safety reports.

1. Submitting premarketing safety reports for CDER IND and IND-Exempt BA/BE

- AS2 Headers
  - Destination: "CDER"
  - XML files: AERS_PREMKT_CDER
  - PDF's: AERS_ATTACHMENTS_PREMKT_CDER

or

- Routing IDs
  - XML files: FDA_AERS_PREMKT_CDER
  - PDF's: FDA_AERS_ATTACHMENTS_PREMKT_CDER

2. Submitting premarketing safety reports for CBER IND

- AS2 Headers
  - Destination: "CBER"
  - XML files: AERS_PREMKT_CBER
  - PDF's: AERS_ATTACHMENTS_PREMKT_CBER

or

- Routing IDs
  - XML files: FDA_AERS_PREMKT_CBER
  - PDF's: FDA_AERS_ATTACHMENTS_PREMKT_CBER

C. XML Header

The addition of an XML header enables FDA to process ICSRs in an XML format successfully. FDA supports only the ISO-8859-1 character set for encoding the submissions.

1. For submissions of postmarketing safety reports for drug and biological products, add the following XML header to the ICSR file:

<?xml version="1.0" encoding="ISO-8859-1"?>

<!DOCTYPE ichicsr SYSTEM "https://www.accessdata.fda.gov/xml/icsr-xml-v2.1.dtd">

2. For submissions of postmarketing safety reports for combination products, add the following XML header to the ICSR file:

<?xml version="1.0" encoding="ISO-8859-1"?>

<!DOCTYPE ichicsr SYSTEM "https://www.accessdata.fda.gov/xml/icsr-xml-

v2.2.dtd">

3. For submissions of premarketing safety reports, add the following XML header to the ICSR file:

<?xml version="1.0" encoding="ISO-8859-1"?>

<!DOCTYPE ichicsr SYSTEM "https://www.accessdata.fda.gov/xml/icsr-xml-v3.0.dtd">

D. ICSR Message Header Information

1. For submissions of postmarketing drug and biological product safety reports, use the value "2.1" for the DTD Descriptor <messageformatversion>:

<messageformatversion>2.1</messageformatversion>

2. For submissions of postmarketing combination product safety reports, use the value "2.2" for the DTD Descriptor <messageformatversion>:

<messageformatversion>2.2</messageformatversion>

3. For submissions of premarketing safety reports, use the value "3.0" for the DTD Descriptor <messageformatversion>:

<messageformatversion>3.0</messageformatversion>

E. ICSR File Extension

Use "xml" as the file extension for ICSRs in XML format. The name of the file should be 200 characters or less, excluding the three-digit extension. FDA does not support file names with multiple periods "." or the use of any special or foreign characters except underscore "_" and dash "-".

V. DATA ELEMENTS FOR ELECTRONIC SUBMISSIONS

A. Minimum Data Elements Requirements

For a submission to be successfully processed, submit an ICSR with the minimum data elements for reporting that are appropriate for the product type. If a sponsor submits an ICSR without the minimum data elements, they will receive a FAERS acknowledgement code 02 stating that the submission was not processed (see section III.B above). The minimum data elements for reporting are provided in Table 1 and the bullets that follow list the data elements to include in an ICSR by product type.

Table 1. Minimum Data Elements

Element	Data
B.1	Identifiable Patient
A.2	Identifiable Reporter
B.2	Reaction or Event
B.4	Suspect Drug Product

- Adverse event reports submitted for unapproved prescription drug products, unapproved nonprescription drug products and products approved for marketing under an abbreviated new drug application (ANDA), biologics license application (BLA), or new drug application (NDA), including combination products should have, at a minimum, the four data elements listed in Table 1.

- Adverse event reports for compounded drugs submitted by registered outsourcing facilities should have at a minimum, a suspect product and an adverse event.

- IND safety reports should include, at a minimum, the four data elements listed in Table 1 and the IND number under which the clinical trial where the event occurred is conducted.

- Serious adverse event reports from IND-exempt BA/BE studies should include, at a minimum, the four data elements listed in Table 1 and the pre-assigned ANDA number (hereafter referred as, Pre-ANDA number).

B. Administrative and Identification Elements

For FDA to successfully process your electronic ICSR submissions, populate the administrative and identification elements as indicated in Table 2.

Table 2. Detailed Description of Administrative Tags*

Element	DTD Descriptor 2.1	Length	Element Values for DTD 2.1
A.1.9	<fulfillexpeditecriteria>	1N	1= Yes (15-Day expedited) 2= No (non-expedited) 4= 5-Day 5= 30-Day 6= 7-Day expedited
A.1.0.1	<safetyreportid>	100AN	Sender's (Case) Safety Report Unique Identifier†
A.1.10.1	<authoritynumb>	100AN	Regulatory authority's case report number
A.1.10.2	<companynumb>	100AN	Other sender's case report number
A.3.1.2	<senderorganization>	60AN	Sender identifier
A.2.3.2^	<sponsorstudynumb>	35AN	IND or Pre-ANDA number under which the clinical trial where the event occurred is conducted
A.1.FDA.16††	<fdasafetyreporttype>	1N	1=IND Safety Report 2=IND-Exempt BA/BE Safety Report 3=Postmarketing Safety Report

* Include either <companynumb> or <authoritynumb> values. FDA cannot process the ICSR without one of these element values.

† The Sender's Safety Report Unique Identifier is comparable to the Manufacturer Report Number (also referred to as the Manufacturer Control Number (MCN)) provided on paper in FDA Form 3500A. This number is the company's unique case identification number, which is used for the life of the case.

^ For IND and IND-exempt BA/BE study safety reports only. An IND-exempt BA/BE study refers to a BA/BE study not conducted under IND.

†† The FDA Safety Report Type data element distinguishes premarketing (IND and IND-Exempt BA/BE) safety reports from postmarketing safety reports and is used to determine which reports are posted publicly. The FDA Safety Report Type data element is optional when using DTD 2.1 and 2.2 for postmarketing safety report submission but is mandatory when using DTD 3.0 for premarketing safety report submission.

C. Authorization/ Application Number Format

In the section designated for drug and biological products information, use the following format for the "Authorization/ Application Number" element (B.4.k.4.1) <drugauthorizationnumb> as indicated in Table 3 and described below.

- For approved drug and biological products marketed under an approved application, include the acronym "NDA" or "ANDA," followed by a space and then the number for the application (e.g., NDA 012345, ANDA 012345). For prescription drug products marketed without an approved application (Rx No Application), use "000000." For a nonprescription drug product marketed without an approved application (Non-Rx No

Application), use "999999." For adverse event reports for compounded drug products submitted by registered outsourcing facilities, use "COMP99."

- For marketed biological products, include the appropriate acronym "BLA," "STN," or "PLA" followed by a space and the primary six-digit number (e.g., STN 123456).

Table 3. Detailed Description of Application Number Formats

Type of Application	Recommended Format
NDA/ ANDA	NDA, ANDA 012345
STN/ BLA/ PLA	STN or BLA or PLA 123456
Rx No Application	000000
Non-Rx No Application	999999
Compounded Products	COMP99

D. Unique Case Identification Numbers for Initial and Follow-Up ICSRs

For the follow-up ICSR safety reports to be correctly linked to your initial ICSR report, follow these steps:

- Use the same <safetyreportid> for the E2BM elements in section A.1.0.1 for the initial ICSR and any of its follow-up ICSRs; this allows the follow-up report to be linked to the initial report in the FAERS database.

- If the initial ICSR was submitted on paper but its follow-up ICSR is submitted electronically, include the Manufacturer Control Number (MCN) listed in Box G9 of the FDA paper Form 3500A from the initial report in both A.1.0.1 <safetyreportid> and in A.1.10.2 <companynumb> field in the follow-up electronic submission.

- Always use the <safetyreportid> that was assigned to the initial ICSR when submitting follow-up reports. If you need to change the <safetyreportid> internally, note the internally reassigned <safetyreportid> in the narrative section of the follow-up report (i.e., element B.5.1) (e.g., "This ICSR has been reassigned to the Company ID number COA12345"). Do not use the internally reassigned <safetyreportid> for any follow-up reports.

- In the event that an incorrect <safetyreportid> has been used in a follow-up report, contact the FAERS electronic submission coordinator at faersesub@fda.hhs.gov so that the follow-up ICSR can be matched to the initial ICSR.

E. MedDRA Specific Elements

Use the ICH Medical Dictionary for Regulatory Activities (MedDRA) to code medical

terminology.[6] When possible, use the Lowest Level Term (LLT), and record the LLT as the MedDRA numeric code rather than the LLT name (e.g., the LLT name is Rash; the MedDRA numeric code for LLT Rash is 10378444).

1. Reaction/Event

a) Reaction/Event as reported by the primary source field

Record the original reporter's words verbatim and/or use short phrases to describe the reaction/event in element (B.2.i.0).

b) Reaction/Event MedDRA Term LLT numeric code or text field

Record the MedDRA LLT that most closely corresponds to the term reported by the original reporter in element (B.2.i.1).

c) Reaction/Event MedDRA Preferred Term (PT) numeric code or text field

Record the MedDRA PT that most closely corresponds to the term reported by the original reporter in element (B.2.i.2).

2. Other E2B Elements

For the E2B elements listed in Table 4, use either MedDRA text or, preferably, the corresponding numeric code.

Table 4. Additional E2B Elements for Preferred MedDRA Coding

Element	DTD Descriptor 2.1	Length
B.1.7.1a.2	<patientepisodename>	250 AN
B.1.8f.2	<patientdrugindication>	250 AN
B.1.8g.2	<patientdrugreaction>	250 AN
B.1.9.2b	<patientdeathreport>	250 AN
B.1.9.4b	<patientdetermineautopsy>	250 AN
B.1.10.7.1a.2	<parentmedicalepisodename>	250 AN
B.1.10.8f.2	<parentdrugindication>	250 AN
B.1.10.8g.2	<parentdrugreaction>	250 AN
B.3.1c	<testname>	100 AN
B.4.k.11b	<drugindication>	250 AN
B.4.k.17.2b	<drugrecuraction>	250 AN
B.4.k.18.1b	<drugreactionasses>	250 AN
B.5.3b	<senderdiagnosis>	250 AN

[6] Companies can license MedDRA from an international maintenance and support services organization (MSSO) (toll free number 877-258-8280; Direct 571-313-2574; fax 571-313-2345; e-mail MSSOhelp@mssotools.com).

F. Drug Description and Case Narrative Elements

To ensure the successful processing of your electronic ICSR submission, applicants are advised to populate the drug description and narrative elements as indicated in Table 5.

Table 5. Detailed Description of Drug(s) and Narrative Elements*†

Element	DTD Descriptor 2.1	Length	Element Values for DTD 2.1
B.4.k.1	<drugcharacterization>	1N	1=Suspect 2=Concomitant 3=Interacting 4=Drug not administered
B.4.k.2.1	<medicinalproduct>	70AN	Proprietary Medicinal Product Name
B.4.k.2.2	<activesubstancename>	100AN	Drug Substance Name
B.5.1	<narrativeincludeclinical>	20000AN	Case Narrative

*Include <medicinalproduct> and/or <activesubstancename>. FDA cannot process the ICSR without at least one of these elements.
†Appendix I lists various examples of correct drug element formats.

1. *Recording Multiple Drugs*

If you are submitting safety reports for products containing multiple drugs, you should follow these steps:

- List the proprietary drug product name in element (B.4.k.2.1) and/or list the drug substance name in element (B.4.k.2.2).
- List the characterization of each reported drug's role, such as suspect, concomitant, interacting, drug not administered, or similar device in element (B.4.k.1).

2. *Medicinal Product Name and Active Drug Substance Name*

FDA validates medicinal product names to the available Structured Product Labeling (SPL)[7], the submitted label (as ICSR attachment), and the Substance Registration System (SRS). These are further described below:

- When the product has an SPL, use the same naming convention as it appears in the SPL when submitting the ICSR.

[7] The SPL is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product and facility information. See https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm.

- When submitting a product label as an attachment to an ICSR, use the name as it appears on the submitted product label.

- If no medicinal product is named and only the active substance is named, use the name of the active substance as it appears in the SRS.[8]

3. Case Narrative

a) Initial ICSR

Record all case narrative information including clinical course, therapeutic measures, outcome, and all additional relevant information in element (B.5.1). If the information exceeds the field length, consider describing the information using fewer words. Although the use of only the most widely used medical abbreviations is permissible if necessary, their use should be limited when possible.

b) Follow-up ICSR

Record both new information and corrections to previously submitted ICSRs in element (B.5.1).

G. Other Data Elements

1. Dosage Information Field

If dosage information cannot be captured in the structured fields in B.4.k.5, then use the element (B.4.k.6) <drugdosagetext>.

2. Pharmaceutical Form Field

Record the pharmaceutical form in element (B.4.k.7) <drugdosageform>. FDA accepts the European Medicines Agency (EMA) dosage codes or text.[9]

3. Route of Administration Field

Code the route of administration in element (B.4.k.8) <drugadministrationroute> as described in the ICH E2B(R2) guidance.

4. Receiver Field (A.3.2)

Complete the receiver using the code or text listed in Table 6.

[8] https://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII/default.htm.

[9] For a complete list of EMA dosage form codes and text, please refer to https://www.ema.europa.eu/documents/other/list-pharmaceutical-dosage-forms_en.xls

Table 6. Receiver Information

Element	DTD Descriptor 2.1	Code or Text
A.3.2.1	<receivertype>	2
A.3.2.2a	<receiverorganization>	FDA
A.3.2.2b	<receiverdepartment>	Office of Surveillance and Epidemiology
A.3.2.2d	<receivergivename>	FAERS
A.3.2.3a	<receiverstreetaddress>	10903 New Hampshire Avenue
A.3.2.3b	<receivercity>	Silver Spring
A.3.2.3c	<receiverstate>	MD
A.3.2.3d	<receiverpostcode>	20993
A.3.2.3e	<receivercountrycode>	US
A.3.2.3l	<receiveremailaddress>	faersesub@fda.hhs.gov

5. Message Receiver Field (M.1.6)

The following two message receiver identifiers are used by FDA to distinguish between test and production submissions:

- Test ICSRs: <messagereceiveridentifier>ZZFDATST</messagereceiveridentifier>
- Production ICSRs: <messagereceiveridentifier>ZZFDA</messagereceiveridentifier>

H. Data Elements for Electronic Submissions of Safety Reports for Postmarketing Combination Products

To ensure the successful processing of your electronic ICSR submission for a marketed drug- or therapeutic biologic led- combination product (e.g., a combination product containing a drug/biologic and device and marketed under an NDA or a BLA), you should populate the data elements indicated in Table 7.

Note: Some of the DTD descriptors listed in Table 7 are under existing E2B(R2) header elements, and some DTD descriptors are under new data elements. Those data element numbers that are new, have the word "FDA" incorporated into the number and are U.S.-specific regional elements related to reporting on combination products.

Table 7. Combination Product Data Elements

Data Element	DTD Descriptor 2.2	Title	Description	Length	Element Values for DTD 2.2	Notes
M.1.2	<messageformatversion>	Message Format Version	Version number of Message Format	3AN	2.2	Use value 2.2 if using icsr-xml-v2.2.dtd Use value 2.1 if using icsr-xml-v2.1.dtd
A.1	<safetyreport>	Header/ Entity	Identification of the case safety report			
A.1.9	<fulfillexpeditecriteria>	Does this case fulfill the local criteria for an expedited report		1N	1=Yes 2=No 4=5-Day 5=30-Day	Element values= 1 for 15-Day Expedited* and 2 for periodic non-expedited† Element value= 4 for remedial action to prevent an unreasonable risk of substantial harm to the public health Element value= 5 for malfunction with no associated adverse event Do not use element value of 3.
A.1.FDA.15	<combinationproductreport>	Combination Product Report Flag	Combination Product Report Flag	1N	1=Yes 2=No	
A.2	<primarysource>	Primary source(s) of information	Header/ Entity		Area below should be a repeatable block	

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Data Element	DTD Descriptor 2.2	Title	Description	Length	Element Values for DTD 2.2	Notes
A.2.1		Primary source(s)	Header			
A.2.1.3.FDA.4	<reporteremailaddress>	Reporter's Email Address		100AN		
B.1.1	<patientinitial>	Patient	Patient Identifier	10AN		If a single report is reported for a malfunction with no adverse event, the element value should be "NONE." If there are multiple malfunction reports with no adverse event, then the element value should be "SUMMARY."
B.4	<drug>	Drug(s) Information	Header/ Entity		Area below should be a repeatable block	
B.4.k.1	<drugcharacterization>	Characterization of drug role		1N	1=Suspect 2=Concomitant 3=Interacting 5=Similar Device	If the product in the report is about a similar device, the element value should be 5=Similar Device.
B.4.k.2		Drug Identification	Header			
B.4.k.2.4.FDA.1a	<expirationdateformat>	Expiration date format	Product Expiration date	3N	102=CCYYMMDD 610=CCYYMM 602=CCYY	
B.4.k.2.4.FDA.1b	<expirationdate>	Expiration date	Product Expiration date	8N		

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Data Element	DTD Descriptor 2.2	Title	Description	Length	Element Values for DTD 2.2	Notes
B.4.k.2.FDA.5	<productavailableforevaluation>	Product available for evaluation	Indicate whether product is available for evaluation	1N	1=Yes 2=No 3=Return	
B.4.k.2.6.FDA.1a	<productreturndateformat>	Product return date format	Date Format	3N	102=CCYYMMDD 610=CCYYMM 602=CCYY	
B.4.k.2.6.FDA.1b	<productreturndate>	Product return date	Date when Product was returned	8N		
B.4.k.20.FDA.1	<brandname>	Brand Name	The trade or proprietary name of the device constituent part of the suspect combination product as used in product labeling or in the catalog	80AN		At least one of the 3 must be reported <brandname> or <commondevicename> or <productcode> for the device constituent part
B.4.k.20.FDA.2	<commondevicename>	Common Device Name	Generic or common name of the device constituent part of the suspect combination product or a generally descriptive name	80AN		At least one of the 3 must be reported <brandname> or <commondevicename> or <productcode> for device constituent part
B.4.k.20.FDA.3	<productcode>	Product Code	Product code	3AN	http://www.acce	At least one of the 3 must be

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Data Element	DTD Descriptor 2.2	Title	Description	Length	Element Values for DTD 2.2	Notes
			assigned to the device constituent part based upon the medical device product classification		ssdata.fda.gov/premarket/ftparea/foiclass.zip	reported <brandname> or <commondevicename> or <productcode> for device constituent part
B.4.k.20.FDA.4	<manufacturer>	Manufacturer	Header/ Entity			
B.4.k.20.FDA.4a	<manufacturername>	Device Manufacturer Name	Manufacturer name of the device constituent part of the suspect combination product	100AN		
B.4.k.20.FDA.4b	<manufactureraddress>	Manufacturer Address	Manufacturer address of the device constituent part of the suspect combination product	100AN		
B.4.k.20.FDA.4c	<manufacturercity>	Manufacturer City	Manufacturer city of the device constituent part of the suspect combination product	35AN		
B.4.k.20.FDA.4d	<manufacturerstate>	Manufacturer State	Manufacturer state of the device	40AN		

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Data Element	DTD Descriptor 2.2	Title	Description	Length	Element Values for DTD 2.2	Notes
			constituent part of the suspect combination product			
B.4.k.20.FDA.4e	<manufacturercountry>	Manufacturer Country	Manufacturer country of the device constituent part of the suspect combination product	2AN	ISO3166	
B.4.k.20.FDA.5	<modelnumber>	Model Number	Model number of the device constituent part	30AN		
B.4.k.20.FDA.6	<catalognumber>	Catalog Number	Catalog number of the device constituent part	30AN		
B.4.k.20.FDA.7	<serialnumber>	Serial Number	Serial number of the device constituent part	30AN		
B.4.k.20.FDA.8	<udinumber>	Unique Identifier UDI#	Unique identifier of the device constituent part	50AN		
B.4.k.20.FDA.9a	<dateimplantedformat>	Device Implant Date Format	Date format of device implant in the patient	3N	102=CCYYMMDD 610=CCYYMM 602=CCYY	For medical devices that are implanted in the patient, provide the implant date or best estimate. If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable

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Data Element	DTD Descriptor 2.2	Title	Description	Length	Element Values for DTD 2.2	Notes
B.4.k.20.FDA.9b	<dateimplanted>	Device Implant Date	Date of device implant in the patient	8N		For medical devices that are implanted in the patient, provide the implant date or best estimate. If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable
B.4.k.20.FDA.10a	<dateexplantedformat>	Device Explant Date Format	Date format of device explant from the patient	3N	102=CCYYMMDD 610=CCYYMM 602=CCYY	If an implanted device was removed from the patient, provide the explant date or best estimate. If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable
B.4.k.20.FDA.10b	<dateexplanted>	Device Explant Date	Date of device explant from the patient	8N		If an implanted device was removed from the patient, provide the explant date or best estimate. If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable
B.4.k.20.FDA.11a	<deviceage>	Approximate age of device/ product	Age of device constituent part	5N		
B.4.k.20.FDA.11b	<deviceageunit>	Approximate age unit of device/	Age unit of device constituent part	3N	800=Decade 801=Year 802=Month	

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Data Element	DTD Descriptor 2.2	Title	Description	Length	Element Values for DTD 2.2	Notes
		product			803=Week 804=Day 805=Hour	
B.4.k.20.FDA.12	<labeledsingleusedevice>	Single Use Device	Indicate whether the device constituent part was labeled for single use or not	1N	1=Yes 2=No	
B.4.k.20.FDA.13a	<devicemanufacturedateformat>	Device Manufacture Date Format	Device Manufacture Date format	3N	102=CCYYMMDD 610=CCYYMM 602=CCYY	
B.4.k.20.FDA.13b	<devicemanufacturedate>	Device Manufacture Date	Device Manufacture Date	8N		
B.4.k.20.FDA.14		Remedial action initiated/ Remedial action taken for the product	Header			
B.4.k.20.FDA.14.1a	<remedialactionrecall>	Recall	Recall initiated	1N	1=Yes 2=No	
B.4.k.20.FDA.14.1b	<remedialactionrepair>	Repair	Repair initiated	1N	1=Yes 2=No	
B.4.k.20.FDA.14.1c	<remedialactionreplace>	Replace	Replace initiated	1N	1=Yes 2=No	
B.4.k.20.FDA.14.1d	<remedialactionrelabel>	Relabeling	Relabeling initiated	1N	1=Yes 2=No	
B.4.k.20.FDA.14.1	<remedialactionnotify>	Notification	Notification	1N	1=Yes	

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Data Element	DTD Descriptor 2.2	Title	Description	Length	Element Values for DTD 2.2	Notes
e			initiated		2=No	
B.4.k.20.FDA.14.1f	<remedialactioninspection>	Inspection	Inspection initiated	1N	1=Yes 2=No	
B.4.k.20.FDA.14.1g	<remedialactionpatientmonitor>	Patient monitoring	Patient monitoring	1N	1=Yes 2=No	
B.4.k.20.FDA.14.1h	<remedialactionmodifyadjust>	Modification/ Adjustment	Modification/ Adjustment initiated	1N	1=Yes 2=No	
B.4.k.20.FDA.14.1i	<remedialactionother>	Other	Other Remedial Action initiated	75AN		
B.4.k.20.FDA.15	<deviceusage>	Device Usage	Indicate the use of the device constituent part of the suspect combination product	1N	1=Initial Use of Device 2=Reuse 3=Unknown	
B.4.k.20.FDA.16	<devicelotnumber>	Device Lot Number	Lot number of the device constituent part of the suspect combination product	35AN		
B.4.k.20.FDA.17	<malfunction>	Malfunction	Malfunction of product	1N	1=Yes 2=No	
B.4.k.20.FDA.18		Follow-up type	Header			
B.4.k.20.FDA.18.1a	<followupcorrection>	Correction	Correction	1N	1=Yes 2=No	
B.4.k.20.FDA.18.1b	<followupadditionalinfo>	Additional information	Additional information	1N	1=Yes 2=No	
B.4.k.20.FDA.18.1	<followupresponsetoFDA>	Response to	Response to FDA	1N	1=Yes	

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Data Element	DTD Descriptor 2.2	Title	Description	Length	Element Values for DTD 2.2	Notes
c		FDA request	request		2=No	
B.4.k.20.FDA.18.1d	<followupdeviceevaluation>	Device Evaluation	Device Evaluation	1N	1=Yes 2=No	
B.4.k.20.FDA.19	<deviceproblemandevaluation>	Device Problem and evaluation codes	Header/ Entity		Area Below Should be a Repeatable Block	
B.4.k.20.FDA.19.1a	<evaluationtype>	Evaluation Type	Type of problem and/or the evaluation	2N	01=Device Problem 02=Method 03=Result 04=Conclusion	
B.4.k.20.FDA.19.1b	<evaluationvalue>	Evaluation Value	The FDA code value based on the respective evaluation type	6N		The value depends on the respective <evaluationtype> If <evaluationtype> = 01 --> https://www.fda.gov/media/146825/download If <evaluationtype> = 02 --> https://www.fda.gov/media/146827/download If <evaluationtype> = 03 --> https://www.fda.gov/media/146828/download If <evaluationtype> = 04 --> https://www.fda.gov/media/146829/download
B.4.k.20.FDA.20	<operatorofdevice>	Operator of	Operator of the	100AN		Use the value “Health

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Data Element	DTD Descriptor 2.2	Title	Description	Length	Element Values for DTD 2.2	Notes
		the Device	Device			Professional" or "Lay User/Patient." If none applicable, then specify the "Other" value

* 21 CFR 314.80(c)(1) and 600.80(c)(1) use the term "15-day Alert reports." In the combination product PMSR final rule (21 CFR 4.101), these reports are defined as "Fifteen-day reports."

† Periodic non-expedited ICSRs are the reports required under 21 CFR 314.80(c)(2)(ii)(B) and 21 CFR 600.80(c)(2)(ii)(B) for serious, expected and nonserious adverse drug experiences.

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I. Data Elements for Electronic Submissions of IND Safety Reports

To ensure the successful processing of your electronic IND ICSR submission, you should populate the following data elements as described in Table 8.

Table 8. Investigational New Drug Clinical Data Elements

Data Element	DTD Descriptor 3.0	Title	Description	Field Length	Element Values for DTD 3.0	Notes
A.1.4	<reporttype>	Type of Report		1N	1=Spontaneous 2=Report from Study 3=Other 4=Not Available to Sender (unknown)	Element value= 2 for Report from Study
A.1.9	<fulfillexpeditecriteria>	Does this case fulfill the local criteria for an expedited report?		1N	1=Yes 2=No 4=5-Day 5=30-Day 6=7-Day	Element value=1 for 15-Day Expedited Element value= 6 for 7-Day Expedited
A.1.12	<linkreportnumb>	Identification Number of the report which is linked to this report		100AN		Used to link all individual cases (safetyreportid) that make up an IND Safety Report submitted as a result of an Aggregate Analysis as per 312.32(c)(1)(i)(C) or for several events

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Data Element	DTD Descriptor 3.0	Title	Description	Field Length	Element Values for DTD 3.0	Notes
						submitted as per (312.32(c)(1)(i)(B)) when a Narrative Summary Report is provided, this field should be populated in the IND Safety Report that contains the Narrative Summary Report.
A.2.3.1	<studyname>	Study Name		100AN	Study ID_$Abbreviated Trial Name	The Study ID should be the same value used in the study tagging file format of the eCTD submission.
A.2.3.2	<sponsorstudynumb>	Sponsor Study Number		35AN	IND number under which the clinical trial where the event occurred is conducted Use the "Parent" IND number* for reports submitted from an Aggregate Analysis as per (312.32(c)(1)(i)(C)) or for several events	Populate this field with the Primary IND in the first block and repeat block A.2 with elements A.2.3.2 and A.2.3.3.as noted below with element value= 5 for sponsor's other INDs evaluating suspect product (where applicable) Include the acronym "IND" followed by a space and then the IND

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Data Element	DTD Descriptor 3.0	Title	Description	Field Length	Element Values for DTD 3.0	Notes
					submitted as per (312.32(c)(1)(i)(B)), from trials conducted under more than one IND	number for the application (e.g. IND 123456) See Appendix II (Case Scenarios) for additional information on how to submit reports from sponsor's other INDs (Cross-reporting).
A.2.3.3	<observestudytype>	Study type in which the Reaction(s)/ Event(s) were observed		1N	1= Clinical Trials 2= Individual Patient Use (e.g., 'Compassionate Use' or 'Named Patient Basis') 3= Other Studies (e.g., Pharmacoepidemiology, Pharmacoeconomics, Intensive Monitoring) 4= Report from	Required if element value for A.1.4 is 2=Report from Study Repeat this field as needed with element value= 5 for each Cross-reported IND. The first block of this element in the report must not be 5. If element value 4 is chosen, then A.1.9= 1. See Appendix II (Case

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Data Element	DTD Descriptor 3.0	Title	Description	Field Length	Element Values for DTD 3.0	Notes
					Aggregate Analysis as per 312.32(c)(1)(i)(C) or for several events submitted as per 312.32(c)(1)(i)(B) if a Narrative Summary Report is provided 5= Cross-reported IND Safety Report	Scenarios) for additional information on how to submit reports from an Aggregate Analysis.
B.1.1	<patientinitial>	Patient Identifier		10AN		For a report from an Aggregate Analysis as per 312.32(c)(1)(i)(C) or for several events submitted as per 312.32(c)(1)(i)(B) if a Narrative Summary Report is provided, the element value should be "AGGREGATE"
B.4.k.2.1	<medicinalproduct>	Proprietary Medicinal Product Name		70AN		For investigational drug and biological products without an established name (i.e. INN or USAN

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Data Element	DTD Descriptor 3.0	Title	Description	Field Length	Element Values for DTD 3.0	Notes
						name), prior to submitting IND safety reports to FAERS, the sponsor should submit a clinical information amendment to the IND, listing the names of the active drug substance/s and the medicinal product as they will be reported in E2B file submissions. The names should fit within the established E2B character length limits. Use company product code if no established name, for multi-ingredient products, or if name exceeds character length
B.4.k.2.2	<activesubstancename>	Active Drug Substance Names		100AN		
B.4.k.18	<drugreactionrelatedness>	Relatedness of Drug to				For IND Safety Reports, at least one suspect

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Data Element	DTD Descriptor 3.0	Title	Description	Field Length	Element Values for DTD 3.0	Notes
		Reaction/ Event				product should have relatedness of drug to reaction/ event
B.4.k.18.1a	<drugreactionassesmeddra version>	MedDRA Version for Reaction Assessed		8AN		
B.4.k.18.1b	<drugreactionasses>	Reaction Assessed		250AN		
B.4.k.18.2	<drugassessmentsource>	Source of Assessment		60AN		Use the value "Sponsor" or "Investigator". Include sponsor and investigator assessment when reporting both in separate blocks
B.4.k.18.3	<drugassessmentmethod>	Method of Assessment		35AN		Use the value "FDA".
B.4.k.18.4	<drugresult>	Result		35AN	1=Suspected 2=Not suspected	For IND Safety Reports, at least one suspect product should have relatedness of drug to reaction/ event
B.5.1	<narrativeincludeclinical>	Case Narrative Including Clinical		20,000 AN		FDA strongly encourages sponsors to construct narratives that fit within the ICH E2B character

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Data Element	DTD Descriptor 3.0	Title	Description	Field Length	Element Values for DTD 3.0	Notes
		Course, Therapeutic Measures, Outcome, and Additional Relevant Information				limit of 20,000 AN. If your narrative exceeds this limit, sponsors should include as much of the narrative as possible in this field and submit an ICSR attachment for any text that exceeds the character limit. Sponsors should not submit an ICSR attachment containing the entire narrative and leave the case narrative field empty. For reports from Aggregate Analysis as per 312.32(c)(1)(i)(C) or for several events submitted as per 312.32(c)(1)(i)(B) where PDF is attached, put "see attached Narrative Summary Report" in this field.

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Data Element	DTD Descriptor 3.0	Title	Description	Field Length	Element Values for DTD 3.0	Notes
B.5.4	<sendercomment>	Sender's Comments		2000 AN		Identification and analysis of previously submitted events (as required by 312.32(c)(1)) should be reported in this field.

* The "parent IND" is the IND under which clinical investigations were initiated in the United States. (If the drug is being evaluated in multiple INDs, this is generally the IND with the lowest number.) NOTE: This may not be the same as the first A.2.3.2 block if the drug is being evaluated under multiple INDs.

NOTE: See FAERS Webpage for case scenario examples for reporting IND safety reports (e.g., IND safety reports where the sponsor is evaluating suspect product under more than one IND, IND safety reports that are a result of an aggregate analysis, and IND safety reports with unapproved and approved drugs listed as suspect products).

J. Data Elements for Electronic Submissions of ICSRs from IND-Exempt Bioavailability (BA)/ Bioequivalence (BE) Studies

For successful processing of your electronic ICSRs submissions for a BA/BE study not conducted under an IND, you should populate the following data elements as described in Table 9.

Table 9. Data Elements for IND-Exempt BA/BE Studies

Data Element	DTD Descriptor 3.0	Title	Description	Field Length	Element Values for DTD 3.0	Notes
A.1.4	<reporttype>	Type of Report		1N	1=Spontaneous 2=Report from Study 3=Other 4=Not Available to Sender (unknown)	Element value=2 for Report from Study

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Data Element	DTD Descriptor 3.0	Title	Description	Field Length	Element Values for DTD 3.0	Notes
A.1.9	<fulfillexpeditecriteria>	Does this Case Fulfill the Local Criteria for an Expedited Report?		1N	1=Yes 2=No 4=5-Day 5=30-Day 6=7-Day	Element value=1 for 15-Day Expedited Or Element value= 6 for 7-Day Expedited
A.2.3.1	<studyname>	Study Name		100AN	Abbreviated Trial Name	
A.2.3.2	<sponsorstudynumb>	Sponsor Study Number		35AN	Pre-ANDA number for the IND-Exempt BA/BE Studies	Include the acronym "Pre-ANDA" followed by a space and then the Pre-ANDA number for the application (e.g. Pre-ANDA 123456)
A.2.3.3	<observestudytype>	Study Type in Which the Reaction(s)/ Event(s) were Observed		1N	1= Clinical Trials 2= Individual Patient Use (*e.g., 'Compassionate Use' or 'Named Patient Basis'*) 3= Other Studies (*e.g., Pharmacoepidemiology, Pharmacoeconomics, Intensive Monitoring*) 4= Report from Aggregate Analysis as per 312.32(c)(1)(i)(C) or for	Element value="1" for Clinical Trials.

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Data Element	DTD Descriptor 3.0	Title	Description	Field Length	Element Values for DTD 3.0	Notes
					Several Events Submitted as per 312.32(c)(1)(i)(B) if a Narrative Summary Report is Provided 5= Cross-Reported IND Safety Report	
B.4.k.2.1	<medicinalproduct>	Proprietary Medicinal Product Name		70AN		
B.4.k.1	<drugcharacterization>	Characterization of drug role		1N	1 = Suspect 2 = Concomitant 3 = Interacting 4 = Drug not administered	For no exposure to a study drug use 4=Drug not administered
B.4.k.2.2	<activesubstancename>	Active Drug Substance Name		100AN		
B.4.k.19	<drugadditional>	Additional Information on Drug		100AN	1 = Test drug 2 = Reference drug 3 = Placebo/Vehicle 4 = Control (negative or positive) 5 = Other drug	Specify whether the product exposed is the Test drug, Reference drug, Placebo, Vehicle, Control or Other drug

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VI. ELECTRONIC FORMAT FOR ICSR ATTACHMENTS

FDA can accept and archive ICSR attachments in PDF format. Currently approved formats for the non-structured component of an ICSR, such as ICSR attachments, are PDF versions 1.4 (current ICH standard) or 1.6 (current version in use at FDA). An ICSR attachment should be electronically submitted to FAERS after the associated ICSR has been submitted and accepted by FAERS.

A. Converting the ICSR Attachment to PDF

Applicants should provide an individual PDF file for each ICSR attachment. If you are submitting multiple ICSR attachments for a particular ICSR, include each attachment in the same PDF file and provide a PDF bookmark to distinguish each attachment. For example, if you are submitting a hospital discharge summary and an autopsy report for a single ICSR, include both in a single PDF file with a bookmark to the hospital discharge summary and a bookmark to the autopsy report.

B. Identification Information in the PDF Document Information Fields

Each PDF file contains fields to be completed by the author of the document. FAERS uses these fields to locate and retrieve the attachments to specific ICSRs. To enable FDA to match the attachment(s) to the correct ICSR, applicants should fill in the PDF document information fields with the appropriate E2B(R2) data elements for the ICSR as indicated in Table 10.

Table 10. Document Information Fields in ICSR Attachments

PDF Document Information Field	Include/ Optional	Document Information*	Length
Title	Include	A.1.0.1 <safetyreportid> Sender's (Case) Safety Report Unique Identifier	100AN
Subject	Include	A.1.10.1 <authoritynumb> Regulatory Authority's Case Report Number OR A.1.10.2 <companynumb> Other Sender's Case Report Number	100AN
Author	Optional	A.1.11.2 <duplicatenumb> Other Identification Number	100AN
Keywords	Optional	A.1.7b <receiptdate> Date of Receipt of the Most Recent Information for this ICSR	8N

* The information refers to the data elements in E2B(R2)

In addition:

- Use the ISO-8859-1 character set for the information fields.
- Do not exceed the character length indicated above for each information field.
- Avoid creating any custom fields with names identical to the information fields listed in Table 10.

If you need assistance, you can contact the FAERS electronic submission coordinator at faersesub@fda.hhs.gov.

VII. SUBMISSION RULES

The submission rules define the condition that shall result in a negative acknowledgement and not be accepted by FAERS.

Table 111. Submission Rules and Acknowledgement Status

Data Element	DTD Descriptor 2.1/2.2/3.0	Rejection Rule Description	Acknowledgement
NA	NA	ICSR submitted via AS2 Header where XML file: AERS or Routing ID where XML file: FDA_AERS and using DTD 3.0	reportacknowledgmentcode (B.1.8) = 02
NA	NA	ICSR submitted via AS2 Header where XML file: AERS_PREMKT or Routing ID where XML file: FDA_AERS_PREMKT and using DTD 2.1 or 2.2	reportacknowledgmentcode (B.1.8) = 02
A.1.FDA.16	<fdasafetyreporttype>	ICSR submitted via AS2 Header where XML file: AERS_PREMKT or Routing ID where XML file: FDA_AERS_PREMKT using DTD 3.0 and data value is empty	reportacknowledgmentcode (B.1.8) = 02
A.2.3.2	<sponsorstudynumb>	ICSR submitted via AS2 Header where XML file: AERS_PREMKT or Routing ID where XML file: FDA_AERS_PREMKT using DTD 3.0 and data value is empty or not prefixed with 'IND' or 'Pre-ANDA'	reportacknowledgmentcode (B.1.8) = 02

APPENDIX I. EXAMPLES OF CORRECT AND INCORRECT APPLICATION NUMBER AND DRUG ELEMENT FORMATS

Table 122. Examples of Application Number Formats and Drug Element Formats

Examples of Application Number Format		Comment
Correct	<drugauthorizationnumb>NDA 012345</drugauthorizationnumb>	
Correct	<drugauthorizationnumb>BLA 123456</drugauthorizationnumb>	
Correct	<drugauthorizationnumb>NDA 012345</drugauthorizationnumb> <drugauthorizationholder>COMPANYX</drugauthorizationholder>	
Incorrect	<drugauthorizationnumb>123456/**10300**</drugauthorizationnumb>	Use the appropriate prefix for the NDA/ ANDA/ STN/ BLA/ PLA. Do not include additional data after the application number
Incorrect	<drugauthorizationnumb>NDA **12-345;IND12,345** </drugauthorizationnumb>	Omit hyphens and commas in the application number. Do not populate the tag with two application numbers
Incorrect	<drugauthorizationnumb>**OTC Product**</drugauthorizationnumb>	For a non-prescription drug product marketed without an approved application (Non-Rx No Application), use “999999"
Incorrect	<drugauthorizationnumb>NDA 012345**(COMPANYX)**</drugauthorizationnumb> <drugauthorizationholder></drugauthorizationholder>	Do not populate the company name in the <drugauthorizationnumb> tag

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Examples of Application Number Format		Comment
Correct	<medicinalproduct>TYLENOL</medicinalproduct> <activesubstancename>ACETAMINOPHEN</activesubstancename>	
Correct	<medicinalproduct>MIRACLE WONDER DRUG</medicinalproduct> <activesubstancename>ACETAMINOPHEN</activesubstancename>	
Incorrect	<medicinalproduct>AMAZING DRUG **OTC®**</medicinalproduct> <activesubstancename>ACETAMINOPHEN **500 mg**</activesubstancename>	
Incorrect	<medicinalproduct>NEW DRUG **40 mcg/mL**</medicinalproduct> <activesubstancename>NEWSUBSTANCE **Inj** </activesubstancename>	
Incorrect	<medicinalproduct>**MWD**</medicinalproduct> <activesubstancename>**APAP**</activesubstancename>	Do not use abbreviations for the brand name or active substance in the <medicinalproduct> and <activesubstance> tags

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APPENDIX II. CASE SCENARIOS FOR IND SAFETY REPORTS SUBMITTED TO FAERS

The following case scenarios are intended to provide examples to sponsors on the use of ICH E2B data standard elements for submission of IND safety reports to FAERS that may differ from postmarketing safety reports.

1. For any IND safety report where the sponsor is evaluating the suspect product under more than one IND (i.e. "Cross-reporting")
    a. Repeat block A.2 for each IND
        i. Use first block A.2 to designate IND where the event occurred = "primary IND"
            1. A.2.3.2 = primary IND
            2. A.2.3.3 = data value could either be 1, 2, 3, or 4
            3. Other relevant information for the report to be populated in block A.2
        ii. Repeat block A.2 as many times as needed with only the following data elements for each IND that the sponsor holds where that suspect product is being evaluated:
            1. A.2.3.2 = IND number for each cross-reported IND

            and

            2. A.2.3.3 = 5

Table 133. Case Scenario 1. For IND Safety Reports Submitted to FAERS

Data Element	DTD Descriptor 3.0	Title	Element Values for DTD
A.2.3.2	<sponsorstudynumb>	Sponsor Study Number	IND number under which the Clinical Trial where the event occurred is conducted

Data Element	DTD Descriptor 3.0	Title	Element Values for DTD
A.2.3.3	<observestudytype>	Study Type in Which the Reaction(s) were observed	1= Clinical Trial 2= Individual Patient Use (*e.g. 'Compassionate Use' or 'Named Patient Basis'*) 3= Other Studies (*e.g. Pharmacoepidemiology, Pharmacoeconomics, Intensive Monitoring*) 4= Report from Aggregate Analysis 312.32(c)(1)(i)(C) or for several events submitted as per 312.32(c)(1)(i)(B) if a Narrative Summary report is provided. 5=Cross-reported IND safety report

2. For an IND safety report that is a result of an aggregate analysis as per 312.32(c)(1)(i)(C) or for several events submitted as per 312.32(c)(1)(i)(B) if a narrative summary report is provided:

    a. Submit one IND safety report with the IND where the event occurred in A.2.3.2 <sponsorstudynumb> (or the "parent" IND if the events occurred in multiple INDs).

    For this IND safety report, populate the data elements below in addition to other relevant information regarding the event and suspect product.

        i. Use data element = 4 in A.2.3.3<observestudytype>

        ii. Use the term "AGGREGATE" in B.1.1 <patientinitial>

    b. Section VII.A.2. of the *FDA Guidance for Industry – "Safety Reporting Requirements for INDs and BA/BE Studies" (December 2012)* discusses several submission requirements for IND safety reports that are a result of an aggregate analysis. The following two sections describe these submission elements and how they are accomplished with electronic submission to FAERS.

        1. The guidance states that IND safety reports that are a result of an aggregate analysis should contain a narrative description of the event and the results of the analysis (hereafter referred to as a "narrative

summary report"). For IND reports submitted to FAERS, attach the narrative summary report to the IND safety report as a PDF attachment (do not put the narrative summary report in the E2B narrative field).

a. These instructions also apply to several events submitted as per 312.32(c)(1)(i)(B) if a narrative summary report is provided.

2. The guidance states that all the individual cases that were analyzed in the aggregate analysis should be submitted. Use the repeatable block A.1.12 to link all the safety report numbers for the individual supportive ICSRs (i.e. the numbers in A.1.0.1 for all the individual cases that are summarized in the narrative summary report).

a. These instructions also apply to several events submitted as per 312.32(c)(1)(i)(B) if a narrative summary report is provided.

b. IND safety reports previously submitted as ICSRs to FAERS do not have to be resubmitted (place the safety report numbers for these previously submitted reports in A.1.12).

c. For IND safety reports previously submitted in eCTD format, the sponsor should list the eCTD sequence number and date of submission in the narrative summary report. (The eCTD sequence number is the unique four-digit number for each IND submission the sponsor submits in the us-regional.xml file for the eCTD submission.)

d. IND safety reports previously submitted on paper should be attached to the IND safety report as PDF attachments.

Table 144. Case Scenario 2. For IND Safety Reports Submitted to FAERS

Data Element	DTD Descriptor 3.0	Title	Element Values for DTD
A.1.12	<linkreportnumb>	Identification number of the report(s) which are linked to this report	Used to link all individual cases (safetyreportid) that make up an IND Safety Report submitted as a result of an Aggregate Analysis as per 312.32(c)(1)(i)(C) or for several events submitted as per 312.32(c)(1)(i)(B) if a narrative summary report is provided
A.2.3.2	<sponsorstudynumb>	Sponsor Study Number	IND number under which the Clinical Trial where the event occurred is conducted

Data Element	DTD Descriptor 3.0	Title	Element Values for DTD
A.2.3.3	<observestudytype>	Study Type in Which the Reaction(s) were Observed	1= Clinical Trials 2= Individual Patient Use (*e.g. 'Compassionate Use' or 'Named Patient Basis'*) 3= Other Studies (*e.g. Pharmacoepidemiology, Pharmacoeconomics, Intensive Monitoring*) 4= Report from Aggregate Analysis 312.32(c)(1)(i)(C) 5=Cross-reported IND safety report
B.1.1	<patientinitial>	Patient Identifier	For a Report from an Aggregate Analysis, the element value should be "AGGREGATE"

3. For adverse events that occur with a marketed drug being evaluated under an IND that meets both IND and post-marketing safety reporting requirements (21 CFR 312.32 and 314.80, 600.80, or 310.305), sponsors must submit two separate ICSRs:

    a. for the marketed drug for the NDA/BLA

    and

    b. for the study drug for the IND (IND number in A.2.3.2)

APPENDIX III. CASE SCENARIOS FOR SAFETY REPORTS FROM IND-EXEMPT BA/BE STUDIES TO FAERS

Table 15 illustrates the ICH E2B data elements and element values for each IND-exempt BA/BE study exposure scenario described below:

Scenario 1: Exposure to a *study drug*:

This scenario applies to all drugs specified in the study protocol. For example, if a BA/BE study protocol for a generic opiate includes administration of naltrexone to each study subject prior to administration of a test or reference drug, naltrexone is a *study drug*, although it is not the test or reference drug. Similarly, a selective 5-HT3 receptor antagonist to prevent nausea and vomiting is considered a *study drug* if the BA/BE study protocol states that the drug is administered to each study subject prior to administration of a test or reference drug.

Scenario 2: Exposure to an *other drug*:

Other drugs are drugs taken by or administered to a subject that are not part of study conduct per protocol. For example, a subject with a diagnosis of hypertension has normal blood pressure while treated with a beta blocker. The subject meets study enrollment criteria and continues to take his beta blocker during study participation. In this situation, the beta blocker is an *other drug*. Similarly, if a subject develops symptoms of heartburn during participation in a BA/BE study and is permitted, by the investigator, to use a nonprescription antacid or H2 blocker for symptomatic relief, the nonprescription drug taken by the subject is an *other drug*.

Scenario 3: No exposure to a study drug:

A serious adverse event a subject experiences after enrollment to the study, but prior to exposure to a study drug, is subject to the expedited safety reporting requirement. To report a serious adverse event with no study drug exposure, the submitter should select values as shown in the Table 15, Scenario 3.

Table 155. ICH E2B Data Element & Value Selections for IND-Exempt BA/BE Study Exposures

Drug Exposure Scenario	Data Element	Element Values
Scenario 1: Exposure to a *study drug*	B.4.k.1	Select one element value
	B.4.k.2.1	Proprietary medicinal product name
	B.4.k.2.2	Drug substance name
	B.4.k.19	Select one from the following: 1 = Test drug 2 = Reference drug 3 = Placebo/Vehicle 4 = Control (negative or positive)
Scenario 2: Exposure to an *other drug*	B.4.k.1	Select one element value
	B.4.k.2.1	Proprietary medicinal product name
	B.4.k.2.2	Drug substance name
	B.4.k.19	5 = Other drug
Scenario 3: No exposure to a *study drug*	B.4.k.1	4 = Drug not administered
	B.4.k.2.1	Proprietary medicinal product name
	B.4.k.2.2	Drug substance name
	B.4.k.19	1 = Test drug

EXHIBIT 40

Letter from FDA to Students for Life of Am. Denying Its 2022 Citizen Petition (Jan. 3, 2023)



Kristan Hawkins, President
Students for Life of America
1000 Winchester Street, Suite 301
Fredericksburg, VA 22401

Kristi Hamrick, Chief Media & Policy Strategist
Students for Life of America
1000 Winchester Street, Suite 301
Fredericksburg, VA 22401

January 3, 2023

Re: Docket No. FDA-2022-P-3209

Dear Ms. Hawkins and Ms. Hamrick:

This letter responds to your citizen petition submitted to the Food and Drug Administration (FDA or Agency) on December 13, 2022, on behalf of Students for Life of America and other signatories (Petition). In the Petition, you request that the "2021 and 2016 modifications to mifepristone's REMS be reversed and the REMS as they were in 2011 be restored." Specifically, you request that:

(1) FDA reverse the 2021 and 2016 modifications to the risk evaluation and mitigation strategy (REMS) for mifepristone[1] by requiring that:

a. "Mifepristone only be administered, in a regimen with misoprostol, for the termination of intrauterine pregnancy, for up to 49 days (7 weeks) gestation" (Petition at 1).
b. "Mifepristone only be administered by or under the supervision of a physically present physician" (Petition at 1).
c. "the use of Mifepristone and misoprostol for the termination of pregnancy necessitate three office visits by the patient" (Petition at 1).

[1] Mifepristone products for medical termination of intrauterine pregnancy through 70 days gestation are subject to a single, shared system REMS known as the Mifepristone REMS Program. We note that on December 16, 2021, FDA completed its review of the Mifepristone REMS Program and determined, among other things, that the REMS must be modified to remove the in-person dispensing requirement and add pharmacy certification. On December 16, 2021, FDA sent REMS Modification Notification letters to the applicants for Mifeprex and the approved generic version of Mifeprex, Mifepristone Tablets, 200 milligrams. Following receipt of these letters, the applicants prepared proposed REMS modifications and submitted them to FDA. On January 3, 2022, FDA approved the REMS modifications.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

(2) "Mifepristone use should be contraindicated for patients who do not have convenient access to emergency medical care," and "[t]his use should be as limited as possible" (Petition at 1).

(3) "Telehealth should not be an option to all women, but only to women in absolute need under extreme circumstances that would make access to a medical care facility impracticable, with a substantial risk that the woman would die without immediate administration of Mifepristone" (Petition at 1).

(4) "To alter the Mifepristone REMS, a formal study should be required" (Petition at 1).

The actions you request in your Petition are the same or substantially the same as the actions requested in the March 29, 2019 citizen petition submitted by the American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) and the American College of Pediatricians (ACP) (FDA-2019-P-1534) (AAPLOG/ACP petition), which were addressed in FDA's December 16, 2021 response to that petition.[2] Your Petition does not provide any new data or evidence beyond what was provided in support of the AAPLOG/ACP Petition. FDA carefully considered the information submitted in the AAPLOG/ACP Petition and issued a detailed response. The December 16, 2021 citizen petition response is available at regulations.gov.

For the reasons explained above, we deny your Petition.

Sincerely,

Patrizia A. Cavazzoni -S

Digitally signed by Patrizia A. Cavazzoni -S
Date: 2023.01.03 09:41:02 -05'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research

[2] Available at https://www.regulations.gov/document/FDA-2019-P-1534-0016.

EXHIBIT 41

REMS Single Shared System for Mifepristone 200mg (Jan. 2023)

Initial Shared System REMS approval: 04/2019
Most Recent Modification: 01/2023

Mifepristone Tablets, 200 mg
Progestin Antagonist

RISK EVALUATION AND MITIGATION STRATEGY (REMS)
SINGLE SHARED SYSTEM FOR MIFEPRISTONE 200 MG

I. GOAL

The goal of the REMS for mifepristone is to mitigate the risk of serious complications associated with mifepristone by:

a) Requiring healthcare providers who prescribe mifepristone to be certified in the Mifepristone REMS Program.

b) Ensuring that mifepristone is only dispensed by or under the supervision of certified prescribers, or by certified pharmacies on prescriptions issued by certified prescribers.

c) Informing patients about the risk of serious complications associated with mifepristone.

II. REMS ELEMENTS

A. Elements to Assure Safe Use

1. Healthcare providers who prescribe mifepristone must be specially certified.
   a. To become specially certified to prescribe mifepristone, healthcare providers must:
      i. Review the Prescribing Information for mifepristone.
      ii. Complete a *Prescriber Agreement Form*. By signing[1] a *Prescriber Agreement Form*, prescribers agree that:
         1) They have the following qualifications:
            a) Ability to assess the duration of pregnancy accurately
            b) Ability to diagnose ectopic pregnancies
            c) Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made plans to provide such care through others, and ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary
         2) They will follow the guidelines for use of mifepristone (see b.i-vii below).
   b. As a condition of certification, prescribers must follow the guidelines for use of mifepristone described below:
      i. Ensure that the *Patient Agreement Form* is reviewed with the patient and the risks of the mifepristone treatment regimen are fully explained. Ensure any questions the patient may have prior to receiving mifepristone are answered.
      ii. Ensure that the healthcare provider and patient sign the *Patient Agreement Form.*

[1] In this REMS, the terms "sign" and "signature" include electronic signatures.

Reference ID: 5103833

iii. Ensure that the patient is provided with a copy of the *Patient Agreement Form* and Medication Guide.

iv. Ensure that the signed *Patient Agreement Form* is placed in the patient's medical record.

v. Ensure that any deaths are reported to the Mifepristone Sponsor that provided the mifepristone, identifying the patient by a non-identifiable reference and including the NDC and lot number from the package of mifepristone that was dispensed to the patient.

vi. If mifepristone will be dispensed by a certified pharmacy:

1) Provide the certified pharmacy a signed *Prescriber Agreement Form*.

2) Assess appropriateness of dispensing mifepristone when contacted by a certified pharmacy about patients who will receive mifepristone more than 4 calendar days after the prescription was received by the certified pharmacy.

3) Obtain the NDC and lot number of the package of mifepristone the patient received in the event the prescriber becomes aware of the death of the patient.

vii. The certified prescriber who dispenses mifepristone or who supervises the dispensing of mifepristone must:

1) Provide an authorized distributor with a signed *Prescriber Agreement Form*.

2) Ensure that the NDC and lot number from each package of mifepristone dispensed are recorded in the patient's record.

3) Ensure that healthcare providers under their supervision follow guidelines i.-v.

c. Mifepristone Sponsors must:

i. Ensure that healthcare providers who prescribe their mifepristone are specially certified in accordance with the requirements described above and de-certify healthcare providers who do not maintain compliance with certification requirements.

ii. Ensure prescribers previously certified in the Mifepristone REMS Program complete the new *Prescriber Agreement Form*:

1) Within 120 days after approval of this modification, for those previously certified prescribers submitting prescriptions to certified pharmacies.

2) Within one year after approval of this modification, if previously certified and ordering from an authorized distributor.

iii. Ensure that healthcare providers can complete the certification process by email or fax to an authorized distributor and/or certified pharmacy.

iv. Provide the Prescribing Information and their *Prescriber Agreement Form* to healthcare providers who inquire about how to become certified.

v. Ensure annually with each certified prescriber that their locations for receiving mifepristone are up to date.

The following materials are part of the Mifepristone REMS Program:

- *Prescriber Agreement Form for Danco Laboratories, LLC*
- *Prescriber Agreement Form for GenBioPro, Inc.*
- *Patient Agreement Form*

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2. Pharmacies that dispense mifepristone must be specially certified
   a. To become specially certified to dispense mifepristone, pharmacies must:
      i. Be able to receive *Prescriber Agreement Forms* by email and fax.
      ii. Be able to ship mifepristone using a shipping service that provides tracking information.
      iii. Designate an authorized representative to carry out the certification process on behalf of the pharmacy.
      iv. Ensure the authorized representative oversees implementation and compliance with the Mifepristone REMS Program by doing the following:
         1) Review the Prescribing Information for mifepristone.
         2) Complete a *Pharmacy Agreement Form*. By signing a *Pharmacy Agreement Form*, the authorized representative agrees that the pharmacy will put processes and procedures in place to ensure the following requirements are completed:
            a) Verify that the prescriber is certified by confirming their completed *Prescriber Agreement Form* was received with the prescription or is on file with the pharmacy.
            b) Dispense mifepristone such that it is delivered to the patient within 4 calendar days of the date the pharmacy receives the prescription, except as provided in c) below.
            c) Confirm with the prescriber the appropriateness of dispensing mifepristone for patients who will receive the drug more than 4 calendar days after the date the pharmacy receives the prescription and document the prescriber's decision.
            d) Record in the patient's record the NDC and lot number from each package of mifepristone dispensed.
            e) Track and verify receipt of each shipment of mifepristone.
            f) Dispense mifepristone in its package as supplied by the Mifepristone Sponsor.
            g) Report any patient deaths to the prescriber, including the NDC and lot number from the package of mifepristone dispensed to the patient, and remind the prescriber of their obligation to report the deaths to the Mifepristone Sponsor that provided the mifepristone. Notify the Mifepristone Sponsor that provided the dispensed mifepristone that the pharmacy submitted a report of death to the prescriber, including the name and contact information for the prescriber and the NDC and lot number of the dispensed product.
            h) Not distribute, transfer, loan or sell mifepristone except to certified prescribers or other locations of the pharmacy.
            i) Maintain records of *Prescriber Agreement Forms*.
            j) Maintain records of dispensing and shipping.
            k) Maintain records of all processes and procedures including compliance with those processes and procedures.
            l) Maintain the identity of the patient and prescriber as confidential, including limiting access to patient and prescriber identity only to those personnel necessary to dispense mifepristone in accordance with the Mifepristone REMS Program requirements, or as necessary for payment and/or insurance purposes.
            m) Train all relevant staff on the Mifepristone REMS Program requirements.

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n) Comply with audits carried out by the Mifepristone Sponsors or a third party acting on behalf of the Mifepristone Sponsors to ensure that all processes and procedures are in place and are being followed.

b. Mifepristone Sponsors must:

i. Ensure that pharmacies are specially certified in accordance with the requirements described above and de-certify pharmacies that do not maintain compliance with certification requirements.

ii. Ensure that pharmacies can complete the certification process by email and fax to an authorized distributor.

i. Verify annually that the name and contact information for the pharmacy's authorized representative corresponds to that of the current designated authorized representative for the certified pharmacy, and if different, require the pharmacy to recertify with the new authorized representative.

The following materials are part of the Mifepristone REMS Program:

- *Pharmacy Agreement Form for Danco Laboratories, LLC*
- *Pharmacy Agreement Form for GenBioPro, Inc.*

3. Mifepristone must be dispensed to patients with evidence or other documentation of safe use conditions as ensured by the certified prescriber in signing the *Prescriber Agreement Form*.

a. The patient must sign a *Patient Agreement Form* indicating that the patient has:

i. Received, read and been provided a copy of the *Patient Agreement Form*.

ii. Received counseling from the healthcare provider regarding the risk of serious complications associated with mifepristone.

B. Implementation System

1. Mifepristone Sponsors must ensure that their mifepristone is only distributed to certified prescribers and certified pharmacies by:

a. Ensuring that distributors who distribute their mifepristone comply with the program requirements for distributors.

i. The distributors must put processes and procedures in place to:

1) Complete the certification process upon receipt of a *Prescriber Agreement Form* or *Pharmacy Agreement Form*.

2) Notify healthcare providers and pharmacies when they have been certified by the Mifepristone REMS Program.

3) Ship mifepristone only to certified pharmacies or locations identified by certified prescribers.

4) Not ship mifepristone to pharmacies or prescribers who become de-certified from the Mifepristone REMS Program.

5) Provide the Prescribing Information and their Prescriber Agreement Form to healthcare providers who (1) attempt to order mifepristone and are not yet certified, or (2) inquire about how to become certified.

ii. Put processes and procedures in place to maintain a distribution system that is secure,

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confidential and follows all processes and procedures, including those for storage, handling, shipping, tracking package serial numbers, NDC and lot numbers, proof of delivery and controlled returns of mifepristone.

iii. Train all relevant staff on the Mifepristone REMS Program requirements.

iv. Comply with audits by Mifepristone Sponsors or a third party acting on behalf of Mifepristone Sponsors to ensure that all processes and procedures are in place and are being followed for the Mifepristone REMS Program. In addition, distributors must maintain appropriate documentation and make it available for audits.

b. Ensuring that distributors maintain secure and confidential distribution records of all shipments of mifepristone.

2. Mifepristone Sponsors must monitor their distribution data to ensure compliance with the Mifepristone REMS Program.

3. Mifepristone Sponsors must ensure that adequate records are maintained to demonstrate that the Mifepristone REMS Program requirements have been met, including, but not limited to records of mifepristone distribution; certification of prescribers and pharmacies; and audits of pharmacies and distributors. These records must be readily available for FDA inspections.

4. Mifepristone Sponsors must audit their new distributors within 90 calendar days and annually thereafter after the distributor is authorized to ensure that all processes and procedures are in place and functioning to support the requirements of the Mifepristone REMS Program. Mifepristone Sponsors will take steps to address their distributor compliance if noncompliance is identified.

5. Mifepristone Sponsors must audit their certified pharmacies within 180 calendar days after the pharmacy places its first order of mifepristone, and annually thereafter audit certified pharmacies that have ordered mifepristone in the previous 12 months, to ensure that all processes and procedures are in place and functioning to support the requirements of the Mifepristone REMS Program. Mifepristone Sponsors will take steps to address their pharmacy compliance if noncompliance is identified.

6. Mifepristone Sponsors must take reasonable steps to improve implementation of and compliance with the requirements of the Mifepristone REMS Program based on monitoring and assessment of the Mifepristone REMS Program.

7. Mifepristone Sponsors must report to FDA any death associated with mifepristone whether or not considered drug-related, as soon as possible but no later than 15 calendar days from the initial receipt of the information by the Mifepristone Sponsor. This requirement does not affect the sponsors' other reporting and follow-up requirements under FDA regulations.

C. Timetable for Submission of Assessments

The NDA Sponsor must submit REMS assessments to FDA one year from the date of the approval of the modified REMS (1/3/2023) and annually thereafter. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 90 calendar days before the submission date for that assessment. The NDA Sponsor must submit each assessment so that it will be received by the FDA on or before the due date.

MIFEPREX® (Mifepristone) Tablets, 200 mg

PRESCRIBER AGREEMENT FORM

Mifeprex* (Mifepristone) Tablets, 200 mg, is indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. Please see Prescribing Information and Medication Guide for complete safety information.

To ***become a certified prescriber***, you must:

- **If you submit Mifeprex prescriptions for dispensing from certified pharmacies**:
  - Submit this form to each certified pharmacy to which you intend to submit Mifeprex prescriptions. The form must be received by the certified pharmacy before any prescriptions are dispensed by that pharmacy.
- **If you order Mifeprex for dispensing by you or healthcare providers under your supervision:**
  - Submit this form to the distributor. This form must be received by the distributor before the first order will be shipped to the healthcare setting.
  - Healthcare settings, such as medical offices, clinics, and hospitals, where Mifeprex will be dispensed by or under the supervision of a certified prescriber in the Mifepristone REMS Program do not require pharmacy certification.

Prescriber Agreement: By signing this form, you agree that you meet the qualifications below and will follow the guidelines for use. You are responsible for overseeing implementation and compliance with the Mifepristone REMS Program. You also understand that if the guidelines below are not followed, the distributor may stop shipping mifepristone to the locations that you identify and certified pharmacies may stop accepting your mifepristone prescriptions.

Mifepristone must be provided by or under the supervision of a certified prescriber who meets the following qualifications:

- Ability to assess the duration of pregnancy accurately.
- Ability to diagnose ectopic pregnancies.
- 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.
- Has read and understood the Prescribing Information for mifepristone. The Prescribing Information is available by calling 1-877-4 EARLY OPTION (1-877-432-7596 toll-free), or by visiting www.earlyoptionpill.com.

In addition to meeting these qualifications, you also agree to follow these guidelines for use:

- Ensure that the *Patient Agreement Form* is reviewed with the patient and the risks of the mifepristone treatment regimen are fully explained. Ensure any questions the patient may have prior to receiving mifepristone are answered.
- Ensure the healthcare provider and patient sign the *Patient Agreement Form*.
- Ensure that the patient is provided with a copy of the *Patient Agreement Form* and Medication Guide.
- Ensure that the signed *Patient Agreement Form* is placed in the patient's medical record.
- Ensure that any deaths of patients who received Mifeprex are reported to Danco Laboratories, LLC, identifying the patient by a non-identifiable reference and including the NDC and lot number from the package of Mifeprex that was dispensed to the patient.

Ensure that healthcare providers under your supervision follow the guidelines listed above.

- If Mifeprex will be dispensed through a certified pharmacy:
  - Assess appropriateness of dispensing Mifeprex when contacted by a certified pharmacy about patients who will receive Mifeprex more than 4 calendar days after the prescription was received by the certified pharmacy.
  - Obtain the NDC and lot number of the package of Mifeprex the patient received in the event the prescriber becomes aware of the death of a patient.
- If Mifeprex will be dispensed by you or by healthcare providers under your supervision:
  - Ensure the NDC and lot number from each package of Mifeprex are recorded in the patient's record.

I understand that a certified pharmacy may dispense mifepristone made by a different manufacturer than that stated on this Prescriber Agreement Form.

Print Name: _____ Title: _____

Signature: _____ Date: _____

Medical License # _____ State _____

NPI # _____

Practice Setting Address: _____

Return completed form to Mifeprex@dancodistributor.com or fax to 1-866-227-3343.

Approved 01/2023 [Doc control ID]

Mifepristone Tablets, 200 mg, is indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. Please see Prescribing Information and Medication Guide for complete safety information.

To ***become a certified prescriber***, you must:

- **If you submit mifepristone prescriptions for dispensing from certified pharmacies**:
  - Submit this form to each certified pharmacy to which you intend to submit mifepristone prescriptions. The form must be received by the certified pharmacy before any prescriptions are dispensed by that pharmacy.
- **If you order mifepristone for dispensing by you or healthcare providers under your supervision:**
  - Submit this form to the distributor. This form must be received by the distributor before the first order will be shipped to the healthcare setting.
  - Healthcare settings, such as medical offices, clinics, and hospitals, where mifepristone will be dispensed by or under the supervision of a certified prescriber in the Mifepristone REMS Program do not require pharmacy certification.

Prescriber Agreement: By signing this form, you agree that you meet the qualifications below and will follow the guidelines for use. You are responsible for overseeing implementation and compliance with the Mifepristone REMS Program. You also understand that if the guidelines below are not followed, the distributor may stop shipping mifepristone to the locations that you identify and certified pharmacies may stop accepting your mifepristone prescriptions.

Mifepristone must be provided by or under the supervision of a certified prescriber who meets the following qualifications:

- Ability to assess the duration of pregnancy accurately.
- Ability to diagnose ectopic pregnancies.
- 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.
- Has read and understood the Prescribing Information for mifepristone. The Prescribing Information is available by calling 1-855-MIFE-INFO (1-855—643-3463 toll-free), or by visiting www.MifeInfo.com.

In addition to meeting these qualifications, you also agree to follow these guidelines for use:

- Ensure that the *Patient Agreement Form* is reviewed with the patient and the risks of the mifepristone treatment regimen are fully explained. Ensure any questions the patient may have prior to receiving mifepristone are answered.
- Ensure the healthcare provider and patient sign the *Patient Agreement Form*.
- Ensure that the patient is provided with a copy of the *Patient Agreement Form* and Medication Guide.
- Ensure that the signed *Patient Agreement Form* is placed in the patient's medical record.
- Ensure that any deaths of patients who received mifepristone are reported to GenBioPro, Inc. that provided the mifepristone, identifying the patient by a non-identifiable reference and including the NDC and lot number from the package of mifepristone that was dispensed to the patient.

Ensure that healthcare providers under your supervision follow the guidelines listed above.

- If mifepristone will be dispensed through a certified pharmacy:
  - Assess appropriateness of dispensing mifepristone when contacted by a certified pharmacy about patients who will receive mifepristone more than 4 calendar days after the prescription was received by the certified pharmacy.
  - Obtain the NDC and lot number of the package of mifepristone the patient received in the event the prescriber becomes aware of the death of a patient.
- If mifepristone will be dispensed by you or by healthcare providers under your supervision:
  - Ensure the NDC and lot number from each package of mifepristone are recorded in the patient's record.

I understand that a certified pharmacy may dispense mifepristone made by a different manufacturer than that stated on this Prescriber Agreement Form.

Print Name: _____ Title: _____

Signature: _____ Date: _____

Medical License # _____ State _____

NPI # _____

Practice Setting Address: _____

Return completed form to **RxAgreements@GenBioPro.com** or fax to 1-877-239-8036

Approved 01/2023 [Doc control ID]

PATIENT AGREEMENT FORM Mifepristone Tablets, 200 mg

Healthcare Providers: *Counsel the patient on the risks of mifepristone. Both you and the patient must provide a written or electronic signature on this form.*

Patient Agreement:

1. I have decided to take mifepristone and misoprostol to end my pregnancy and will follow my healthcare provider's advice about when to take each drug and what to do in an emergency.
2. I understand:
   - **a.** I will take mifepristone on Day 1.
   - **b.** I will take the misoprostol tablets 24 to 48 hours after I take mifepristone.
3. My healthcare provider has talked with me about the risks, including:
   - heavy bleeding
   - infection
4. I will contact the clinic/office/provider right away if in the days after treatment I have:
   - a fever of 100.4°F or higher that lasts for more than four hours
   - heavy bleeding (soaking through two thick full-size sanitary pads per hour for two hours in a row)
   - severe stomach area (abdominal) pain or discomfort, or I am “feeling sick,” including weakness, nausea, vomiting, or diarrhea, more than 24 hours after taking misoprostol
     — these symptoms may be a sign of a serious infection or another problem (including an ectopic pregnancy, a pregnancy outside the womb).

   My healthcare provider has told me that these symptoms listed above could require emergency care. If I cannot reach the clinic/office/provider right away, my healthcare provider has told me who to call and what to do.
5. I should follow up with my healthcare provider about 7 to 14 days after I take mifepristone to be sure that my pregnancy has ended and that I am well.
6. I know that, in some cases, the treatment will not work. This happens in about 2 to 7 out of 100 women who use this treatment. If my pregnancy continues after treatment with mifepristone and misoprostol, I will talk with my provider about a surgical procedure to end my pregnancy.
7. If I need a surgical procedure because the medicines did not end my pregnancy or to stop heavy bleeding, my healthcare provider has told me whether they will do the procedure or refer me to another healthcare provider who will.
8. I have the MEDICATION GUIDE for mifepristone.
9. My healthcare provider has answered all my questions.

Patient Signature: _____ **Patient Name** (print): _____ **Date**: _____

Provider Signature: _____ **Provider Name** (print): _____ **Date**: _____

Patient Agreement Forms may be provided, completed, signed, and transmitted in paper or electronically.

01/2023

Reference ID: 5103833

MIFEPREX®(Mifepristone) Tablets, 200mg

PHARMACY AGREEMENT FORM

Pharmacies must designate an authorized representative to carry out the certification process and oversee implementation and compliance with the Mifepristone REMS Program on behalf of the pharmacy.

Healthcare settings, such as medical offices, clinics, and hospitals, where mifepristone will be dispensed by or under the supervision of a certified prescriber in the Mifepristone REMS Program do not require pharmacy certification.

By signing this form, as the Authorized Representative I certify that:

- Each location of my pharmacy that will dispense Mifeprex is able to receive *Prescriber Agreement Forms* by email and fax.
- Each location of my pharmacy that will dispense Mifeprex is able to ship Mifeprex using a shipping service that provides tracking information.
- I have read and understood the Prescribing Information for Mifeprex. The Prescribing Information is available by calling 1-877-4 EARLY OPTION (1-877-432-7596 toll-free) or online at www.earlyoptionpill.com; and
- Each location of my pharmacy that will dispense Mifeprex will put processes and procedures in place to ensure the following requirements are completed. I also understand that if my pharmacy does not complete these requirements, the distributor may stop accepting Mifeprex orders.
    - Verify that the prescriber is certified in the Mifepristone REMS Program by confirming their completed *Prescriber Agreement Form* was received with the prescription or is on file with your pharmacy.
    - Dispense Mifeprex such that it is delivered to the patient within 4 calendar days of the date the pharmacy receives the prescription, except as provided in the following bullet.
    - Confirm with the prescriber the appropriateness of dispensing Mifeprex for patients who will receive the drug more than 4 calendar days after the date the pharmacy receives the prescription and document the prescriber's decision.
    - Record in the patient's record the NDC and lot number from each package of Mifeprex dispensed.
    - Track and verify receipt of each shipment of Mifeprex.
    - Dispense mifepristone in its package as supplied by Danco Laboratories, LLC.
    - Report any patient deaths to the prescriber, including the NDC and lot number from the package of Mifeprex dispensed to the patient, and remind the prescriber of their obligation to report the deaths to Danco Laboratories, LLC. Notify Danco that your pharmacy submitted a report of death to the prescriber, including the name and contact information for the prescriber and the NDC and lot number of the dispensed product.
    - Not distribute, transfer, loan or sell mifepristone except to certified prescribers or other locations of the pharmacy.
    - Maintain records of *Prescriber Agreement Forms*, dispensing and shipping, and all processes and procedures including compliance with those processes and procedures.
    - Maintain the identity of Mifeprex patients and prescribers as confidential and protected from disclosure except to the extent necessary for dispensing under this REMS or as necessary for payment and/or insurance.
    - Train all relevant staff on the Mifepristone REMS Program requirements.
    - Comply with audits carried out by the Mifepristone Sponsors or a third party acting on behalf of the Mifepristone Sponsors to ensure that all processes and procedures are in place and are being followed.

Any new authorized representative must complete and submit the *Pharmacy Agreement Form*.

Authorized Representative Name: _____ Title: _____

DANCO
Support • Progress • Options

*MIFEPREX is a registered trademark of Danco Laboratories, LLC

P.O. Box 4816-New York, NY 10185
1-877-4-EARLY-OPTION (1-877-432-7596) www.earlyoptionpill.com

Signature: _____ Date: _____

Email: _____ Phone: _____ Preferred __ email __ phone

Pharmacy Name: _____

Pharmacy Address: _____

Return completed form to Mifeprex@dancodistributor.com or fax to 1-866-227-3343.

PHARMACY AGREEMENT FORM **Mifepristone Tablets, 200 mg**

Pharmacies must designate an authorized representative to carry out the certification process and oversee implementation and compliance with the Mifepristone REMS Program on behalf of the pharmacy.

Healthcare settings, such as medical offices, clinics, and hospitals, where mifepristone will be dispensed by or under the supervision of a certified prescriber in the Mifepristone REMS Program do not require pharmacy certification.

By signing this form, as the Authorized Representative I certify that:

- Each location of my pharmacy that will dispense mifepristone is able to receive *Prescriber Agreement Forms* by email and fax.
- Each location of my pharmacy that will dispense mifepristone is able to ship mifepristone using a shipping service that provides tracking information.
- I have read and understood the Prescribing Information for mifepristone. The Prescribing Information is available by calling 1-855-MIFE-INFO (1-855-643-3463 toll-free) or online at www.MifeInfo.com; and
- Each location of my pharmacy that will dispense mifepristone will put processes and procedures in place to ensure the following requirements are completed. I also understand that if my pharmacy does not complete these requirements, the distributor may stop accepting mifepristone orders.
    - Verify that the prescriber is certified in the Mifepristone REMS Program by confirming their completed *Prescriber Agreement Form* was received with the prescription or is on file with your pharmacy.
    - Dispense mifepristone such that it is delivered to the patient within 4 calendar days of the date the pharmacy receives the prescription, except as provided in the following bullet.
    - Confirm with the prescriber the appropriateness of dispensing mifepristone for patients who will receive the drug more than 4 calendar days after the date the pharmacy receives the prescription and document the prescriber's decision.
    - Record in the patient's record the NDC and lot number from each package of mifepristone dispensed.
    - Track and verify receipt of each shipment of mifepristone.
    - Dispense mifepristone in its package as supplied by GenBioPro, Inc.
    - Report any patient deaths to the prescriber, including the NDC and lot number from the package of mifepristone dispensed to the patient, and remind the prescriber of their obligation to report the deaths to GenBioPro, Inc. Notify GenBioPro that your pharmacy submitted a report of death to the prescriber, including the name and contact information for the prescriber and the NDC and lot number of the dispensed product.
    - Not distribute, transfer, loan or sell mifepristone except to certified prescribers or other locations of the pharmacy.
    - Maintain records of *Prescriber Agreement Forms*, dispensing and shipping, all processes and procedures including compliance with those processes and procedures.
    - Maintain the identity of mifepristone patients and prescribers as confidential and protected from disclosure except to the extent necessary for dispensing under this REMS or as necessary for payment and/or insurance purposes.
    - Train all relevant staff on the Mifepristone REMS Program requirements.
    - Comply with audits carried out by the Mifepristone Sponsors or a third party acting on behalf of the Mifepristone Sponsors to ensure that all processes and procedures are in place and are being followed.

Any new authorized representative must complete and submit the *Pharmacy Agreement Form*.

Authorized Representative Name: _____ Title: _____

Signature: _____ Date: _____

Email: _____ Phone: _____ Preferred __ email __ phone

Pharmacy Name: _____

Pharmacy Address: _____

Return completed form to **RxAgreements@GenBioPro.com** or fax to **1-877-239-8036.**

EXHIBIT 42

Pam Belluck, *CVS and Walgreens Will Begin Selling Abortion Pills This Month*, New York Times (March 1, 2024)

CVS and Walgreens Will Begin Selling Abortion Pills This Month

The pill mifepristone will be available with a prescription at pharmacy counters in a few states to start.



By Pam Belluck

March 1, 2024

The two largest pharmacy chains in the United States will start dispensing the abortion pill mifepristone this month, a step that could make access easier for some patients.

Officials at CVS and Walgreens said in interviews on Friday that they had received certification to dispense mifepristone under guidelines that the Food and Drug Administration issued last year. The chains plan to make the medication available in stores in a handful of states at first. They will not be providing the medication by mail.

Both chains said they would gradually expand to all other states where abortion was legal and where pharmacies were legally able to dispense abortion pills — about half of the states.

President Biden said in a statement on Friday that the availability of the pill at pharmacies was "an important milestone in ensuring access to mifepristone, a drug that has been approved by the Food and Drug Administration as safe and effective for more than 20 years."

"I encourage all pharmacies that want to pursue this option to seek certification," he added.

Walgreens will start providing the pill within the next week in a small number of its pharmacies in New York, Pennsylvania, Massachusetts, California and Illinois, said Fraser Engerman, a spokesman for the chain. "We are beginning a phased rollout in select locations to allow us to ensure quality, safety and privacy for our patients, providers and team members," he said.

CVS will begin dispensing in all of its pharmacies in Massachusetts and Rhode Island "in the weeks ahead," Amy Thibault, a spokeswoman for the company, said.

The chains will be monitoring the prospects in a few states, including Kansas, Montana and Wyoming, where abortion bans or strict limitations have been enacted but are enjoined because of legal challenges.

Mr. Engerman said that Walgreens was "not going to dispense in states where the laws are unclear" to protect its pharmacists and staff members.

As for CVS, "we continually monitor and evaluate changes in state laws and will dispense mifepristone in any state where it is or becomes legally permissible to do so," Ms. Thibault said. In some states where abortion is legal, she said, pharmacists are prohibited from dispensing mifepristone because laws require that to be done by doctors or in a hospital or clinic.

It is uncertain how much initial demand there will be for the service at brick-and-mortar pharmacies. In the states where the chains will begin dispensing, abortion pills are already available in clinics or easily prescribed through telemedicine and sent through the mail. But some women prefer to visit doctors, many of whom do not have the medication on hand. The new development will allow doctors and other eligible providers to send a prescription to a pharmacy for the patient to pick up.

"Now that doctors no longer have to stock the medicine themselves and dispense it, it increases the likelihood that a patient can go to their own doctor, the person with whom they already have a relationship, and say, 'I'm pregnant — I don't want to be,'" said Kirsten Moore, the director of the Expanding Medication Abortion Access Project.

She said it might also motivate more doctors and other health providers to obtain the special certification that the F.D.A. requires for prescribers of mifepristone. The steps to becoming a certified prescriber are simple, but some doctors have been deterred because of the paperwork and logistics of having to order and stock the pills.

As the availability in retail pharmacies expands, they may become a more popular alternative, and depending on the outcome of a case the Supreme Court will hear later this month, the pharmacy option could take on more importance.

In that case, abortion opponents have sued the F.D.A., seeking to remove mifepristone from the market in the United States. An appeals court ruling in that case did not go that far but effectively banned the mailing of mifepristone and required in-person doctor visits. If the Supreme Court upholds that ruling, it could mean that patients would have to obtain mifepristone by visiting a clinic or doctor. If such a ruling allowed pharmacies to continue dispensing, more patients might obtain the medication there.

Abortion opponents criticized the pharmacy chains' decision. "As two of the world's largest, most trusted 'health' brands, the decision by CVS and Walgreens to sell dangerous abortion drugs is shameful, and the harm to unborn babies and their mothers incalculable," Katie Daniel, the state policy director of Susan B. Anthony Pro-Life America, said in a statement.

In order to obtain certification, the pharmacy chains had to take specific steps, including ensuring that their computerized systems protected the privacy of prescribers, who are certified under a special program that the F.D.A. applies to mifepristone and several dozen other medications.

Pharmacy certification is granted by manufacturers of mifepristone. Walgreens was certified by the brand name manufacturer Danco Laboratories, and is seeking certification from the generic manufacturer GenBioPro, Mr. Engerman said. CVS was certified by GenBioPro.

Medication abortion is a two-drug regimen that is now the most common method of terminating pregnancies in the United States and is typically used through 12 weeks of pregnancy. Mifepristone, which blocks a hormone necessary for pregnancy development, is taken first, followed 24 to 48 hours later by misoprostol, which causes contractions that expel pregnancy tissue.

The same regimen is also used for miscarriages, and those patients can now also obtain mifepristone from the pharmacy chains.

Mifepristone has been tightly regulated by the F.D.A. since its approval in 2000. It had previously been available primarily from the prescribers or from clinics or telemedicine abortion services, in which the pills were generally shipped from one of two mail-order pharmacies that were authorized. Misoprostol has never been as tightly restricted as mifepristone and is used for many different medical conditions. It is easily obtained at pharmacies through a typical prescription process.

The American Pharmacists Association urged the F.D.A. to allow retail pharmacies to distribute mifepristone, even though the medication is unlikely to generate significant revenue. In a statement last year, the association said that it wanted the agency “to level the playing field by permitting any pharmacy that chooses to dispense this product to become certified.”

Shortly after the F.D.A. policy change was announced in January 2023, Walgreens and CVS said they planned to become certified and offer mifepristone in states where laws would allow pharmacies to dispense it.

Walgreens later became the focus of a consumer and political firestorm after it responded to threatening letters from Republican attorneys general in 21 states, confirming that it would not dispense the medication in those states.

Both chains have had protests outside their stores, mostly from anti-abortion advocates, and similar protesters interrupted a meeting of shareholders at Walgreens Boots Alliance, the chain’s parent company.

CVS is the nation’s largest chain with over 9,000 stores in all 50 states. Walgreens has about 8,500 stores in all states except North Dakota. Neither chain would discuss the price of the medication, but both noted that some insurance policies would cover it in some states.

A handful of small independent pharmacies began dispensing mifepristone last year.

science, neurological disorders, mental health and genetics. More about Pam Belluck

A version of this article appears in print on , Section A, Page 1 of the New York edition with the headline: 2 Major Chains Prepare to Sell Abortion Pills

EXHIBIT 43

Mifeprex Prescriber Agreement (2023)

PRESCRIBER AGREEMENT FORM

Mifeprex® (Mifepristone) Tablets, 200 mg

Mifeprex* (Mifepristone) Tablets, 200 mg, is indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. Please see Prescribing Information and Medication Guide for complete safety information.

TO *BECOME A CERTIFIED PRESCRIBER*, YOU MUST:

If you submit Mifeprex prescriptions for dispensing from certified pharmacies:

- Submit this form to each certified pharmacy to which you intend to submit Mifeprex prescriptions. The form must be received by the certified pharmacy before any prescriptions are dispensed by that pharmacy.

If you order Mifeprex for dispensing by you or healthcare providers under your supervision:

- Submit this form to the distributor. This form must be received by the distributor before the first order will be shipped to the healthcare setting.
- Healthcare settings, such as medical offices, clinics, and hospitals, where Mifeprex will be dispensed by or under the supervision of a certified prescriber in the Mifepristone REMS Program do not require pharmacy certification.

Prescriber Agreement: By signing this form, you agree that you meet the qualifications below and will follow the guidelines for use. You are responsible for overseeing implementation and compliance with the Mifepristone REMS Program. You also understand that if the guidelines below are not followed, the distributor may stop shipping mifepristone to the locations that you identify and certified pharmacies may stop accepting your mifepristone prescriptions.

Mifepristone must be provided by or under the supervision of a certified prescriber who meets the following qualifications:

- Ability to assess the duration of pregnancy accurately.
- Ability to diagnose ectopic pregnancies.
- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others, and ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
- Has read and understood the Prescribing Information for mifepristone. The Prescribing Information is available by calling our toll free number, 1-877-4 Early Option (1-877-432-7596), or logging on to our website, **www.earlyoptionpill.com**.

In addition to having these qualifications, you also agree to follow these guidelines for use:

- Ensure that the Patient Agreement Form is reviewed with the patient and the risks of the mifepristone treatment regimen are fully explained. Ensure any questions the patient may have prior to receiving mifepristone are answered.
- Ensure the healthcare provider and patient sign the Patient Agreement Form.
- Ensure that the patient is provided with a copy of the Patient Agreement Form and Medication Guide.
- Ensure that the signed Patient Agreement Form is placed in the patient's medical record.

- Ensure that any deaths of patients who received Mifeprex are reported to Danco Laboratories, LLC, identifying the patient by a non-identifiable reference and including the NDC and lot number from the package of Mifeprex that was dispensed to the patient.

Ensure that healthcare providers under your supervision follow the guidelines listed above.

If Mifeprex will be dispensed through a certified pharmacy:

- Assess appropriateness of dispensing Mifeprex when contacted by a certified pharmacy about patients who will receive Mifeprex more than 4 calendar days after the prescription was received by the certified pharmacy.
- Obtain the NDC and lot number of the package of Mifeprex the patient received in the event the prescriber becomes aware of the death of a patient.

If Mifeprex will be dispensed by you or by healthcare providers under your supervision:

- Ensure the NDC and lot number from each package of Mifeprex are recorded in the patient's record.

I understand that a certified pharmacy may dispense mifepristone made by a different manufacturer than that stated on this Prescriber Agreement Form.

Print Name: _____ Title: _____

Signature: _____ Date: _____

Medical License # _____ State _____

NPI # _____

Practice Setting Address: _____

_____

Return completed form to Mifeprex@dancodistributor.com or fax to 1-866-227-3343.

Mifeprex®
(Mifepristone) Tablets, 200 mg
THE ORIGINAL EARLY OPTION PILL

DANCO

Danco Laboratories, LLC • P.O. Box 4816 • New York, NY 10185
1-877-4 Early Option (1-877-432-7596) • www.earlyoptionpill.com

*MIFEPREX is a registered trademark of Danco Laboratories, LLC.

1/2023

EXHIBIT 44

Mifeprex Patient Agreement (2023)

PATIENT AGREEMENT FORM Mifepristone Tablets, 200 mg

Healthcare Providers: *Counsel the patient on the risks of mifepristone. Both you and the patient must provide a written or electronic signature on this form.*

Patient Agreement:

1. I have decided to take mifepristone and misoprostol to end my pregnancy and will follow my healthcare provider's advice about when to take each drug and what to do in an emergency.
2. I understand:
   a. I will take mifepristone on Day 1.
   b. I will take the misoprostol tablets 24 to 48 hours after I take mifepristone.
3. My healthcare provider has talked with me about the risks, including:
   - heavy bleeding
   - infection
4. I will contact the clinic/office/provider right away if in the days after treatment I have:
   - a fever of 100.4°F or higher that lasts for more than four hours
   - heavy bleeding (soaking through two thick full-size sanitary pads per hour for two hours in a row)
   - severe stomach area (abdominal) pain or discomfort, or I am “feeling sick,” including weakness, nausea, vomiting, or diarrhea, more than 24 hours after taking misoprostol
     — these symptoms may be a sign of a serious infection or another problem (including an ectopic pregnancy, a pregnancy outside the womb).

   My healthcare provider has told me that these symptoms listed above could require emergency care. If I cannot reach the clinic/office/provider right away, my healthcare provider has told me who to call and what to do.
5. I should follow up with my healthcare provider about 7 to 14 days after I take mifepristone to be sure that my pregnancy has ended and that I am well.
6. I know that, in some cases, the treatment will not work. This happens in about 2 to 7 out of 100 women who use this treatment. If my pregnancy continues after treatment with mifepristone and misoprostol, I will talk with my provider about a surgical procedure to end my pregnancy.
7. If I need a surgical procedure because the medicines did not end my pregnancy or to stop heavy bleeding, my healthcare provider has told me whether they will do the procedure or refer me to another healthcare provider who will.
8. I have the MEDICATION GUIDE for mifepristone.
9. My healthcare provider has answered all my questions.

Patient Signature: _____ **Patient Name** (print): _____ **Date**: _____

Provider Signature: _____ **Provider Name** (print): _____ **Date**: _____

Patient Agreement Forms may be provided, completed, signed, and transmitted in paper or electronically.

01/2023

Reference ID: 5103833

EXHIBIT 45

Letter from Danco Labs to Emergency Room Doctors (Nov. 12, 2004)

DANCO LABORATORIES

PO Box 4816
New York, NY 10185

infoline
1.877.4.EARLY OPTION

www.earlyoptionpill.com

November 12, 2004

Dear Emergency Room Director:

Danco Laboratories is providing this information to assist you in taking care of patients who may present in an emergency room setting following treatment with Mifeprex® (mifepristone) and misoprostol. In particular, you should be aware of the rare events – serious infection, prolonged heavy bleeding and ruptured ectopic pregnancy – discussed below. From September 2000, when Mifeprex* was approved in the United States for marketing, through September 2004, approximately 360,000 women have been treated with Mifeprex in the U.S.

The Mifeprex treatment, Mifeprex followed by misoprostol, is indicated for non-surgical abortion in patients who are ≤ 49 days pregnant, dated from the first day of the last menstrual period (LMP). Medical abortion with Mifeprex and misoprostol presents no differently from a spontaneous abortion, with bleeding and cramping expected in the hours after taking misoprostol. In clinical trials, Mifeprex was highly effective, with a 92-95% success rate in women who were ≤ 49 days pregnant. The remainder have a surgical termination for various reasons, including ongoing pregnancy, incomplete abortion, bleeding and patient request; the vast majority of these women are treated by the physician who initially provided the Mifeprex treatment or by referral to a colleague.

However, there may be some women who present to an emergency room with serious and sometimes fatal infections and bleeding that occur rarely following spontaneous (miscarriage), surgical and medical abortions, including following Mifeprex use, and childbirth. A high index of suspicion is needed for timely diagnosis and intervention in these patients. Danco Laboratories has updated the BOXED WARNING and WARNINGS sections of the Prescribing Information as well as the MEDICATION GUIDE and the PATIENT AGREEMENT to provide information about these topics. Additional information is provided on ectopic pregnancy, which is a contraindication for Mifeprex (see WARNINGS).

Copies of the updated Prescribing Information, which includes the MEDICATION GUIDE and the PATIENT AGREEMENT, are enclosed, and it is important for you to read them carefully. A summary of the updated warnings follows:

Infection and Sepsis
In postmarketing experience following the use of Mifeprex and misoprostol, we have received a few reports of cases of serious bacterial infection, including very rare cases of fatal septic shock (see WARNINGS). No causal relationship between these events and the use of Mifeprex and misoprostol has been established. Although infection following medical abortion is rare, we ask that you be alert to the possibility of infection in your patients. In particular, a sustained fever of 100.4 degrees Fahrenheit or higher, severe abdominal pain, or pelvic tenderness in the days after taking Mifeprex and misoprostol may be an indication of infection. Atypical presentations of serious infection and sepsis, without fever, severe abdominal pain, or pelvic tenderness, but with significant leukocytosis, tachycardia, or hemoconcentration can occur.

Vaginal Bleeding
Vaginal bleeding occurs in almost all patients during the treatment procedure (see WARNINGS). According to data from the U.S. and French trials, women should expect to

* Mifeprex is a registered trademark of Danco Laboratories, LLC.

experience vaginal bleeding or spotting for an average of nine to 16 days, while up to 8% of all subjects may experience some type of bleeding for 30 days or more. Prolonged heavy bleeding (soaking through two thick full-size sanitary pads per hour for two consecutive hours) may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed to prevent the development of hypovolemic shock. Patients should be counseled to seek immediate medical attention if they experience prolonged heavy vaginal bleeding following a medical abortion. Excessive vaginal bleeding usually requires treatment by uterotonics, vasoconstrictor drugs, curettage, administration of saline infusions, and/or blood transfusions.

Ectopic Pregnancy
Additionally, in postmarketing experience we have received a small number of reports of ruptured ectopic pregnancy. No causal relationship between these events and Mifeprex and misoprostol has been established. Mifeprex is contraindicated in patients with a confirmed or suspected ectopic pregnancy since Mifeprex is not effective for terminating these pregnancies (see CONTRAINDICATIONS). Physicians should remain alert to the possibility that a patient who is undergoing a medical abortion could have an undiagnosed ectopic pregnancy since some of the expected symptoms of a medical abortion may be similar to those of a ruptured ectopic pregnancy. The presence of an ectopic pregnancy may have been missed even if the patient underwent ultrasonography prior to being prescribed Mifeprex.

The MEDICATION GUIDE and PATIENT AGREEMENT have also been updated to reflect the new safety information. Each patient should have received a MEDICATION GUIDE from her health care provider before taking Mifeprex and been advised to take her MEDICATION GUIDE with her if she visits an emergency room, so that you will be aware that the patient is undergoing a medical abortion.

Abortion, whether medical or surgical, is “generally very safe and is therefore infrequently associated with complications”.[1] However, we thought that the enclosed recent publication, Phillip G. Stubblefield, MD and Lynn Borgatta, MD, “Complications of Induced Abortion” in *Obstetric & Gynecologic Emergencies Diagnosis and Management* (New York: McGraw-Hill, 2004), 65-86, may be helpful to you in your practice as it includes information on the diagnosis and treatment of possible complications following abortion, including infection and ectopic pregnancy.

The safety and efficacy of Mifeprex and misoprostol were well established in clinical trials reviewed by the FDA. The overall safety and efficacy profile remains unchanged.

We rely on medical feedback from health care professionals and therefore remind you to report serious adverse events and any on-going pregnancies following treatment with the Mifeprex regimen to us. Please provide a brief clinical synopsis (by postal mail, email or phone):

Medical Director
Danco Laboratories, LLC
P.O. Box 4816
New York, NY 10185
Medicaldirector@earlyoptionpill.com
Toll free at 1-877-4-Early Option (1-877-432-7596)

[1] Phillip G. Stubblefield, MD and Lynn Borgatta, MD, “Complications of Induced Abortion” in *Obstetric & Gynecologic Emergencies Diagnosis and Management* (New York: McGraw-Hill, 2004), 65-86.

For more information on Mifeprex, please visit www.earlyoptionpill.com or call our 24-hour toll free number at 1-877-4-Early Option (1-877-432-7596). If you have an urgent question, a physician will usually return your call within the hour. For general questions, our Medical Director typically returns calls within 24 hours.

Sincerely,
Danco Laboratories, LLC

Enclosures

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EXHIBIT 46

Letter from SFP to Stephen Ostroff (Feb 4, 2016)

CONFIDENTIAL

February 4, 2016

Stephen Ostroff, M.D., Acting Commissioner of Food and Drugs
Robert M. Califf, M.D., Deputy Commissioner for Medical Products and Tobacco
Janet Woodcock, M.D., Director of the Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Drs. Ostroff, Califf, and Woodcock,

The following 30 organizations write to ask the U.S. Food and Drug Administration (FDA) to lift the Risk Evaluation and Mitigation Strategy (REMS) imposed in 2000 when it approved the use of Mifeprex© (mifepristone) for pregnancy termination, and to extend the indicated use through a gestational age of 70 days. In the 15 years since mifepristone's approval, multiple clinical trials, dozens of studies, and extensive experience across the globe have confirmed the FDA's finding that mifepristone is a safe and reliable method of abortion. Studies have shown that mifepristone in combination with misoprostol is up to 99% effective for first trimester abortion[1,2] and that serious complications are rare.[3] The steady increase in use of medication abortion – now 23% of U.S. abortions – shows that many women prefer this option, and that it has the ability to improve access to abortion, even in states with restrictive laws. Provider interest in offering mifepristone has also increased substantially: in 2011, 59% of abortion providers offered early medication abortions, up from 33% in 2008.[4] This growing use of medication abortion has made a major difference in people's lives. We thank the FDA for ensuring mifepristone is available on the market for patients' reproductive health care needs.

However, many who could benefit from mifepristone still do not have access to it due to multiple types of restrictions, including those required by the FDA. In November 2015, a group of organizational and individual researchers submitted a letter to the FDA (hereinafter "Technical Letter") asking the agency to lift the REMS on mifepristone and extend the indicated use to 70 days gestational age, presenting data showing that the current restrictions and limited gestational age indication are unnecessary for the safe and effective use of the drug for pregnancy termination.

As policy, advocacy, social science, research, and academic organizations, we ask the FDA to consider the substantial evidence presented in the Technical Letter, alongside the burdens that the REMS and the label's 49-day gestational age indication place on patient access, which we describe here. The FDA held a public meeting in October 2015 to discuss improving patient access to drugs under REMS,[5] evidencing the agency's own awareness of patient burden caused specifically by restrictions imposed under REMS. We applaud these efforts and urge the FDA to use its regulatory authority to remove the medically unnecessary barriers to mifepristone.

Mifepristone underwent a lengthy approval process in the late 1990s, during which it became subject to a rarely-used approval mechanism: Subpart H of the FDA's Title 21, Chapter 314 regulations. Subpart H is used primarily for drugs with very serious and well-documented safety concerns.[6] In 2007, Subpart H restrictions on all drugs were converted automatically into a Risk Evaluation and Management Strategy (REMS),[7] a mechanism created by Congress whereby FDA can impose Elements to Assure Safe Use (ETASU). Under this law, as the Agency stated in preparation for its October 2015 meeting on REMS,[8] Congress mandated that the FDA engage in a balancing analysis to ensure that the risks mitigated by a REMS program do not unduly burden patients' access to health care:

> [E]lements to assure safe use [ETASU] ... shall–
>
> (A) be commensurate with the specific serious risk listed in the labeling of the drug;
>
> ...
>
> (C) considering such risk, not be unduly burdensome on patient access to the drug, considering in particular–
>
> (i) patients with serious or life-threatening diseases or conditions; and
>
> (ii) patients who have difficulty accessing health care (such as patients in rural or medically underserved areas)….[9]

Although the FDA may have decided 15 years ago that the balance of risk and burden came out in favor of restricting mifepristone's indicated use and distribution, today both science and the current conditions surrounding patient access to abortion care call strongly for a reevaluation of the mifepristone label and REMS restrictions, especially its Elements to Assure Safe Use (ETASU).

We support the following changes to the mifepristone label:

- The drug should be indicated for use in medication abortions beyond 49 days gestation.
- The recommended dose regimen should be mifepristone 200 mg followed 24-48 hours later by misoprostol 800 mcg.
- The location where the patient should take these drugs should not be restricted.
- An in-person visit should be indicated as not always necessary for follow-up assessment.
- Any licensed health care provider should be able to prescribe the drug.

We expand below upon further specific changes that should be made based on scientific evidence of mifepristone's safety and efficacy, as well as the numerous burdens on patients' access to abortion care that would be greatly alleviated if the REMS were eliminated and the gestational age indication in the label were increased to 70 days.

1. **Eliminate the REMS and ETASU for mifepristone.**
   a. **Expand dispensing venues.** The ETASU state that mifepristone may only be dispensed to patients in a clinic, medical office, or hospital, and not through pharmacies.[10] The Technical Letter discusses why this requirement is not medically warranted. The requirement should be removed entirely, so that mifepristone can also be distributed via retail pharmacies like other prescription medications, in addition to being directly distributed to providers.

      This requirement significantly curtails mifepristone's potential to expand patient access to abortion care. The up-front costs (including substantial costs for pre-ordering the drug) and logistical requirements (e.g., increased staffing at provider offices) are a burden to providers and, therefore, deter some health care providers from offering medication abortion. When fewer providers are willing to stock mifepristone in their offices because of the REMS and ETASU, fewer patients can access medication abortion. In some cases this requirement may also force the patient to make an unnecessary visit to a clinic, medical office, or hospital to pick up the medication, rather than being able to pick up an order called into a pharmacy. This requirement is especially significant in underserved and rural areas where access to a health care provider is already difficult, and for those with low incomes for whom taking off work or getting to a provider multiple times in short order is impossible due to cost or family needs.[11] The Turnaway Study, a prospective longitudinal study conducted by Advancing New Standards in Reproductive Health (ANSIRH) at the University of California-San Francisco examining the effects of unintended pregnancy on individuals' lives, demonstrates that the majority of people who seek abortion care are already in difficult financial situations, and are

disproportionately people of color.[12] Costly and unnecessary visits to the doctor significantly increase financial and logistical burdens for these individuals and communities.

Any venue expansion, however, should not preclude the direct distribution of mifepristone to providers who want to dispense from their clinical settings. In many places, pharmacy refusal laws allow pharmacists to decline to fill prescriptions for reproductive health drugs such as emergency contraception and birth control, and federal policy allows providers to refuse to provide abortions.[13] So, although pharmacists' ability to dispense mifepristone would expand patient access to medication abortion in places where providers cannot easily store mifepristone in their offices, providers should retain the option to have mifepristone directly distributed to their offices to ensure continued access to medication abortion for those living in places where pharmacists can refuse to fill mifepristone prescriptions.

b. **Eliminate the Prescriber Agreement certification requirement.** Under the REMS and ETASU, providers must have a physician supervisor submit a Prescriber Agreement form to the drug's distributor attesting: 1) that mifepristone will only be provided by or under the supervision of a physician; and 2) that the physician can assess pregnancy duration, 3) diagnose ectopic pregnancies, and 4) make a plan for a patient to have surgical intervention if necessary.[10] This requirement should be eliminated for several reasons:

i. *The Prescriber's Agreement is unnecessary for the safe dispensation of mifepristone.* As the Technical Letter explains, health care professionals are already subject to many laws, policies, and ordinary standards of practice that ensure they can accurately and safely understand and prescribe medications. Provider certification is not required for health care professionals to dispense other drugs, including drugs that carry black box, or boxed, warnings about their medical risks. Accutane, for example, has a boxed warning that describes the potential risks of the drug,[14] but Accutane prescribers are not required to submit a certification form in order to prescribe it. Mifeprex also has a boxed warning[15] and there is no medical reason for a Prescriber's Agreement to be required in addition.

ii. *The Prescriber's Agreement forces providers to identify themselves as abortion providers to a centralized entity (Danco Laboratories) inspected and regulated by the FDA, which could discourage some from offering medication abortion care to their patients*. In 2014, more than half of U.S. health care facilities that provide abortions (52%) experienced threats and other types of targeted intimidation, and one in five experienced severe violence, such as blockades, invasions, bombings, arsons, chemical attacks, physical violence, stalking, gunfire, bomb threats, arson threats, or death threats.[16] Robert Dear's November 27, 2015, standoff at a Planned Parenthood health center in Colorado, which resulted in three deaths, provides one recent and chilling example of anti-abortion violence.[17] Given such escalating harassment and violence against known abortion providers,[18] clinicians may be understandably reluctant to add their names to a centralized database of mifepristone providers.

iii. *The Prescriber's Agreement would be incompatible and unnecessary if there were an expanded distribution system*. If dispensing venues are expanded as proposed in section 1a, ordinary standards of practice and state regulations would govern pharmacists' and providers' distribution of mifepristone, and a specific certification process would be unnecessary. Furthermore, a distribution system that incorporates the Prescriber's Agreement would be extremely difficult to maintain as a practical matter. Pharmacists would need to check the certification status of each prescriber before filling a prescription, which they do not normally have to do when filling other prescriptions.

Alternatively, pharmacists would need to become certified providers themselves, thus facing the deterrence problem of adding their names to a centralized database of mifepristone providers.

iv. *The Prescriber's Agreement as currently written prevents independent non-physician prescribers from being able to prescribe mifepristone without supervision by a physician*. The Prescriber's Agreement currently states that mifepristone "must be provided by or under the supervision of a physician."[19] However, nowhere in the outline piece of the REMS document written by the FDA is the word "physician" used. The REMS references only "providers" and "prescribers." [10] The Prescriber's Agreement's narrow interpretation of the REMS is medically unnecessary and severely limits patients' access to medication abortion care, because non-physician providers must work under physician supervision to prescribe mifepristone. All states give certain advanced practice clinicians prescribing authority, including for controlled substances, and 27 states allow them to dispense medications directly.[20] Advanced practice clinicians provide an increasing proportion of basic health care in the U.S., and several states authorize these clinicians to provide abortion care. If the Agreement is not eliminated, then at least enlarging the pool of health care providers that can submit the Prescriber's Agreement would help improve access and be consistent with individual state law regarding scope of practice. If the FDA does not eliminate the Agreement altogether, it should make clear that any licensed health care provider with prescribing authority is also eligible for certification to prescribe mifepristone.

c. **Remove the confusing and unnecessary Patient Agreement.** The REMS requires that each patient sign a Patient Agreement form before receiving mifepristone. This requirement is medically unnecessary and interferes with the clinician-patient relationship. It should be eliminated entirely.

In addition to being outdated and inconsistent with requirements for drugs with similar safety profiles, the Patient Agreement creates confusion for patients. Except in the few states that require that patients follow the regimen that appears on the mifepristone label, the majority of clinicians use an evidence-based regimen that is different from the regimen described in the label. Requiring a patient to sign an agreement to a treatment plan that differs from the one prescribed by her provider is confusing and could undermine trust in the clinician.

Patients have been using mifepristone safely and effectively according to evidence-based regimens recommended by their clinicians for many years, diverging from the regimen described in the Patient Agreement.[3] A wealth of data and experience since mifepristone's approval have demonstrated that this drug is extremely safe, that clinicians with routine professional training can provide it appropriately, and that patients are able to use it as directed by their health care provider.[21,22] Requiring a patient to sign an agreement to a treatment plan that differs from the one prescribed by her provider may create unnecessary confusion.

d. **Allow evidence-based follow-up assessment.** Under the Federal Food, Drug, and Cosmetic Act, the FDA should ensure that a REMS does not unduly burden patients, especially those in rural or medically underserved areas.[9] However, the documents appended to the REMS (the Medication Guide, Prescriber's Agreement, and Patient Agreement) all indicate the patient should to return to the clinic for follow-up 14 days after the patient takes mifepristone.[10] Such an in-person appointment is not always medically necessary and, when required, creates significant additional costs for patients, who must find time for another appointment at the provider's office and potentially incur substantial costs for travel, childcare, and/or lost wages.

These burdens are often increased for patients living in rural and other medically underserved areas. In 2008, 33% of all abortion patients traveled more than 25 miles to obtain care, and 74% of all patients living in rural areas traveled at least 50 miles to obtain the procedure.[23] Medical technology and telemedicine have advanced considerably since 2000,[24] and a growing body of evidence shows that alternatives to in-person follow-up, such as serum chorionic gonadotropin (hCG), multi-level pregnancy tests, and telephone counseling are safe, effective, and improve access and satisfaction for patients.[25,26,27]

2. **Increase the gestational age for indicated use on the label.**
The current label indicates use of mifepristone through 49 days after the start of the patient's last menstrual period (LMP). The Technical Letter discusses the substantial evidence demonstrating that the evidence-based medication abortion regimen is highly effective later than 49 days LMP, through at least the 10th week (64-70 days) of gestation.[28,29,30] The National Abortion Federation's (NAF) annual *Clinical Policy Guidelines*, which NAF develops by consensus based on a rigorous review of current medical literature and known patient outcomes, recommend that an evidence-based medication abortion regimen be used through 70 days LMP.[31] The time between 49 and 70 days LMP is critical for patient access, as approximately 30% of women who seek an abortion present for care during this time, according to the Centers for Disease Control.[32]

Consider the current legal and social climate

The overall legal and social climate around abortion care intensifies all of the burdens that the mifepristone REMS places on patients and makes it even more critical that the FDA lift medically unnecessary restrictions on the drug. Since mifepristone's approval, a multitude of laws and regulations at the federal and state level have dramatically restricted access to abortion care. In the first five years of this decade alone, states enacted 288 abortion restrictions – more than the entire previous decade.[33] These restrictions are typically unsupported by medical evidence and serve only to reduce access to abortion care.[34] In 2000, the Guttmacher Institute, a nonpartisan research and policy organization that seeks to advance sexual and reproductive health and rights and ensure the highest standard of sexual and reproductive health care, considered 13 states to be hostile to abortion, meaning that those states had 4-5 types of restrictions on abortion. In 2014, the number of states considered hostile had more than doubled, now including more than half of all states. [34]

Providers have increasingly been forced to close their doors as a result of mounting restrictions. There were about 1,800 abortion providers in the U.S. in 2000. Stand-alone abortion clinics constituted 447 (25%) of all providers in 2000, and those clinics provided 71% of all abortions.[35] By 2008, only 378 abortion clinics were still providing 70% of abortions.[36] Abortion clinic closures have accelerated since 2008, as lawmakers began passing restrictions at an unprecedented rate.[37] The Associated Press estimated in June 2015 that 70 abortion clinics had closed in a dozen states since 2010.[38] This wave of state restrictions and clinic closures has continued unabated in the last five years.

Some of these measures specifically block access to medication abortion by invoking the FDA-approved label. North Dakota, Ohio, and Texas currently require mifepristone to be administered solely according to the regimen that appears on the FDA label.[39] The Arkansas legislature just passed a similar law in 2015, though a federal judge issued a temporary restraining order blocking enforcement of the law until a hearing on March 14, 2016.[40] In these states, mifepristone cannot be prescribed in accordance with evidence-based practices developed in the last 15 years,[*] which improve patient access in multiple ways:

- enabling patients to take a lower dose of mifepristone, resulting in fewer side effects and lower cost;

[*]The one deviation that Texas allows from the label is one other dosage amount of Mifeprex and misoprostol.[39]

- allowing patients to take mifepristone, misoprostol, or both at home, and/or confirm termination of pregnancy at home, resulting in fewer visits to the provider;
- and offering medication abortion to patients later than 49 days LMP. [3]

Studies have also shown that these "label laws" have had a negative impact on patient access to abortion. For example, a recent study showed that after passage of laws that restricted use of mifepristone to the FDA label in Texas and Ohio, medication abortion declined dramatically while it rose in New York and California, states without restrictive laws.[41] Furthermore, these laws run counter to the FDA's own guidance, which states that a "package insert is informational only."[42,43,44] As long as the FDA-approved label diverges from evidence-based regimens, states can hide behind it as they restrict access to abortion. If the FDA does not update mifepristone's label to reflect the most current, evidence-based practice, the number of women adversely affected will only increase as additional states pass laws to exploit this discrepancy.

Other state restrictions are not specific to medication abortion, but affect all kinds of abortion care, including access to mifepristone. These medically unnecessary restrictions include the following: requirements that facilities where abortion is provided meet standards for ambulatory surgical centers; physician admitting privileges at local hospitals; and requirements that the patient and prescribing clinician must be in the same physical location, prohibiting the use of telemedicine technology. On top of these legal restrictions, anti-abortion stigma, harassment, and violence deter many health care professionals from providing abortion care. Authorizing distribution of mifepristone in pharmacies could diminish the impact of these barriers and allow providers to offer abortion care without fear of retaliation.

These restrictions, and the concomitant politicization and stigmatization of abortion care, have also seeped into other aspects of health care and prevented progress on the use of mifepristone for other indications. Removing the REMS program would make mifepristone more readily available for non-abortion therapies as well.[45,46]

In summary, the burdens on patient access to medication abortion, exacerbated by the REMS requirements placed on mifepristone, strongly outweigh any medical risk to the patient associated with the drug. In this climate of legal restrictions, clinic closures, and mounting stigma, it is increasingly important that any regulation of mifepristone be based solely on medical evidence, rather than the discretion of politicians who are determined to restrict access to abortion at any price. We recognize that the FDA is not responsible for most restrictions on abortion access. However, whenever the FDA evaluates indications and restrictions on an approved product, it does so in the context of the real-world circumstances in which the product is sold and the condition is treated. We believe this is vital in the case of mifepristone in particular, where the broad landscape of laws regulating abortion has measurable negative impact on the clinical provision of abortion care.

Mifepristone continues to hold immense promise for patient access to a safe and effective early abortion option, but medically unnecessary regulations are impeding its full potential. Extensive scientific and clinical evidence of mifepristone's safety and efficacy, and the ever-increasing burden on patient access to abortion care, clearly demonstrate that mifepristone's REMS program is not needed to protect patients. In light of the FDA's statutory mandate from Congress to consider the burden caused to patients by REMS, and the agency's own stated commitment to ensuring that drug restrictions do not unduly burden patient access, we ask that the FDA lift mifepristone's REMS and amend the label to extend the indicated use to 70 days.

Sincerely,

Advancing New Standards in Reproductive Health (ANSIRH), Department of Obstetrics, Gynecology & Reproductive Sciences, University of California, San Francisco
American Civil Liberties Union
Association of Reproductive Health Professionals
Bixby Center for Global Reproductive Health, Department of Obstetrics, Gynecology & Reproductive Sciences, University of California, San Francisco
Cambridge Reproductive Health Consultants
Carafem
Center for Reproductive Rights
Center on Reproductive Rights and Justice at the University of California, Berkeley, School of Law
Feminist Majority Foundation
Guttmacher Institute
Gynuity Health Projects
Ibis Reproductive Health
Jacobs Institute of Women's Health
Legal Voice
Medical Students for Choice
NARAL Pro-Choice America
National Abortion Federation
National Advocates for Pregnant Women
National Institute for Reproductive Health
National Latina Institute for Reproductive Health
National Network of Abortion Funds
National Partnership for Women and Families
National Women's Health Network
National Women's Law Center
Planned Parenthood Federation of America
Physicians for Reproductive Health
Provide
Reproaction
Reproductive Health Technologies Project
Society of Family Planning

cc:
Valerie Jarrett, Chair, White House Council on Women and Girls
Tina Tchen, Executive Director, White House Council on Women and Girls
Jordan Brooks, Deputy Executive Director, White House Council on Women and Girls
Nancy C. Lee, M.D., Deputy Assistant Secretary of Health, Women's Health, Director of the Office on Women's Health, Department of Health and Human Services
Bobby Clark, Counselor for Public Health and Science, U.S. Department of Health and Human Services, Office of the Secretary

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[6] Report to the U.S. Government Accountability Office: Approval and Oversight of the Drug Mifeprex. *U.S. Food and Drug Administration* August 2008;GAO-08-751:20-24. Washington, DC: U.S. Government Accountability Office. http://www.gao.gov/new.items/d08751.pdf. Accessed December 21, 2015.
[7] Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110–85, § 909(b)(1), 121 Stat 823 ("(1) A drug that was approved before the effective date of this Act is, in accordance with paragraph (2), deemed to have in effect an approved risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act").
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[43] Agency Request for Comments: Citizen Petition Regarding the Food and Drug Administration's Policy on Promotion of Unapproved Uses of Approved Drugs and Devices, 59 Fed. Reg. 59820-01 (Nov. 18, 1994) ("FDA has long recognized that physicians and other health care professionals may prescribe approved therapies for unapproved uses").
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EXHIBIT 47

The FDA and RU-486: Lowering the Standard for Women's Health: Hearing Before the Subcomm. on Crim. Just., Drug Pol'y, & Hum. Res. of the H. Comm. on Gov't Reform, 109th Cong. 4 (2006)

UNITED STATES HOUSE OF REPRESENTATIVES
GOVERNMENT REFORM COMMITTEE

OCTOBER 2006

THE FDA AND RU-486: LOWERING THE STANDARD FOR WOMEN'S HEALTH

STAFF REPORT

PREPARED FOR THE HON. MARK SOUDER
CHAIRMAN, SUBCOMMITTEE ON CRIMINAL JUSTICE,
DRUG POLICY AND HUMAN RESOURCES

B-377 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, D.C. 20515
(202) 225-2577

WWW.REFORM.HOUSE.GOV/CJDPHR

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I. EXECUTIVE SUMMARY

This report explores the Food and Drug Administration's activities as they relate to RU-486 – the abortion pill – including the highly unusual process by which the drug was approved, the failures to ensure that the drug is dispensed as the Food and Drug Administration (FDA) requires, the subsequent illnesses, hospitalizations and deaths known to be associated with the drug and the failure to provide any meaningful restrictions despite evidence of its association with a 100% fatal septic infection.

On May 17, 2006, Congressman Mark Souder, Chairman of the Subcommittee on Criminal Justice, Drug Policy and Human Resources ("Subcommittee"), House Committee on Government Reform, convened a hearing to inquire into the safety of the FDA-approved drug Mifeprex (the trade name for mifepristone) commonly known as RU-486. The hearing was entitled, "RU-486 - Demonstrating a Low Standard for Women's Health?" The Subcommittee's hearing followed several months of investigative inquiries with the FDA after the Agency's July 2005 disclosure that four women had died of a septic infection after taking RU-486 to induce an abortion.[1]

This Subcommittee Staff Report ("Report") provides background information about RU-486, including the reasons the drug was brought to market. It also explores the allegation that FDA disregarded various statutes and rules in the RU-486 approval process, and it examines RU-486's safety record in the United States. The accumulation of safety data from "real world" use of the drug in America has allowed Subcommittee investigators to more completely grasp FDA's understanding of the risks posed by RU-486 when it approved the drug on September 28, 2000.

Based on the significant demonstrated danger this drug poses to women, the Report examines options for withdrawing this drug from the market.

II. BACKGROUND

RU-486 is the common name for mifepristone, which in the United States is marketed under the trade name Mifeprex. Shanghai HuaLian Pharmaceutical Co., Ltd.[2] of China produces the drug, which is imported and distributed by Danco Laboratories, [3] a corporate entity located in the Caribbean nation of the Cayman Islands. RU-486, Danco's sole product, [4] is approved for the

[1] FDA Public Health Advisory: Sepsis and Medical Abortion, July 19, 2005. Available at http://www.fda.gov/cder/drug/advisory/mifeprex.htm (last visited October 14, 2006).

[2] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Senator Jim DeMint (August 11, 2006) (on file with Subcommittee).

[3] *See, Foes criticize Chinese manufacture of abortion pill for U.S.*, CNN.com, (Oct. 13, 2000) at http://archives.cnn.com/2000/HEALTH/women/10/13/abortionpill.plant.ap/index.html (last visited October 10, 2006).

[4] Unlike other drug companies with multiple products that are approved by or in application before the FDA--and which therefore cooperate with the FDA to withdraw drug products when recognizable problems arise--Danco has

termination of an established pregnancy through 49 days development (LMP),[5] when used in conjunction with the prostaglandin, misoprostol.[6]

RU-486 terminates pregnancy by blocking progesterone receptors in the uterus, a hormone necessary for the maintenance of pregnancy.[7] This leads to degeneration of the uterine lining, blocking nutrition to the prenate, thus resulting in its death.[8] Mifeprex is used in combination with a prostaglandin called misoprostol, which causes contractions that expel the contents of the uterus.[9] This is an off-label use for misoprostol, which contains an FDA-mandated black-box warning against using the drug during pregnancy.[10]

Under the protocol approved by the FDA – one considerably less stringent than the agency's proposed protocol leaked to the public a few months prior to approval – if the patient is

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no other products for which it must be answerable to the FDA. *See also,* Rogoff, Natasha L, *Haven or Havoc?*, PBS Frontline, February 19, 2004 at http://www.pbs.org/wgbh/pages/frontline/shows/tax/schemes/cayman.html.

[5] FDA Approval Memo (September 28, 2000); "LMP" refers to the first day of the last menstrual period, and is the customary measure of gestational age, from approximately 14 days pre-fertilization of the conceptus.

[6] The FDA examined misoprostol to see if the deadly *Clostridium Sordellii* bacteria that killed four California women after taking RU-486 was associated with misoprostol, rather than the Mifeprex: "An FDA Public Health Advisory in mifepristone dated July 22, 2005 reported 4 cases of septic death in California following the use of mifepristone and intravaginal misoprostol for medical abortion. For this reason, DRUP [Division of Reproductive and Urologic Products] and DDRE [Division of Drug Risk Evaluation] met on July 19, 2005, to discuss searches of the AWRS database to further investigate this cluster of repo0rts. At this meeting, DDRE agreed to provide 3 consults to examine this issue… The proposed consults were as follows:

- Consult #1: Review of all reports of serious infections with misoprostol in women of childbearing age
- Consult #2: Review of all reports for suspected intravaginal products with a fatal outcome
- Consult #3: Review of all serious, unusual infections with intravaginal products."

"This review did not identify any new safety signal associated with intravaginal product administration, especially in regards to infection or pregnancy status." FDA Office of Drug Safety Postmarketing Safety Review, December 8, 2005 (on file with the Subcommittee).

The FDA also tested the manufacturing lots from which the misoprostol was distributed and eliminated that drug product as a source of contamination that would have caused the fatal *C. Sordellii* infections. *See* Marc Fischer, M.D., M.P.H., CDC, *Clostridium sordelli Toxic Shock Syndrome Following Medical Abortion*, Public Workshop on Emerging Clostridial Disease," (CDC Conference Center: Atlanta, Georgia, May 11, 2006). Available at http://www.fda.gov/cder/meeting/clostridial/fisher.pdf (last visited October 20, 2006).

[7] See., e.g., University of Chicago Department of Obstetrics and Gynecology, Information on Hormonal Imbalance, available at http://babies.bsd.uchicago.edu/endo/hormoneImbalance.htm (last visited October 10, 2006).

[8] Etienne-Emile Baulieu, "RU-486 as an Antiprogesterone Steroid: From Receptor to Contragestion and Beyond," *Journal of the American Medical Assn*. 262:13; 1808-1814 (October 6, 1989).

[9] Pfizer (along with their generic subsidiary) and Teva Pharmaceuticals, the makers of misoprostol, have never filed a New Drug Application to seek approval from the FDA for its use in abortion. It was approved for use with ulcers, and is contraindicated for pregnancy. Pfizer's German affiliate recently pulled the drug from the market.

[10] Cytotec (misoprostol) Full Revised Label, April 17, 2002, available at www.fda.gov/cder/foi/label/2002/19268slr037.pdf (last visited October 10, 2006).

found to be a candidate for a chemical abortion (according to criteria such as gestational age of 49 days or less, absence of ectopic pregnancy and a host of health contraindications), she is given 600 mg of Mifeprex to consume at once and instructed to return two days later to consume orally 400 mcg of misoprostol. Patients are further instructed to return in 14 days for a follow-up, which could include a surgical abortion in the three percent to 7.9% of cases in which the chemical abortion fails.[11]

Many providers, however, deviate from the FDA protocol, extending the RU-486 abortion cut-off to 56 and even 63 days' gestation,[12] cutting the dose of Mifeprex by two-thirds, and handing the patient misoprostol pills to insert vaginally at home two days later.[13] Failure rates at these gestational ages are approximately 17% and 23% respectively.

In the decade preceding FDA approval of RU-486 for use in the United States, advocates of RU-486 promoted the drug as a private, easy, safe and effective method of pregnancy termination,[14] offering women the choice of ending pregnancy at an earlier stage and in a less "invasive," instrumented manner, when compared to surgical and suction abortion methods.[15] In sum, the public was told that access to RU-486 had everything to do with women's privacy and choices.

Cited as justification for RU-486 approval and use were the following goals: "defusing the abortion conflict,"[16] putting abortion "into the medical mainstream and out of this ghettoized place it's been in,"[17] making "abortion … more socially acceptable,"[18] "expanding the number

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[11] See Mifeprex Label ("Medical abortion failures should be managed with surgical termination." Also, "Each patient must understand…that medical abortion treatment failures are managed by surgical termination.") at http://www.fda.gov/cder/foi/label/2005/020687s013lbl.pdf (last visited October 10, 2006).

[12] Some abortion providers (e.g., Planned Parenthood of New York City at www.ppnyc.org/services/factsheets/mifep.htm, Capital Care Women's Center at www.capitalcarewomenscenter.com/services.php, and Camelback Family Planning at www.camelbackfamilyplanning.com/abortionpill.html.), even advertise the availability of RU-486 through 63 days LMP, by which time the rate of incomplete abortion, infection, and other complications rises sharply. In U.S. clinical trials, the failure rate for RU-486 abortions jumps to 17% at 50-56 days LMP, and to 23% at 57-63 days LMP, from 8% at 49 days or less. Irving Spitz *et al*., "Early pregnancy termination with mifepristone and misoprostol in the United States," *New England Journal of Medicine* 1998, 338:1241-47.

[13] Evidence of this method deviation can be found in many Adverse Event Reports, including those reporting on the deaths of four California women from toxic shock related to *C. Sordellii.*

[14] Lawrence Lader. RU486: The Pill that Could End the Abortion Wars and Why American Women Don't Have It. Reading, Mass.: Addison-Wesley Publ. Co., 1991, 17-26.

[15] Planned Parenthood of New York City Press Release, December 4, 2000: "Women will now have access to this option of a very safe, early abortion without undergoing an invasive procedure. … By allowing women to take part in their own care, mifepristone offers women more privacy in their decisions and control over their bodies."

[16] Margaret Talbot, "The Little White Pill," *New York Times Magazine*, July 11, 1999, quoting Seattle abortion provider Suzanne Poppema, M.D.

[17] *Ibid*, quoting Carole Joffe, professor of sociology, University of California-Davis.

[18] *Ibid*.

of abortion providers"[19] and even advancing the U.S. aim of "population control"[20] in the developing world. One vocal advocate explained: "Abortion in the U.S. is this degraded, shameful, violence-surrounded thing. …It's not like that in Europe. So that makes our context for medical [e.g., RU-486] abortion unique."[21] Safety and efficacy questions were brushed aside with assurances that several hundred thousand women in France and China had already used RU-486 to induce abortion.[22]

One might reasonably wonder why, when the surgical option is readily available and exponentially safer,[23] the FDA would approve, or the abortion industry would support, a chemical procedure that subjects women to increased pain and risk. To answer this question, it is helpful to understand abortion industry fears concerning the dwindling number of providers, and to assess the industry's leverage and access within the FDA.

The National Abortion Federation reported in May 2004 that the "number of abortion providers has declined by 37% since 1982."[24] In 1997, 36% of ob/gyns reported ever performing elective abortions.[25] Among them, 57% were fifty years of age or older and another 30% were 40 or older.[26] In other words, the abortion industry perceived that—unless drastic measures were taken—it was in danger of losing nearly 57% of its doctors by 2012 and 87% of its doctors by 2022, significantly reducing the availability of abortion in the United States.[27]

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[19] Margaret Talbot, "The Little White Pill," *New York Times Magazine*, July 11, 1999, quoting Seattle abortion provider Suzanne Poppema, M.D.

[20] Nathanson, Bernard, "Drugs for the Production of Abortion: A Review," Obstet & Gyn Survey 25:8; 727-731 (1970); Renate Klein *et al*., RU 486: Misconceptions, Myths and Morals. Melbourne, Aus.: Spinifex Press, 1991 The book is out of print, but the full text is available at http://www.spinifexpress.com.au/non-fict/ru486.htm (last visited October 20, 2006) at 59: "It is a further misconception to believe that this [RU-486] research took place in order to expand or improve women's 'choices' to control their reproduction. Quite unmistakenly, the concept evolved as a means of population control. More than 20 years ago, the Center of Population Research of the U.S. National Institutes of Health became interested in the corpus luteum and called for research to determine whether to find 'means to inhibit corpus luteum function is a desirable goal'. The specific intention of such research was to restrict population growth in countries that were judged to be 'under-developed.' If successful, the method(s) could be extended to groups in the United States, Black, Hispanic and Native American Women (Department of Health, Education and Welfare, NIH, USA, 1969)."

[21] Margaret Talbot, "The Little White Pill," *New York Times Magazine*, July 11, 1999, quoting Carole Joffe, professor of sociology, University of California-Davis.

[22] Lawrence Lader. A Private Matter: RU-486 and the Abortion Crisis. Amherst, N.Y.: Prometheus Books, 1995, 115-117.

[23] The Alan Guttmacher Institute, an affiliate of Planned Parenthood, reports that the mortality rate for women who procure a surgical abortion is 0.1 in 100,000 during the first eight weeks of pregnancy, the period for which RU-486 is available for women. Dr. Michael Green, based on usage rates of 460,000 and 4 deaths, suggested that the risk of death from chemical abortion is ten times greater. *See,* Michael F. Green, M.D., *Fatal Infections Associated with Mifepristone-Induced Abortion*, Dec. 1, 2005, N. ENGL. J. MED 353;22 *at* 2318.

[24] Abortion Access Project, Fact Sheet: The Shortage of Abortion Providers, May 6, 2004, available at www.abortionaccess.org/AAP/publica_resources/fact_sheets/shortage_provider.htm (last visited October 10, 2006).

[25] Kaiser Family Foundation, *Abortion*, Issue update, Menlo Park, CA: Kaiser Family Foundation, May 1999.

[26] *Ibid.*

[27] Lawrence B. Finer and Stanley K. Henshaw, "Abortion Incidence and Services In the United States in 2000," Perspectives on Sexual and Reproductive Health, 2003, 35(1):6-15.

The industry, then, out of concern for its own preservation, pinned its hopes on chemical abortion. A Kaiser Family Foundation survey, for example, noted: "Many reproductive health groups in the U.S. have looked to widespread availability and marketing of mifepristone … to expand access to abortion in this country."[28] Pediatrician Eric Schaff, who oversaw at least one RU-486 trial, put the matter somewhat more crudely. Objecting to an FDA proposal (never formally adopted) that any doctor dispensing RU-486 would have to be trained in surgical abortion, Dr. Schaff explained, "The whole idea of [RU-486] was to increase access. … [The FDA proposal] kills the drug if it can't be used by primary care providers."[29]

Despite the problems associated with RU-486 (discussed in depth in Section III, below), it looked like a panacea for the abortion industry. Advocates predicted that the number of providers would increase. The Kaiser Family Foundation stated that one-third of all ob/gyns who did not perform abortions said they would be "very" or "somewhat" likely to prescribe mifepristone for abortions if approved by the FDA.[30] Furthermore, rather than limiting abortion procedures to medical doctors alone, advocates saw an opportunity for nurse practitioners, nurses, and others to administer abortions to women.[31]

In June 1989, one year after its introduction into the French market, the FDA issued an import alert on RU-486. The concern was that women would obtain the drug themselves and use it without support from a physician. The wisdom of this policy is supported by the fact that, as the RU-486 label states, nearly *all* users of RU-486 will experience adverse events.[32] But it wasn't long before Democrats, led by then-Representative Ron Wyden of Oregon, seized this opportunity to politicize the approval process.

Under the auspices of the Committee on Small Business's Subcommittee on Regulation, Business Opportunities and Energy, as early as September 18, 1990, Representative Wyden was investigating the FDA's import alert on RU-486, alleging that the FDA's overriding concerns for the alert were political, rather than medical, and that the actions of the FDA were preventing cures for several diseases, including breast and brain cancer, Cushing's disease, glaucoma and

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[28] Kaiser Family Foundation, News Release, June 8, 2000, available at www.kff.org/womenshealth/20000613a-PressRelease2.cfm (last visited October 10, 2006).

[29] Sheryl Gay Stolberg, "F.D.A. Adds Hurdles in Approval of Abortion Pill," *New York Times*, June 8, 2000.

[30] Kaiser Family Foundation, News Release, June 8, 2000, available at www.kff.org/womenshealth/20000613a-PressRelease2.cfm (last visited October 10, 2006).

[31] Press release, Ibis Reproductive Health, the National Abortion Federation, and the Abortion Access Project, May 9, 2006, available at www.prochoice.org/news/releases/20060509.html (last visited October 10, 2006).

[32] Mifeprex Label, available at http://www.fda.gov/cder/foi/label/2005/020687s013lbl.pdf (last visited September 28, 2006): "Nearly all of the women who receive Mifeprex and misoprostol will report adverse reactions, and many can be expected to report more than one such reaction."

diabetes. Two hearings in his committee followed, one in November of 1990[33] and another in December, 1991.[34]

Following these hearings, Representative Wyden introduced legislation to prohibit the FDA from taking any action to bar the import of RU-486 unless the FDA finds that it is being imported for an illegal use.[35]

It is interesting to contrast the interests of Representative Wyden and the abortion industry with the concerns of the American Medical Association (AMA), which offered this view about the health and safety of women who might obtain and use RU-486 without a physician's supervision:

> "[I]t is the AMA's understanding that RU-486 poses a severe risk to patients unless the drug is administered as part of a complete treatment plan under the supervision of a physician…Rumors exist that the FDA, due to political pressure, is standing in the way of research on RU-486. We do not believe this to be true. On the contrary, it is the FDA's responsibility to ban a drug that has not met legal and regulatory requirements for importation into the United States. Because RU-486 has not met these requirements, the FDA complied with its charge and acted well within its authority in issuing its June 9, 1989, automatic detention import alert concerning the drug."[36]

In the meantime, women's groups orchestrated an offensive consisting of media stunts to exert political pressure on the FDA. Lawrence Lader, founding chairman of the then-National Abortion Rights Action League (NARAL), and Ms. Leona Benton, who volunteered to serve as a "test case," traveled to Europe to acquire RU-486 with the specific purpose of being apprehended by Customs agents when they returned on July 1, 1992.[37] Agents seized the pills, and 45 members of the press showed up to publicize her "plight."

Ms. Benton immediately filed suit against the FDA in federal district court (Brooklyn), and Judge Charles Sifton ruled in her favor on July 14. Before she could physically recover the confiscated pills, however, government attorneys filed an appeal with the U.S. Court of Appeals for the Second Circuit, where a three-judge panel reversed Judge Sifton's order. The U.S. Supreme Court accepted an expedited appeal and, on July 17, ruled 7-2 against releasing the

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[33] *RU-486: The Import Ban and its Effect on Medical Research: Hearing before the House Subcommittee on Regulation, Business Opportunities and Energy, Committee on Small Business*, 101st Cong. (Nov. 19, 1990).

[34] *Safety and Effectiveness of the Abortifacient RU-486 in Foreign Markets: Opportunities and Obstacles to U.S. Commercialization: Hearing before the House Subcommittee on Regulation, Business Opportunities and Energy, Committee on Small Business*, 101st Cong. (Dec. 5, 1991).

[35] H.R. 875 "RU-486 Regulatory Fairness Act of 1991," introduced February 6, 1991.

[36] *RU-486: The Import Ban and its Effect on Medical Research: Hearing before the House Subcommittee on Regulation, Business Opportunities and Energy, Committee on Small Business*, 101st Cong. (Nov. 19, 1990) (statement of Dr. John P. Seward, Board Member, American Medical Association).

[37] Lawrence Lader, A Private Matter: RU 486 and the Abortion Crisis. Amherst, N.Y.: Prometheus Books, 1995, 135-136.

pills.[38] In the interim, she and Lawrence Lader gained widespread publicity concerning RU-486 in the media. She had a surgical abortion.[39]

In that same month, Public Media Video released a documentary financed by the Chicago abortion advocacy group, Women's Issues Network, entitled, "Science Held Hostage: RU-486 and the Politics of Abortion," hosted by Cybil Shepard. They held a screening on Capitol Hill.

In the six years since approval, mounting evidence points unavoidably to one conclusion: the political motivations for bringing RU-486 to the U.S. market overwhelmed considerations of women's health and safety.

In a September 28, 2000 interview following the announcement of the FDA's approval of RU-486, then-FDA Commissioner Dr. Jane E. Henney stated: "Politics had no role in this decision."[40] That assurance has been called into question by documents made public this year which reveal the Clinton Administration's vigorous role from 1993 forward[41] in facilitating the abortion drug's entry and approval. The actors behind these documents approached approval as a matter of logistics rather than as involving an open-minded scientific inquiry. One memorandum goes so far as to advise the Administration on how to contextualize the anticipated FDA approval of the drug in terms of "promoting women's health and maintaining the close relationship of the Administration to these [pro-choice women's] groups."[42]

However, had the FDA undertaken a thorough review of the scientific literature evaluating RU-486/prostaglandin abortions before approving RU-486, the agency would have been alerted to paramount safety concerns. Certainly, the FDA Medical Officer's Review, discussed in detail below, falls short of endorsing the safety of RU-486. Even so, only two additional studies are referenced in the Medical Officer's Review[43] apart from discussion of the U.S. clinical trials and the two so-called "pivotal French trials" conducted by the manufacturer. In light of this omission, and more significantly, in light of the FDA's approval of RU-486, one wonders why numerous studies demonstrating the inherent risks to women who undergo RU-486 abortions did not appear to influence the FDA's decision to approve RU-486.

And, in fact, such a thorough review of medical and scientific literature on RU-486 had already been published in 1991 by three women who describe themselves as pro-choice

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[38] *Benten v. Kessler*, 505 U.S. 1084 (1992).

[39] *Ibid*., at 139.

[40] Gina Kolata, "U.S. Approves Abortion Pill; Drug Offers More Privacy, and Could Reshape Debate," *The New York Times*, September 29, 2000.

[41] See, various documents compiled by Judicial Watch, Inc.. and appended to "A Judicial Watch Special Report: The Clinton RU-486 Files," April 26, 2006, available at http://JudicialWatch.org/archive/2006/jw-ru486-report.pdf.

[42] HHS Chief of Staff Kevin Thurm, Memorandum to White House Director of Public Policy Carol Rasco, Subject: RU-486, dated May 11, 1994.

[43] Beverly Winikoff *et al*., "The Acceptability of Medical Abortion In China, Cuba and India," *Int Fam Plan Perspect*. (1997) 23:73-78 & 89; and J.T. Jensen *et al*., "Outcomes of Suction Curettage and Mifepristone Abortion in the United States," *Contraception* (1999): 153-159.

feminists. A brief synopsis of some of the studies they review will help set the context for the discussion of the FDA's approval process, which follows in Part II (below).

Renate Klein,[44] Janice G. Raymond[45] and Dr. Lynette J. Dumble[46] co-authored a "comprehensive literature review and analysis of hundreds of medical and scientific articles on RU 486/PG [prostaglandin], a large percentage of which have a connection with Roussel Uclaf,"[47] the pharmaceutical company that developed RU-486 in the 1980s.

The first clinical trial of RU-486 in humans took place in October 1981 in Geneva, Switzerland after only 17 months of animal research with rats, rabbits and monkeys,[48] although the results of animal trials were not such a resounding success that they justified the rush to human trials. "RU 486 caused the death in two out of three monkeys in toxicity tests,"[49] for example. None of the eleven women in Geneva who were given 200 mg of RU-486 per day for three consecutive days died, but only nine pregnancies were terminated (eight after five days and the ninth at nine days). Furthermore, one woman claimed initially as a "success" later required uterine evacuation, and another woman needed emergency surgery and a blood transfusion due to heavy bleeding.[50] Klein *et al.* describe how the Parisian newspaper *Liberation* reported on the Geneva trial: "Liberation commented that, given these associated complications and risks, RU 486 was no 'abortion miracle.' *Liberation* also reported that RU 486 is not only an anti-progesterone but an anti-glucocorticosteroid which can take the place of cortisone in the adrenal glands, and that contraindications emanating from this double action of the drug could be a problem,"[51] as it turned out to be for two out of three monkeys.

Roussel Uclaf staff proceeded next to clinical trials on small groups of women in France, Sweden, Australia, Holland, the United States of America, England, Finland and China. The manufacturer supplied RU-486 for these trials, and its staff and consultants co-authored articles reporting on the results.[52] The success rates (defined as "a complete termination of pregnancy

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[44] Ms. Klein is a biologist, professor of sociology and women's studies and author/editor of numerous books on reproductive technologies.

[45] Then Professor, University of Massachusetts and associate director of MIT's Institute on Women and Technology.

[46] Then visiting professor of surgery at the University of Texas and senior research fellow in the University of Melbourne's Department of Surgery, Royal Melbourne Hospital.

[47] Renate Klein *et al*., RU 486: Misconceptions, Myths and Morals. Melbourne, Aus.: Spinifex Press, 1991 The book is out of print, but the full text is available at http://www.spinifexpress.com.au/non-fict/ru486.htm (last visited October 20, 2006) at 4.,.

[48] *Ibid*., at 9-10.

[49] Lawrence Lader. RU486: The Pill that Could End the Abortion Wars and Why American Women Don't Have It. Reading, Mass.: Addison-Wesley Publ. Co., 1991, 17-26, at 48.

[50] Renate Klein *et al*., RU 486: Misconceptions, Myths and Morals. Melbourne, Aus.: Spinifex Press, 1991 The book is out of print, but the full text is available at http://www.spinifexpress.com.au/non-fict/ru486.htm (last visited October 20, 2006) at 10, citing Etienne-Emile Baulieu, "RU-486 as an Antiprogesterone Steroid: From Receptor to Contragestion and Beyond," *Journal of the American Medical Assn*. 262:13; 1808-1814 (October 6, 1989)..

[51] *Ibid*., at 10.

[52] *Ibid*.

without the need for further medical intervention") using RU-486 alone ranged from 54%[53] and 61%[54] to a high of 85%[55] and 90%[56] -- at best substantially below the 99% success rate for surgical abortion.

The Kovacs *et al*. trial, finding a 61% average efficacy, illustrates some of the risks encountered in RU-486 use. A total of 37 women "with amenorrhea of 42 days or less" were given RU-486 twice daily for four days at several different levels of dosage. All patients attended three follow-up visits at one, two and five-to-six weeks after the "therapy" began. In three patients (8%) pregnancy was unaffected by the drug. Two patients required blood transfusion and curettage due to heavy bleeding, and another was found at the second follow-up visit to have an extra-uterine pregnancy. Kovacs *et al*. concluded that "treatment with RU 486 may provide a novel therapy for 'menstrual regulation' but the efficacy of the treatment needs to be improved to compete with alternatives such as vacuum aspiration."[57]

In 1984, researchers in Sweden began using a prostaglandin in conjunction with RU-486 to improve efficacy rates (achieving complete abortions in 32 of 34 women subjects, or 94%), without, however, having first undertaken basic research into the potential adverse effects arising from interactions between these drugs.[58]

In late 1988, the French Minister of Health issued approval for the marketing of RU-486 in France.[59] A distinguished committee of scientific and medical experts, which included the president of France's National Academy of Medicine, the head of Nephrology Department, Necker Hospital (Paris), research directors at the (French) National Institute for Health and Medical Research and National Center for Scientific Research, began reviewing data on 30,000 women who by then had used RU-486. In April 1990, this committee issued its scathing "Report of the International Inquiry Commission on RU 486", which faults the approval of RU-486 on several grounds and which warns of the inherent and well-documented risks of RU-

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[53] Herrmann, W.L., Wyss, Rolf, Riondel, A., Philibert, Daniel, Teutsch, Georges, Sakiz, Eduoard and Baulieu, Etienne-Emile. (1982). Effet d'un stéroide antiprogesterone chez la femme: interruption du cycle menstruel et de la grossesse au début. *C R Acad Sci Paris* 294.933-938.[The effect of an anti-progesterone steroid on women: interruption of the menstrual cycle and early pregnancy. Reports of Proceedings of the Academy of Sciences, Paris].

[54] Kovacs, L., Sas, M., Resch, B.A, Ugocsai, G. Swahn, Marja-Lisa, Bygdeman, Marc and Rowe, PJ. (1984). Termination of early pregnancy by RU 486 - an antiprogestational compound. *Contracep* 29.399-410.

[55] Couzinet, Béatrice, Le Strat, Nelly, Ulmann, André, Baulieu, Etienne-Emile and Schaison, Gilbert. (1986). Termination of early pregnancy by the progesterone antagonist RU 486 (Mifepristone). *New England Journal of Medicine* 315.1565-1570.

[56] Grimes, David A., Mishell, Daniel R., Shoupe, Donna and Lacarra, Maria. (1988). Early abortion with a single dose of the antiprogestin RU-486. *American Journal of Obstetrics and Gynecology* 158: 1307-1312.

[57] Kovacs, L., Sas, M., Resch, B.A, Ugocsai, G. Swahn, Marja-Lisa, Bygdeman, Marc and Rowe, PJ. (1984). Termination of early pregnancy by RU 486 - an antiprogestational compound. *Contracep* 29.399-410.

[58] Bygdeman, Marc and Swahn, Marja-Liisa. (1985). Progesterone receptor blockage: Effect on uterine contractility and early pregnancy. *Contraception* 32; 45-51, cited in Klein *et al*., RU 486: Misconceptions, Myths and Morals. Melbourne, Aus.: Spinifex Press, 1991 The book is out of print, but the full text is available at http://www.spinifexpress.com.au/non-fict/ru486.htm (last visited October 20, 2006) at 11.

[59] Report of the International Inquiry Commission on RU 486, April 1990, available at http://www.trdd.org/RU486/RUCIEE.HTM (last visited Oct. 18, 2006).

486/prostaglandin abortions. They note cardiovascular and respiratory risks – a full year before the first such fatality, but already evident from the report of one woman who lapsed into a 36-hour-long coma during an RU-486 abortion.[60]

Among the many serious issues raised by the International Inquiry Commission on RU 486 are these:

- the "very strong anti-glucocorticoid" effect of RU-486 (with which the FDA is now familiar, following the deaths from septic shock of four California women)
- the continued uncertainty surrounding RU-486's mode of action
- the necessity of using a prostaglandin to achieve marginally acceptable effectiveness, in light of the known serious side effects of prostaglandin
- metrorrhagia in over 90% of cases, lasting from 1 to 35 days (in "many cases an emergency 'Revision Uterine' [uterine evacuation] was necessary to contain the hemorrhaging. In certain cases, the only recourse was an emergency blood transfusion, with all the risks this involves.")
- "Beyond far heavier risks [compared to] the surgical method … there is – with the medicinal method – an uncertainty about the result during 5 to 12 days," as well as
  - "failure for 5% of the women who will therefore undergo surgery,
  - "around 5 to 10% persistent hemorrhages will need medicinal or surgical treatment,
  - "absolute necessity, some days after abortion, to [perform] an ultrasound examination and a HCG dosage, to be completely sure there [are] no traces of the fetus."
- the risks to women who do not return for follow-up treatment
- recently published studies demonstrating "a strong stimulating effect by RU 486 on the growth of a breast cancerous cellular line"[61] and immune system inhibition.[62]

On immune system inhibition, one wonders how the FDA could have failed to take note of the World Health Organization's 1991 study,[63] in which "9 of the 341 women (2.6%) with complete abortion and … 5 of the 17 subjects (29.4%) with incomplete abortion" had to be given "antibiotic therapy to prevent or cure suspected genitourinary infection" during the six-week follow-up period.[64] Nearly *thirty percent* of incomplete abortions involved infection.

A last example of facts the FDA should have taken into account in the agency's review of RU-486 is the personal story of Tamara Keta Hodgson, a nurse who took part in the RU-486

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[60] *Ibid*.

[61] The referenced report cites RT Bowden, JR Hissom, MR Moore. (1989) "Growth stimulation of T47D human breast cancer cells by the anti-progestin RU-486," *Endocrinology* 124; 2642-2644.

[62] BJ Van Voorhis, DJ Anderson, and JA Hill (1989), "The effects of RU 486 on immune function and steroid-induced immunosuppression in vitro," *J Clin Endocrinol Metab* 69:1195-1199.

[63] World Health Organization. (1991) "Pregnancy termination with mifepristone and gemeprost: a multicenter comparison between repeated doses and a single dose of mifepristone. *Fertil Steril* 56: 32-40.

[64] *Id*., at 37.

trials conducted by Dr. David Grimes in Los Angeles. In a letter published in the *Los Angeles Times* under the heading "Pros and Cons of 'Dr. Grimes' bitter pill,' " Ms. Hodgson writes:

> I took RU-486 in December, 1986, when I was three weeks pregnant. Twenty-four hours later I began to have severe cramping and started vomiting. When this had gone on for 10 to 12 hours, a friend took me to the County-USC Emergency Room. After an excruciating pelvic exam, I was given a shot of Demerol, which did nothing, and a prescription for a prostaglandin inhibitor to slow down the process, which did relieve the pain. I had mild bleeding for a few days and then six days after taking the drug, I began to hemorrhage. I continued to bleed or spot until mid-March, 1987.
>
> I'm not sure why I had such an extreme response. I chose to take the drug rather than have a surgical abortion because it had been presented to me as a relatively benign experience. I also thought it might help advance the causes of both science and women.
>
> Do I think RU-486 should be licensed in the United States? I'm not sure. I had access to many resources not available to the general population of women who might take this drug. I am a registered nurse who works at one of the most sophisticated hospitals in the world. I was cared for by the research team investigating the drug. I had no children who needed to be cared for.
>
> The same cannot be said for women of the Third World. It also cannot be said for women in the United States who do not have access to adequate health care.[65]

Despite all this, what many abortion advocates promoted as a "miracle pill"[66] has turned out to be anything but. Even before its approval, the medical community knew what American women would soon learn by experience:

- mifepristone interferes with the body's immune response[67]

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[65] *Los Angeles Times*, May 6, 1990, at E-20.

[66] David Van Biema, "But Will It End the Abortion Debate?" *Time*, June 14, 1993; available at http://www.time.com/time/magazine/article/0,9171,978680,00.html (last visited October 20, 2006).

[67] *See,* Jeanette I. Webster and Esther M. Sternberg, *Role of the Hypothalamic-Pituitary-Adrenal Axis, Glucocorticoids and Glucocorticoid Receptors in Toxic Sequelae of Exposure to Bacterial and Viral Products*, Journal of Endocrinology 2004, 181:207-221 ("Natural and synthetic glucocorticoids protect against the lethal effects of many bacterial and viral components...agents that block the hypothalamic-pituitary-adrenal axis, as in…mifepristone…enhance lipopolysaccharide (LPS) and endotoxin lethality and LPS-induced fever. Even the normally endotoxin-nonresponsive C3H/HeJ mice could be made endotoxin sensitive by RU-486."). *See also,* Ralph P. Miech, *Pathophysiology of Mifepristone-Induced Septic Shock Due to Clostridium Sordellii*, The Annals of Pharmacotherapy, September 2005, 39:

> "Mifepristone is a potent progesterone antagonist that, in addition to its ability to block glucocorticoid receptors, blocks progesterone receptors...Blockade of progesterone receptors…results in rejection of the developing placenta and death of the embryo. Prolonged ischemia of the decidua and the embryonic placenta causes necrosis [death] of these tissues. Mifepristone also [causes] cervical dilation and liquefaction of the cervical mucus plug. The combined loss of a closed cervix and the protective cervical mucus plug permits contamination of

- it is more inconvenient than surgical abortion[68]
- it is more painful[69]
- it is less effective[70]
- it is associated with more adverse events[71]
- it causes more frequent and more severe hemorrhage than its surgical counterpart[72]

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the decidua and the intrauterine necrotic cells with aerobic and anaerobic bacteria from the normal vaginal flora."

See also, Sharon Worchester, *Mifepristone Deaths Raise Unanswered Questions*, Ob. Gyn. News, (October 1, 2005) at 13. (Quoting Dr. James A. McGregor)("Mifepristone has multiple pharmacologic properties that may interfere with innate immune responses to infection, toxin exposures, and inflammatory stimuli.").

[68] *See* FDA Medical Officer's Review of Amendments 024 and 033, Final Reports for the U.S. Clinical Trials Inducing Abortion up to 63 Days Gestational Age and Complete Responses Regarding Distribution System and Phase 4 Commitments, Finalized November 22, 1999 (dated January 27, 2000), available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_medr_P1.pdf (last visited September 28, 2006):

> This method of pregnancy termination is of limited value because of the relatively short window of opportunity, [sic] in which it can be employed. Its safety and effectiveness is based on its use during the seven weeks following the first day of the last menstrual period. This means that most women would not suspect that they are pregnant and have a confirmatory pregnancy test until at least four weeks after the beginning of their last menses. This, then, leaves only a three week period for the women to secure this method of abortion.
>
> Another disadvantage of this method of pregnancy termination is the need for at least three visits to the medical facility [sic] including at least a four hours [sic] stay after the administration of the misoprostol.
>
> In addition, medical follow-up is required to ensure that surgical termination is performed in case the medical termination attempt fails since misoprostol has been reported to be teratogenic in humans (limb defects and skull defects)...
>
> [In a comparison of medical termination of pregnancy with surgical termination,] [t]he medical regimen had more adverse events, particularly bleeding, than did surgical abortion. Failure rates for medical abortion exceeded those for surgical abortion…[and] increased with gestational age. Specific symptoms and adverse events, including cramping, nausea, and vomiting, were far more frequent among the medical than the surgical abortion patients… On the whole, medical abortion patients reported significantly more blood loss than did surgical abortion patients…

[69] *See, e.g.,* B. Elul, et.al, *Side Effects of Mifepristone-Misoprostol Abortion Versus Surgical Abortion, Data From a Trial in China, Cuba, and India*, Contraception 59:107-114, 111 (1999): China—60.3% chemical, 36.0% surgical patients experienced pain / cramps; Cuba—89.2 % chemical, 65.4% surgical; India—61.9% chemical, 36.8% surgical.

[70] *See, e.g.,* Beverly Winikoff, et. al., *Safety, efficacy and acceptability of medical abortion in China, Cuba, and India: A comparative trial of Mifepristone-misoprostol versus surgical abortion*, Am. J. Obstet. Gynecol. 431, 434 (Feb. 1997). Failure Rates: China—chemical 8.6%, surgical .4%; Cuba—chemical 16.0%, surgical 4.0%; India—chemical 5.2%, surgical 0%.

[71] *See, e.g.,* E. Cabezas, *Medical versus surgical abortion,* 63 Internat. J Gynecol. & Obstet. Supp. 1, S141, S144 (1999). Cramping: chemical 60.0%, surgical 48.3%; Nausea: chemical 30.6%, surgical 8.9%; Vomiting: chemical 15.1%, surgical 2.0%.

[72] *See Ibid.*, chemical abortion patients experienced 2.3 days of heavy bleeding, 4.8 days of normal bleeding, and 4.9 days of light bleeding compared to 0.3, 1.8, and 3.3 days for surgical, respectively. Furthermore, 50.8% of chemical abortion patients bled more than expected, compared to 7.3% for surgical patients; and 64.1% of chemical abortion patients bled longer than expected, compared to 18.7% of surgical abortion patients. *See also,* Y.F. Chan, et.al.,

The safety issues associated with RU-486 are discussed in depth in Section III, below.

III. RU-486 APPROVAL IRREGULARITIES

Since FDA approved RU-486 in September 2000, a number of criticisms have been lodged against FDA alleging procedural irregularities in the approval process.[73] The Subcommittee investigators were aware of these criticisms and requested information from FDA regarding the issues raised by opponents of the approval. This section assesses the claims made and FDA's responses to the following allegations: 1) that FDA's approval was based solely on data from uncontrolled trials; 2) that FDA used Subpart H unlawfully when it approved the drug and, furthermore, that the clinical data used in support of the application was insufficient to satisfy Subpart H requirements; and, 3) that FDA unlawfully mandated the unapproved use of a drug, misoprostol, as part of the RU-486 abortion regimen.

A. The Approval was Unlawfully Based Solely on Data from Uncontrolled Trials

FDA's reputation as the world's foremost regulator of drug products is based largely on the rigor which it demands for data submitted in support of drug applications. The law requires, in Section 505(d)(5) of the Food, Drug and Cosmetic Act, that FDA shall not approve a drug when "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."[74] "Substantial evidence" means "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved . . . ."[75]

Over the years, FDA's high standard in supervising the production of clinical trial data has been referred to as its "gold standard." Typically, FDA requires data from two clinical trials that are randomized, blinded and controlled against a "comparator" – often a placebo but more typically an alternative therapy.[76] FDA's Section 314.126(e) indicates that "[u]ncontrolled

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Blood Loss in Termination of Early Pregnancy by Vacuum Aspiration and by Combination of Mifepristone and Gemeprost, Contraception 47:85-95, 90 (1993): Groups receiving 200mg, 400mg, and 600mg of mifepristone experienced an average loss of 84.1ml, 99.9ml, and 101.4ml of blood respectively (ranges were 16.8 - 371.3ml, 16.7 - 524.3ml, and 20.8 - 472.4ml, respectively) compared to an average blood loss of 53.2ml for patients undergoing a vacuum aspiration abortion (range of 29.3ml - 226.0ml).

[73] For example several groups have filed a "citizen petition" with FDA regarding RU-486's approval. *See* Citizen Petition of the American Association of Pro Life Obstetricians and Gynecologists, the Christian Medical Association, and Concerned Women for America, Request for Stay and Repeal of the Approval of Mifeprex (mifepristone) for the Medical Termination of Intrauterine Pregnancy through 49 Days' Gestation, Docket No. 02P-0377 (filed Aug. 20, 2002) ("Mifeprex Citizen Petition"). On October 10, 2003, these groups filed a response to the Danco Laboratories and the Population Council's Opposition to the Citizen Petition which was filed in March 2003. These documents are available in FDA Docket No. 02P-0377.

[74] 21 U.S.C. § 355(d)(5).

[75] 21 U.S.C. § 355(d).

[76] FDA issued a guidance document in 1998 ("Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products," May 1998)("FDA Clinical Evidence Guidance") that outlines the

studies or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness."[77] The question of whether the RU-486 trial data was produced solely by uncontrolled clinical trials was examined by the Subcommittee investigators.

The French and American trial data were generated by trials in which the participants were given mifepristone and misoprostol to chemically end pregnancies. The RU-486 regimen was judged to have been effective, "defined as the termination of pregnancy with complete expulsion of the conceptus without the need for a surgical procedure."[78] The studies measured the rate at which RU-486/misoprostol abortions succeeded or failed at different gestational ages.

However, neither the French nor American RU-486 trials randomized trial participants concurrently against either a placebo or the most similar RU-486 alternative, first-trimester surgical abortion.[79] Neither the French trials,[80] nor the American trial was concurrently controlled.[81] Furthermore, no discussion of controls can be found in FDA analyses of the French trials[82] or in the Spitz Study[83] that reported the results of the U.S. trial. Thus, the question arose as to whether the RU-486 trials were in fact uncontrolled.

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requirements of its drug trial policies with respect to proving effectiveness. Additionally, FDA has signed on to the principles enunciated in documents produced by the International Conference on Harmonization on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH").

[77] 21 C.F.R. § 314.126(e).

[78] Spitz, Bardin, Benton, and Robbins, "Early Pregnancy Termination with Mifepristone and Misoprostol in the United States," 338 *New England Journal of Medicine* (1998), 1241-47.

[79] Blinding would have been very difficult to achieve with respect to the medical personnel performing the surgical abortion or dispensing the drugs to the patient, but blinding of abortion evaluators might have been achievable. In any event, scientifically rigorous randomized and concurrently controlled trials could have been performed with limited or no blinding.

[80] Center for Drug Evaluation and Research, Food and Drug Administration, Statistical Review and Evaluation for NDA 2-687 (Mifepristone), at 2-4 (May 21, 1996). The French trial is referred to as FFR/91/486/14. Available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_statr.pdf.

[81] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (August 17, 2006) (on file with Subcommittee).

[82] Center for Drug Evaluation and Research, Food and Drug Administration, Statistical Review and Evaluation for NDA 2-687 (Mifepristone) (May 21, 1996). The French trial is referred to as FFR/91/486/14. Available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_statr.pdf.

[83] Spitz, Bardin, Benton, and Robbins, "Early Pregnancy Termination with Mifepristone and Misoprostol in the United States," 338 *New England Journal of Medicine* (1998), 1241-47.

At the Subcommittee's May 17, 2006 hearing, *RU-486: Demonstrating a Low Standard for Women's Health?,* Dr. Woodcock, Deputy Commissioner for Operations for the Food and Drug Administration, asserted in her written testimony for the Subcommittee that "[FDA's] finding of drug effectiveness was based on a comparison to a historical control of the expected rate of continued pregnancy."[84]

In response to a post-hearing Subcommittee question, FDA noted that the historical control, used in the RU-486 clinical trials, comprised of "the well-established data and pool of medical knowledge concerning both the natural course of pregnancy itself, including the well-documented rate of spontaneous abortion or miscarriage (less than 20%), and surgical abortion."[85] We take this to mean that the spontaneous abortion rate and the rate of induced abortion were together subtracted from the expected rate of ongoing pregnancy. It is important, then, to examine the FDA's claim that the French and U.S. trials were historically controlled.

First, FDA's assertion that the French and U.S. trials were historically controlled appears to be a *post hoc* assertion. There is no mention of any control group in the Spitz Study;[86] the word "control" does not appear in the article. Moreover, an FDA statistician reviewing the French trial data asserted that "[i]n the *absence of a concurrent control group* in each of these studies, it is a matter of clinical judgment whether or not the sponsor's proposed therapeutic regimen is a viable alternative to uterine aspiration for the termination of pregnancy"[87] (emphasis added). The reviewer made no mention of a historical control to which mifepristone would be compared, and it is well known that controls have to be specified *before* trials are performed. The lack of a prior delineation of the controls demonstrates that FDA's claims are not supported by the record.

Second, the U.S. RU-486 trials were conducted with specific groups of persons excluded. The Spitz Study[88] lists those disqualified from participation as follows:

> "Women with liver, respiratory, renal, adrenal, or cardiovascular disease, thromboembolism, hypertension, anemia, insulin-dependent diabetes mellitus, coagulopathy, or known allergy to prostaglandins were excluded, as were women less than 18 years of age or those more than 35 years of age who smoked more

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[84] See *RU-486: Demonstrating a Low Standard for Women's Health? Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Res., Committee on Government Reform*, 109th Cong. (May 17, 2006) (statement of Janet Woodcock, M.D., Deputy Commissioner for Operations, FDA) Available at http://reform.house.gov/UploadedFiles/Woodcock%20Testimony.pdf.

[85] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (August 17, 2006) (on file with Subcommittee).

[86] Spitz, Bardin, Benton, and Robbins, "Early Pregnancy Termination with Mifepristone and Misoprostol in the United States," 338 *New England Journal of Medicine* (1998), 1241-47.

[87] Center for Drug Evaluation and Research, Food and Drug Administration, Statistical Review and Evaluation for NDA 2-687 (Mifepristone) at 7-8 (May 21, 1996). The French trial is referred to as FFR/91/486/14. Available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_statr.pdf.

[88] Spitz, Bardin, Benton, and Robbins, "Early Pregnancy Termination with Mifepristone and Misoprostol in the United States," 338 *New England Journal of Medicine* (1998), 1241-47.

> than 10 cigarettes per day and had another cardiovascular risk factor. Women were also excluded if they had in situ intrauterine devices, were breast-feeding, were receiving anticoagulation or long-term glucocorticoid therapy, had adnexal masses, had ectopic pregnancies, or had signs or symptoms suggesting they might abort spontaneously.[89]

Yet when FDA was asked what populations were excluded from its control group, the Subcommittee was told that "[a] historical control group does not include specific individuals, but rather is based on experience historically derived from the adequately documented natural history of the condition."[90] FDA made this additional point: "Thus, historical control populations usually cannot be assessed with respect to certain variables, such as the inclusion or exclusion of specific sub-populations."[91] This answer is methodologically insufficient, and it underscores the conclusion that, regardless of FDA's statement to the contrary, these trials were uncontrolled. The trial and control groups must be matched to each other in almost all possible ways if there is to be a meaningful control. If it was not possible to match the populations with the historical data set, then a concurrent control should have been used.

Finally, FDA allowed the use of uncontrolled trials for medical abortion because it defined the clinical endpoint too restrictively.[92] Neither spontaneous nor medical abortions produce only simple zero or one outcomes – that is, one-dimensional instances of success or failure. Not all abortions, whether spontaneous or medical, pass by themselves. Many require surgical intervention to be completed, or serious complications may ensue. FDA's cramped definition of RU-486 "effectiveness" ignores this.[93] A control should have been used in the RU-486 trial that compared different methods of producing the experimental outcome – first-trimester pregnancy termination – while assessing each method's ability to manage highly predictable, regular complications of medical abortion (*i.e.*, hemorrhage, incomplete abortion). As the International Conference on Harmonization[94] has noted, "non-defined" external controls

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[89] *Ibid*, at 1241-2.

[90] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (August 17, 2006) (on file with Subcommittee).

[91] *Ibid*.

[92] *Ibid*.

[93] *Ibid*. ("In the case of medical abortion, determining the effectivness of the drug is straightforward, because it is relatively easy to determine whether the pregnancy has been terminated. Therefore, it is unnecessary to utilize a randomized clinical trial design.").

[94] FDA, "International Conference on Harmonisation; Guidance on General Considerations for Clinical Trials," *Notice*, 62 Fed. Reg. 66113 (Dec. 17, 1997) (*FDA Guidance (ICH: E8): General Considerations*). The International Conference on Harmonization "is a unique project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration. The purpose is to make recommendations on ways to achieve greater harmonisation in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines. The objective of such harmonisation is a more economical use of human, animal and material resources, and the elimination of unnecessary delay in the global development and availability of new medicines whilst maintaining safeguards on quality, safety and efficacy, and regulatory obligations to protect public health." *See* www.ich.org (last visited October 10, 2006).

– those in which "a comparator group [is] based on general medical knowledge of outcome" – are "particularly dangerous" and "such trials are generally considered uncontrolled."[95] Such a characterization pertains in instances like this in which the study's dependent variable (i.e., the termination of pregnancy) has been defined so narrowly as to give the false impression of complete knowledge of a simple medical outcome.

B. FDA's Abuse of Subpart H

RU-486 was approved through an important part of FDA's drug approval rules called "Subpart H."[96] In the Subcommittee's May 17 hearing, Dr. Woodcock told the Subcommittee, "FDA approved the Mifeprex NDA [new drug application] under Subpart H at the sponsor's request because the Agency determined that post-marketing distribution restrictions on the product were necessary to ensure its safe use."[97]

These rules were promulgated by FDA in 1992 as part of an attempt to correct perceived deficiencies in FDA's approval process made apparent by the need to quickly develop drugs for HIV/AIDS patients. However, in order to benefit from the provisions contained in Subpart H (*e.g.*, its restricted distribution provisions in the case of RU-486) certain conditions must be satisfied, and in the RU-486 instance, Subpart H was unlawfully used for its approval.

Inducing Medical Abortion Does Not Qualify for Subpart H

Supbart H can only be applied to drug products "that have been studied for their safety and effectiveness in treating *serious or life-threatening illnesses*…."[98] (emphasis added). FDA was aware of this requirement, and FDA asserted in its approval memo to the Population Council "that the termination of an unwanted pregnancy is a *serious condition* within the scope of Subpart H…."[99] (emphasis added).

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[95] *FDA Guidance (ICH E10): Choice of Control Group* at 5 (§ 1.3.5). Section 2.5.4 adds the following point to this discussion: "An externally controlled trial should generally be considered only when prior belief in the superiority of the test therapy to all available alternatives is so strong that alternative designs appear unacceptable and the disease or condition to be treated has a well-documented, highly predictable course. It is often possible, even in these cases, to use alternative, randomized, concurrently controlled designs."

[96] Medical Officer's Review of Amendments 024 and 033, Final Reports for the U.S. Clinical Trials Inducing Abortion up to 63 Days Gestational Age and Complete Responses Regarding Distribution System and Phase 4 Commitments, Finalized November 22, 1999 (dated January 27, 2000), available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_medr_P1.pdf (last visited September 28, 2006).. The Subpart H rules are found at 21 C.F.R. § 314.500ff.

[97] See *RU-486: Demonstrating a Low Standard for Women's Health? Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Res., Committee on Government Reform*, 109th Cong. (May 17, 2006) (statement of Janet Woodcock, M.D., Deputy Commissioner for Operations, FDA) Available at http://reform.house.gov/UploadedFiles/Woodcock%20Testimony.pdf. We note that the Mifeprex Citizen Petition references a letter from Sandra Arnold of the Population Council to FDA, dated Sept. 6, 2000, in which she vociferously protests Mifeprex's approval under Subpart H. Mifeprex Citizen Petition at 20 (". . . it is clear that the imposition of Subpart H is unlawful, unnecessary, and undesirable. We ask FDA to reconsider.").

[98] 21 C.F.R. § 314.500.

[99] Medical Officer's Review of Amendments 024 and 033, Final Reports for the U.S. Clinical Trials Inducing Abortion up to 63 Days Gestational Age and Complete Responses Regarding Distribution System and Phase 4

Linguistic gymnastics notwithstanding, pregnancy or the termination of pregnancy is not a "serious or life-threatening illness," and therefore does not fall within the defined reach of Subpart H; the term "serious condition" is not found in the Subpart H rule. Subpart H is intended for the treatment of "serious or life-threatening illnesses," not conditions. There 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.

It is difficult to find a credible counter-argument from FDA or any private party defending the use of Subpart H to approve RU-486. This is not a mere technicality. If the condition being treated did not qualify for Subpart H approval, then the various restrictions that could be imposed pursuant to Subpart H to ensure the safe distribution of the drug would not have been available to the agency.

The FDA imposed several such restrictions on the distribution of Mifeprex.[100] (These restrictions, however, are less rigorous than what was initially proposed prior to approval.[101])

Mifepristone must be provided by or under the supervision of a physician who meets the following qualifications:

- Ability to assess the duration of pregnancy accurately
- Ability to diagnose ectopic pregnancies
- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through other qualified physicians, and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary
- Has read and understood the prescribing information of Mifeprex
- Must provide each patient with a Medication Guide and must fully explain the procedure to each patient, provide her with a copy of the Medication Guide and Patient Agreement, given her an opportunity to read and discuss both the Medication Guide and the Patient Agreement, obtain her signature on the Patient Agreement and must sign it as well
- Must notify the sponsor or its designate in writing as discussed in the Package Insert under the heading DOSEAGE AND ADMINISTRATION in the event of an on-going

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Commitments, Finalized November 22, 1999 (dated January 27, 2000), available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_medr_P1.pdf (last visited September 28, 2006).

[100] Memorandum from FDA Center for Drug Evaluation and Research to Population Council 6, (Sept. 28, 2000). Available at http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf (last visited October 15, 2006).

[101] FDA "Division Director Memo to File" on Mifepristone NDA, September 17, 1996 (on file with the Subcommittee): "The applicant has appropriately proposed that drug distribution be limited to licensed physicians (with prior training in assessing the length of pregnancy, in diagnosing ectopic pregnancy, and in the performanceof surgical abortion) who will attend educational seminars on the safe use of this regimen." The final restrictions allow for distribution under the supervision of a physician, rather than limiting it to licensed physicians, and do not require educational training on the safe use of the regimen.

pregnancy, which is not terminated subsequent to the conclusion of the treatment procedure
- Must report any hospitalization, transfusion or other serious events to the sponsor or its designate
- Must record the Mifeprex package serial number in each patient's record

With respect to the aspects of distribution other than physician qualifications described above, distribution of Mifeprex will be in accordance with the system described in the Population Council's submission of March 30, 2000, which includes the following:

- Secure manufacturing, receiving, and holding areas for the drug
- Secure shipping procedures, including tamper-proof seals
- Controlled returns procedures
- Tracking system ability to trace individual packages to the patient level, while maintaining patient confidentiality
- Use of authorized distributors and agents with necessary expertise to handle distribution requirements for the drug
- Provision of drug through a direct, confidential physician distribution system that ensures only qualified physicians will receive the drug for patient dispensing

In addition, the Population Council agreed to two post-marketing studies on the effects of RU-486 on women[102] (though earlier reviews considered six post-marketing studies, four of them were dropped when the drug was approved[103]). In the six years since the approval of RU-486, these studies have not been completed.[104]

The RU-486 Trials Did Not Establish a "Substantial Benefit" for Subpart H

In addition to being intended for drug products studied for their safety and effectiveness in treating serious or life-threatening illnesses, Subpart H is intended only for those products that "provide meaningful therapeutic benefit to patients over existing treatments (e.g., ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy.)"[105] FDA's Approval Memo stated that, for RU-486, "….[t]he meaningful therapeutic benefit over existing surgical abortion is the avoidance of a surgical procedure."[106] The French and American clinical trial data did not satisfy the requirements established in the

[102] Memorandum from FDA Center for Drug Evaluation and Research to Population Council 6, (Sept. 28, 2000). Available at http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf (last visited October 15, 2006).

[103] Center for Drug Evaluation and Research, Food and Drug Administration, Office Memo to Population Council (documenting the approval action for RU-486) September 28, 2000. Available at http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf (last visited October 15, 2006).

[104] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (July 31, 2006) (on file with Subcommittee).

[105] 21 C.F.R. § 314.500.

[106] Memorandum from FDA Center for Drug Evaluation and Research to Population Council 6, (Sept. 28, 2000). Available at http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf (last visited October 15, 2006).

Subpart H rules for establishing a meaningful therapeutic benefit to patients over existing treatments.

First, RU-486 was 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. FDA baldly asserted that there was a clinical benefit for chemical abortion, and made no effort to produce statistical evidence of an actual benefit.

Second, surgery is an integral part of the RU-486 abortion process, because a substantial proportion of women require D&C's after beginning the mifepristone regimen. Therefore, women who have RU-486 abortions must be able to tolerate the surgical procedure. This fact alone makes it all the more difficult to accept FDA's bald assertion of a meaningful therapeutic benefit above that presented by surgical abortion. While such a benefit may exist, the law requires FDA to make its judgments based on scientific evidence. Subpart H requires that both safety and effectiveness be established for the Subpart H drug above the existing standard of care. At the very least, FDA should have required the drug sponsor to conduct non-inferiority trials to generate data for the drug application.

Third, even though some women may prefer RU-486 abortions over surgical abortions, that fact does not establish the existence of a therapeutic benefit in and of itself. One can imagine numerous ways of delivering therapies that are more desirable for the patient – for example, pills rather than injection – but FDA must establish this fact statistically.

Fourth, it appears that no concurrently-controlled trials comparing medical and surgical abortion were required by FDA, because the Agency already knew that medical abortion—i.e., abortion by RU-486—is unambiguously inferior to surgical abortion with respect to safety and effectiveness. Prior to the approval of the RU-486 NDA, the FDA medical officer made the following observations about studies that had compared medical and surgical abortion:

> [In a study comparing medical and surgical abortion in India, Cuba, and China (n = 1373)], [t]he medical regimen had more adverse events, particularly bleeding, than did surgical abortion. Failure rates for medical abortion exceeded those for surgical abortion (8.6% versus 0.4% in China, 16.0% versus 4.0% in Cuba, and 5.2% versus 0% in India)…. Three patients (all medical abortions) received blood transfusions. This is a serious potential disadvantage of the medical method. On the whole, medical abortion patients reported significantly more blood loss than did surgical abortion patients….[107]
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> [In another non-concurrent study of 377 patients comparing mifepristone to surgical abortion in the U.S patients], [f]our mifepristone patients required curettage for acute bleeding while no surgical patients did. Nine mifepristone

[107] Medical Officer's Review of Amendments 024 and 033, Final Reports for the U.S. Clinical Trials Inducing Abortion up to 63 Days Gestational Age and Complete Responses Regarding Distribution System and Phase 4 Commitments, Finalized November 22, 1999 (dated January 27, 2000), available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_medr_P1.pdf (last visited September 28, 2006).

> patients required curettage to manage ongoing pregnancy while no surgical patients did. Five mifepristone patients required suction curettage because of incomplete abortion while no surgical patients did. Fourteen mifepristone and eight surgical patients required suction curettage for persistent bleeding. The median time delay for therapeutic curettage was significantly longer in the mifepristone group than in the surgical group (35 days versus 8 days). Mifepristone patients experienced significantly longer postprocedure bleeding than did surgical patients. The mean difference in bleeding days between cohorts was 9.6 days (95% CI, 6.8, 12.4)…. Overall, mifepristone abortion patients reported significantly higher levels of pain, nausea, vomiting, and diarrhea during the actual abortion than did surgical patients… Mifepristone patients reported more problems during the follow-up interval than did surgical patients. Post-abortion pain occurred in 77.1% of mifepristone patients compared with only 10.5% of surgical patients…. Nausea or vomiting in the follow-up interval was common in the mifepristone group (68.6%), but rare among surgical patients."[108]

Given these comments, it is impossible to conclude that RU-486 medical abortions provide a meaningful therapeutic benefit over surgical abortion. Consequently, FDA's approval of the RU-486 NDA using Subpart H was unjustified and unlawful.

C. The Highly Unusual Placement of Misoprostol on the Mifeprex Label

When FDA approved the Population Council's RU-486 application it also mandated the use of another drug, misoprostol, as part of a two-drug abortion regimen. The use of misoprostol was not only an unapproved or off-label use – it was actually contraindicated at that time.[109] This aspect of the approval highlights another irregular component of FDA's approach to reviewing the RU-486 NDA. Shortly after FDA's approval of mifepristone, Peter Barton Hutt, a former FDA general counsel and noted commenter on food and drug law, told the Wall Street Journal that FDA appeared to have created "an extraordinary precedent", because FDA was "seemingly encouraging a drug's unapproved use."[110] He added that the agency is in an "embarrassing and uncomfortable position."[111]

The Subcommittee's questions to FDA on this matter have produced some information but no clear sense as to what FDA's policy is with respect to placing off-label or contraindicated drug uses on another drug's label.[112]

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[108] *Ibid*.

[109] On April 17, 2002, the misoprostol label was amended to remove "the contraindication and precaution that Cytotec should not be used in women who are pregnant."

[110] Rachel Zimmerman, "Clash Between Pharmacia and FDA May Hinder the Use of RU-486," *Wall Street Journal* (Oct. 18, 2000): at B1.

[111] *Ibid*.

[112] In addition to questioning the FDA on this matter, the Subcommittee has looked for, and failed, to find any FDA Guidance documents on this topic.

Attention is drawn to two problems. First, it is well known that the NDA-holder for misoprostol (Searle) did not want to have its product used or labeled to reflect off-label uses as an abortifacient. [113] Thus, FDA mandated misoprostol's use in this abortion regimen and placed information about Searle's product on the Mifeprex label. Second, the entire edifice of FDA's regulation of drugs rests on the principle that only indications whose effectiveness has been demonstrated with "substantial evidence" may be placed on the label. FDA has procedures by which new indications can be approved using the supplementary new drug applications. No supplementary drug application was ever filed for misoprostol's use as an abortifacient.

In her prepared testimony before the Subcommittee, Dr. Woodcock noted that the FDA was "aware that questions ha[d] been raised about the use of misoprostol, a drug indicated for the prevention of NSAID-induced gastric ulcers, in the medical abortion regimen with mifepristone, without a separate approval and labeling of misoprostol for this use."[114] She then observed that numerous cases existed "where the labeling of one drug recommends its use with a second drug without the approval of the sponsor of the second drug."[115]

This statement is troubling and warrants further investigation. First, Woodcock's use of "recommends" is grossly inaccurate. In the Mifeprex regimen, the use of misoprostol is mandated. A physician might use an off-label variant of the regimen and, therefore, use another prostaglandin, but the Mifeprex label gives very specific directives to use misoprostol.[116] The non-optional nature of the regimen is carried forward into the language of the Patient Agreement Form which states: "I understand that I will take misoprostol in my provider's office two days after I take Mifeprex (Day 3)."[117] Second, Subcommittee investigators finds it problematic that FDA can dictate that a drug – under the proprietary control of a firm whose NDA has been approved – can be approved for a use to which it objects.

In a letter to Chairman Souder, FDA provided two examples in which non-approved uses appear on FDA-approved labels.[118] The examples relate to coronary heart disease and metastatic

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[113] See letter from Searle warning against the use of misoprostol in abortion: http://www.fda.gov/medwatch/safety/2000/cytote.htm (last visited October 20, 2006).

[114] See *RU-486: Demonstrating a Low Standard for Women's Health? Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Res., Committee on Government Reform*, 109th Cong. (May 17, 2006) (statement of Janet Woodcock, M.D., Deputy Commissioner for Operations, FDA) Available at http://reform.house.gov/UploadedFiles/Woodcock%20Testimony.pdf.

[115] *Ibid*.

[116] Mifeprex Label, available at http://www.fda.gov/cder/foi/label/2005/020687s013lbl.pdf (last visited September 28, 2006).

[117] Mifeprex Patient Agreement, Item # 6, available at http://www.fda.gov/cder/drug/infopage/mifepristone/patientAgreement20050719.pdf (last visited October 20, 2006).

[118] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (May 2, 2006) (on file with Subcommittee). *See also*, See *RU-486: Demonstrating a Low Standard for Women's Health? Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Res., Committee on Government Reform*, 109th Cong. (May 17, 2006) (statement of Janet Woodcock, M.D., Deputy Commissioner for Operations, FDA) Available at http://reform.house.gov/UploadedFiles/Woodcock%20Testimony.pdf.

breast cancer, and the relevant labels should be read to understand the comments that follow.[119] Some comments are in order. First, there is no *mandated* use of the second/off-label drug in either example. Second, in the coronary disease case, the drugs were designed and approved to work on aspects of cardiovascular system-blood pressure regulation. There is nothing unusual in this use of drugs intended to manage cardiac failure.

These facts provide a qualitative difference with the Mifeprex regimen in which misoprostol was *not* designed to work to produce abortions – or uterine contractions for that matter. Rather, misoprostol was a medication intended to protect the gastro-intestinal tract from adverse events related to the use of non-steroidal anti-inflammatory medication – an indication far removed from misoprostol's novel application as an abortifacient.

Finally, FDA's Herceptin/Taxol example is somewhat disingenuous. After reading each drug's label, one recognizes that Taxol is approved for metastatic breast cancer treatment as a single agent, and so is Herceptin, but neither is specifically indicated for metastatic breast cancer treatment where no prior chemotherapy has been given. The combination use is approved (but not MANDATED) for patients with metastatic breast cancer overexpressing HER2 protein who have not received any prior chemotherapy.

Both drugs are approved for use in metastatic breast cancer. Herceptin's indication is more specifically tied to use when there is overexpression of HER2 protein. If there has been no other chemotherapy given then both may be used together. FDA seems to be splitting hairs when it claims that the use of Taxol in such cases is off-label. That characterization depends upon a fine distinction having to do with a specific tumor marker and whether or not other chemotherapy had been used.

The tenuousness of FDA's examples leads the Subcommittee to conclude that FDA is having difficulty finding examples that parallel the mandated, dissimilar off-label use of misoprostol in the Mifeprex regimen.

IV. SAFETY

Since the introduction of RU-486 to the U.S. market, the FDA has acknowledged, as of May 2, 2006, the deaths of six women associated with the drug, nine life-threatening incidents, 232 hospitalizations, 116 blood transfusions, and 88 cases of infection.[120] These and other cases have added up to a total of 1070 adverse event reports (AERs) as of April 2006.[121]

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[119] The relevant information can be found using the website: <www.rxlist.com>.

[120] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (May 2, 2006) (on file with Subcommittee).

[121] Numbers do not convey the full story. More telling are the first-hand accounts of women who have lived these events. Below are some examples from the Individual Safety Reports (ISRs) which describe in detail the type of experience RU-486 chemical abortion has turned out to be (mistakes are as they appear in the originals):

Event of January 1, 2000, reported September 27, 2000, one day before the approval of Mifeprex: "I was issued RU-486 in effort of obtaining an abortion. I followed directions exactly, and after taking the ru-486, I was in

excrutiating physical pain, for at least 12 hours straight and I was bleeding extremely excessively. I was bleeding through my pants but was in so much pain I couldn't even clean myself. It was the worst physical pain I've ever experienced in my life. This extreme pain was constant the whole 12 hours, it did not let up at all the whole time. I vomited continuously but couldn't even hold my head up. I had unbelievable abdominal pains, I can't even put in words. I couldn't speak, eat, drink, sit up, and had difficulty breathing. The only thing I could do was lie on the floor and pull my hair to deal with the pain. I couldn't clean myself or go to the bathroom, I thought I was going to die. After about 7 hours of this, I really wanted to die because I couldn't take the pain anymore. I wanted to call the hospital but I was hours from any hospital because I went to our cabin in a remote area to have privacy during this time. The administering clinic was closed since it was the weekend…. I was not informed of the extent of these side effects, I was told it would be just like a menstrual period. I never would have taken this had I been properly informed, even of the possibility of those effects…I was not told that this drug was experimental and not approved by the FDA…I believe they outright lied to me…when I returned to the clinic after the abortion was complete, they were not very attentive or interested in me, I explained to them my pains even though they didn't ask me any questions. I filled out a questionairre that they gave me before I took the drug and they said I have to do the questionnaire ever couple hours during the abortion, but when I offered it to them upon return, they didn't even want the questionaire, they didn't take it."

Event of July 26, 2002, reported September 28, 2002: "28 year old Gr5. Para 2 Ab 2 at 6 weeks 5 days gestation received 200 mg Mifeprex on [redacted] and inserted 800 mcg misoprostol vaginally on [redacted] at 11:00 a.m. The bleeding was 'normal' until 3:30 p.m. when it became heavier. That evening she stated 'it was like water coming out of me' and she felt dizzy. That evening she reported that she briefly 'passed out' twice. She went to an emergency room and received [missing] litres of IV fluid and had a D&C. Her hemoglobin on arrival was 8.7 gm/dl and was [missing] gm/dl after the D&C. She was started on iron supplementation. On [redacted] her hematocrit was 28% at the clinic and she reported that she was resting, on limited to light activity and doing well."

Event of August 15, 2004, reported July 25, 2005: "I took RU-486 last year and it caused me serious problems. After 15 days after taking it I hemorrhaged while at work requiring subsequent D&C, then had an infection that would not go away despite multiple antibiotics. I ended up being hospitalized and having multiple tests due to the infection and pain. I was hospitalized for four days in september of last year. Even after being hospitalized I was very ill for quite some time. I believe it took me until December to fully recover, during this time I lost quiet a bit of weight and had to enter counseling as a result of all the problems after using RU486."

Event of October 31, 2002, reported August 13, 2005: "Previous to 2002 I had two pregnancies and two live births…In 2002, 2003, and 2004, I had a three abortions at a very early stage, using the 'French' pill—RU-486—with each being almost exactly a year apart. I had the same experience each time. I developed a very bad case of bacterial vaginosis…I also was told to insert the final pill vaginally in all three cases. I had no idea it could even be taken orally."

Event of September 8, 2004, reported August 17, 2005: "I was given 2-step Abortion Pill. In the middle of the night I was awoken by severe abdominal pains. Having had endometriosis has built my pain tolerance quite high, but this pain was excruciating. Between the pain and diarrhea, I wanted to pass-out. I laid on the cold tile of the bathroom floor for 4 hours to keep me from fainting and because I couldn't get up. I thought it would eventually taper off, but after 4 hours I was exhausted and couldn't tolerate the pain. I yelled until my sister woke up to help me and asked her to call 911. She knew that I never go to the hospital, much less ask for 911, she immediately called. At the hospital, blood tests –b-hcg- kept coming back positive and I was still in alot of pain. They sent me for ultrasounds, blood tests again, and pelvic exams. I asked for more morphine, but they told my sister that they gave me the maximum dose and were surprised that I was still moaning of pain. The doctor said that my body was going through labor over and over, but wasn't ridding of anything. After the 3rd pelvic exam and blood test, the HCG count started coming down."

Event of December 14, 2005, reported December 27, 2005: "Approximately 2 1/2 weeks after taking Mifeprex and Cytotec to end a pregnancy, I began having very heavy bleeding. This was after I had not bled for a week, and after a 2 week follow up at a clinic—in which was told I was fine—I began hemorraging on the evening of the 14th, passing clots approximately 3 inches in size. I went through approximately 7 pads in 2 hours. The clinic wanted me to wait until the morning to get care from their facility, but when we called the local ER, they told me I needed to come in right away to get examined. I was cold, weak, and fatigued during the 2 hours my bleeding was excessively heavy. Unfortunately I was not able to make it into the ER because I am a single mother of 4, and had noone to care

A. Adverse Events for RU-486

These reports are based on the FDA's Adverse Event Reporting System (AERS), a voluntary system, with inherent underreporting. Common estimates of the proportion of adverse events actually captured by FDA in AERS are from one to ten percent. FDA acknowledges that it does not capture all adverse events associated with a drug: "When evaluating reports from the AERS system, it is important to recognize several caveats. First, *accumulated case reports cannot be used to calculate actual incidences of adverse events or estimates of risk for a product, as the reporting of adverse events is a voluntary process with inherent underreporting*"[122] (emphasis added).

The Government Accountability Office (GAO) has also commented on the underreporting of Adverse Events: "FDA cannot establish the true frequency of adverse events in the population with AERS data. The inability to calculate the true frequency makes it hard to establish the magnitude of a safety problem, and it makes comparisons of risks across similar drugs difficult."[123]

FDA nonetheless claims that it is capturing most adverse events associated with RU-486: "Because healthcare professionals who prescribe Mifeprex have agreed in writing" (with the manufacturer, Danco, *not* the FDA) "to report 'any hospitalizations, transfusions or other serious events' to the manufacturer, FDA believes that there are unlikely to be significant numbers of serious adverse events, including deaths, associated with Mifeprex that have not been reported to the Agency."[124]

During the Subcommittee staff's review of the 1070 Adverse Event Reports that had been reported through April 2006, ISRs were found that had been submitted through MedWatch, the voluntary reporting mechanism for AERS, rather than through Danco. FDA acknowledged that these reports were not matched by reports submitted through Danco,[125] undermining the Agency's claim that it is capturing most adverse events.

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for my children. Luckily for me, the bleeding lessened. I was told it was 'normal' to bleed for up to 4 weeks, but I am NOW at day 32 and still bleeding."

[122] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (May 2, 2006) (on file with Subcommittee).

[123] Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process GAO-06-402 March 31, 2006.

[124] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (July 31, 2006) (on file with Subcommittee).

[125] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (June 30, 2006) (on file with Subcommittee).

In light of FDA's repeated claim that it captures most RU-486-related adverse events—despite the Agency's own acknowledgement of underreporting and experience to the contrary—it is important to note that there is no true enforcement mechanism, either by Danco or the FDA, for ensuring that doctors report all adverse events, and there is little incentive on the part of the prescribing physician to do so.[126]

Even Danco has noted that the FDA's "obligatory" reporting system is of little value. In 2003, Dr. Richard Hausknecht, Medical Director for Danco, wrote that "[t]he obligatory reporting of adverse events is limited to transfusions, hospitalizations, ongoing pregnancies or 'other serious adverse events,' which allows considerable subjective judgment on the part of the providers. In addition, the reporting of other common adverse events may not be reported at all."[127]

Moreover, emergency room personnel and medical professionals who do not prescribe RU-486, but who may likely treat the infected or hemorrhaging patient, or provide surgical intervention, *have no obligation whatsoever to report adverse events for RU-486*, even assuming that the healthcare worker is aware the patient took the RU-486 drug regimen.[128] In such scenarios, prescribing physicians may remain unaware of adverse events that take place after they administer RU-486, alleviating them of reporting requirements. This underscores the fact that there is not an accurate picture of the total adverse events that are being experienced with this drug.

In addition to the fact that there is no accurate number of adverse events to serve as a realistic "numerator" for evaluating the rate of adverse events actually being experienced in the population, the FDA does not use an accurate figure for the true number of patients who have taken RU-486 as a "denominator." Rather, FDA accepts and reports "estimates" proposed by Danco. The most recent estimate is that 612,000 women in the U.S. have used RU-486 as of July 24, 2006.[129]

This estimate is likely inflated, since Danco arrives at its estimate by basing it on the number of packages sold (in three-pill packages of 200 mg pills) and multiplying that number by three to account for the number of doses that are given at the off-label 200 mg dose (rather than

[126] Although RU-486 is approved for use through 49 days of pregnancy, it is commonly prescribed in the United States up to 63 days of pregnancy. Physicians also commonly prescribe a dosing regimen that is different from that approved by the FDA. Therefore, it has been suggested that in fact there is a *dis*incentive on the part of prescribing physicians to report adverse events that may be attributed to a physician's negligence or willingness to prescribe a regimen that is outside the FDA-approved regimen for RU-486.

[127] Hausknecht, R., "Mifepristone and Misoprostol for Early Medical Abortion: 18 Months Experience in the United States," *Contraception* 67 (2003) 463-465.

[128] Treating personnel might never know that a woman has taken RU-486; Women who seek medical treatment for adverse reactions after RU-486 may be too sick to disclose, may fail to disclose, or may simply refuse to disclose (because she does not want it in her medical record) that she has taken the RU-486 drug regimen.

[129] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (August 17. 2006) (on file with Subcommittee).

the FDA approved 600 mg dose).[130] That Danco is allowed to provide a loosely-figured *estimate* flouts the restricted approval provision for RU-486, which requires Danco to distribute the drug with a tracking system allowing the company to track packages "to the patient level while maintaining patient confidentiality."[131]

For FDA to rely upon guesses as a basis for understanding safety problems with RU-486 is highly problematic. Danco's estimate is used as the denominator for determining the rate of adverse events associated with the drug. The larger the denominator, the lower the percentage of adverse events. This inaccuracy of using Danco's estimate is inexcusable in light of the way the estimate is relied upon to determine and discuss the rate of adverse events associated with RU-486.

B. RU-486 Safety Issues Known Prior to Approval

Prior to FDA's approval of RU-486, the Agency's own medical experts recognized that any benefits that could be gained from the use of this drug for a "medical abortion" were limited at best and that significant dangers were inherent in its use. These dangers are especially acute when compared to surgical abortion. According to the FDA's medical reviewer, writing before the drug's approval:

> This method of pregnancy termination is of limited value because of the relatively short window of opportunity, [sic] in which it can be employed. Its safety and effectiveness is based on its use during the seven weeks following the first day of the last menstrual period. This means that most women would not suspect that they are pregnant and have a confirmatory pregnancy test until at least four weeks after the beginning of their last menses. This, then, leaves only a three week period for the women to secure this method of abortion.
>
> Another disadvantage of this method of pregnancy termination is the need for at least three visits to the medical facility [sic] including at least a four hours [sic] stay after the administration of the misoprostol.
>
> In addition, medical follow-up is required to ensure that surgical termination is performed in case the medical termination attempt fails since misoprostol has been reported to be teratogenic in humans (limb defects and skull defects)...
>
> [In a comparison of medical termination of pregnancy with surgical termination,] [t]he medical regimen had more adverse events, particularly bleeding, than did surgical abortion. Failure rates for medical abortion exceeded those for surgical

[130] Richard Hausknecht, Medical Director for Danco, described how Danco estimates the usage figures for RU-486: "Denominators… were estimated from sales figures. Although the FDA-approved regimen specified a single oral dose of mifepristone 600 mg, many physicians are using a lower dose (200 mg), …[an] estimated range was based upon Planned Parenthood practices and National Abortion Federation (NAF) polling of their membership practices…[and by] [a]djusting for utilization patterns of providers." *Contraception* 67 (2003): 463-65.

[131] CDER Office Memo to Population Council, September 28, 2006. At http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf (last visited September 28, 2006).

> abortion…[and] increased with gestational age. Specific symptoms and adverse events, including cramping, nausea, and vomiting, were far more frequent among the medical than the surgical abortion patients… On the whole, medical abortion patients reported significantly more blood loss than did surgical abortion patients….[132]

The negative physical experience of RU-486 was explained this way by Dr. Tom Tvedten, an abortion provider in Little Rock, Arkansas: "With medical termination, the discomfort is significant because they have to go through mini-labor…There's a lot of hard cramps and usually significant bleeding. It's cheaper, safer and less painful to have a surgical termination."[133]

In fact, as explained in the RU-486 label, "nearly all of the women who receive Mifeprex and misoprostol will report adverse reactions, and many can be expected to report more than one such reaction,"[134] including: abdominal pain; uterine cramping; nausea; headache; vomiting; diarrhea; dizziness; fatigue; back pain; uterine hemorrhage; fever; viral infections; vaginitis; rigors (chills/shaking); dyspepsia; insomnia; asthenia; leg pain; anxiety; anemia; leucorrhea; sinusitis; syncope; endrometritis / salpingitis / pelvic inflammatory disease; decrease in hemoglobin greater than 2 g/dL; pelvic pain; and fainting.[135]

The FDA's Medical Officer's review notes that, "[m]ore than one adverse event was reported for most patients…Approximately 23% of the adverse events in each gestational age group were judged to be severe."[136]

In addition to these known, startling adverse effects, of which the FDA was aware during the RU-486 NDA review process, the incredibly high failure rate of the drug was also known, averaging 14.6% in the U.S. trial testing the drug through 63 days gestation.

The FDA's Medical Officer's review noted that in the U.S. trial of 2015 women, "[a] total of 295 patients were classified as having failed medical abortion."[137] This represents a

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[132] Medical Officer's Review of Amendments 024 and 033, Final Reports for the U.S. Clinical Trials Inducing Abortion up to 63 Days Gestational Age and Complete Responses Regarding Distribution System and Phase 4 Commitments, Finalized November 22, 1999 (dated January 27, 2000), available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_medr_P1.pdf (last visited September 28, 2006).

[133] John Leland, *Under Din of Abortion Debate, an Experience Shared Quietly*, N.Y. TIMES, Sept. 18, 2005, *at* http://www.nytimes.com/glogin?URI=http://www.nytimes.com/2005/09/18/national/18abortion.html&OQ=_rQ3D1&OP=41647c1fQ2FQ2AQ7EklQ2AbBG)ABB7FQ2AFqqjQ2AqQ2FQ2A42Q2A-_7VB-_YQ2A42_lBA7VB-vC7KY. (Quoting Dr. Tom Tvedten of Little Rock, Arkansas).

[134] Mifeprex Label, available at http://www.fda.gov/cder/foi/label/2005/020687s013lbl.pdf (last visited September 28, 2006).

[135] *Ibid.*

[136] Medical Officer's Review of Amendments 024 and 033, Final Reports for the U.S. Clinical Trials Inducing Abortion up to 63 Days Gestational Age and Complete Responses Regarding Distribution System and Phase 4 Commitments, Finalized November 22, 1999 (dated January 27, 2000), available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_medr_P1.pdf (last visited September 28, 2006).

[137] *Ibid*.

failure in 14.6% of total patients. "Of these patients, 79 (27%) had ongoing pregnancies, 126 (43%) had incomplete abortions, 30 (10%) requested and had surgical terminations, and the remaining 60 (20%) patients had surgical terminations performed because of medical indications directly related to the medical procedure."[138]

The "best" outcome was in the patient group consisting of women whose pregnancies were less than or equal to 49 days. In this group, 7.9% of patients required surgical intervention after taking RU-486. As the gestational age increases, the failure rate of RU-486 increases rapidly, to 17% in the 50-56 days gestation group, and 23% in the 57-63 days gestation group.

By any objective standard, a failure rate approaching eight percent and requiring subsequent surgical intervention as the "best" outcome is a dismal result. Nonetheless, the Medical Officer stated that "[t]he 92% success rate in the ≤ 49 days group is an acceptable one."[139] This failure rate, along with the anticipated adverse events that patients would experience, is explicit in the FDA Medical Officer's review, and also part of the RU-486 label.[140]

Despite these known problems with adverse events and high failure rates, the FDA recommended and gave approval for distributing this drug to women.

B. Post-Approval Hemorrhage, Infections and Deaths

As stated above, the FDA has acknowledged the deaths of six U.S. women associated with RU-486, nine life-threatening incidents, 232 hospitalizations, 116 blood transfusions and 88 cases of infection. [141] A quarter all the patients were hospitalized.[142] These and other cases add up to a total of 1070 adverse event reports (AERs) as of April 2006.

A review[143] of only a portion of all the reported AERs demonstrates in real world experience how women have suffered after taking dangerous drug. Out of only 607 unique adverse events submitted to the FDA, the high number of serious and life-threatening events is startling:

> The most frequent [adverse event reports] were hemorrhage (n=237) and infection (66). Hemorrhages included 1 fatal, 42 life threatening, and 168 serious case; 68 required transfusions. Infections included 7 cases of septic shock (3 fatal, 4 life-threatening) and

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[138] *Ibid*.

[139] *Ibid*.

[140] Mifeprex Label, available at http://www.fda.gov/cder/foi/label/2005/020687s013lbl.pdf (last visited September 28, 2006).

[141] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (May 2, 2006) (on file with Subcommittee).

[142] *Ibid*.

[143] M. M. Gary, D. J. Harrison, *Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient*, The Annals of Pharmacotherapy, February 2006, 40.

> 43 cases requiring parenteral antibiotics. Surgical interventions were required in 513 cases (235 emergent, 278 nonemergent). Emergent cases included 17 ectopic pregnancies (11 ruptured). Second trimester viability was documented in 22 cases (9 lost to follow-up, 13 documented fetal outcome). Of the 13 documented cases, 9 were terminated without comment on fetal morphology, 1 was enrolled in fetal registry, and 3 fetuses were diagnosed with serious malformations, suggesting a malformation rate of 23%.[144]

Since this review by Gary and Harrison, there have been hundreds more adverse event reports and two additional reported septic infection deaths. Nearly all among the afflicted and dead who experienced these serious adverse events following RU-486 were healthy women of child-bearing age. (This is in sharp contrast to other drugs with inherent risks—Viagra, for example—which result in adverse events often after repeated use over long intervals of time, in patients with other risk factors associated with age or disease.) Without access to emergency room services, women who suffered severe hemorrhage would have died.

In total, there are eight known deaths following RU-486: four Californians and one Canadian from *C. Sordellii* septic infection; a Tennessee woman with ruptured ectopic pregnancy; a Swedish teen, from massive hemorrhage; and a British female, from "unknown etiology," (but her clinical presentation of shock and an autopsy revealing one liter of blood in her stomach makes sepsis a plausible etiology).[145]

Five of the eight known deaths following the use of RU-486 have been the result of a toxic shock-like syndrome initiated by the bacteria *C. Sordellii.* This bacteria is thought to exist in low numbers in the reproductive tracts of many women and is normally contained by the immune system.[146] Experts in immunology,[147] pharmacology[148] and maternal-fetal medicine[149]

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[144] *Ibid*.

[145] *Ibid*.

[146] Letter to the Editor, James A. McGregor and Ozlem Equiles, *Risks of Mifepristone Abortion in Context*, Contraception 2005, 71: 161.

[147] *See,* Jeanette I. Webster and Esther M. Sternberg, *Role of the Hypothalamic-Pituitary-Adrenal Axis, Glucocorticoids and Glucocorticoid Receptors in Toxic Sequelae of Exposure to Bacterial and Viral Products*, Journal of Endocrinology 2004, 181:207-221 ("Natural and synthetic glucocorticoids protect against the lethal effects of many bacterial and viral components...agents that block the hypothalamic-pituitary-adrenal axis, as in…mifepristone…enhance lipopolysaccharide (LPS) and endotoxin lethality and LPS-induced fever. Even the normally endotoxin-nonresponsive C3H/HeJ mice could be made endotoxin sensitive by RU-486.")

[148] *See,* Ralph P. Miech, *Pathophysiology of Mifepristone-Induced Septic Shock Due to Clostridium Sordellii*, The Annals of Pharmacotherapy, September 2005, 39:

> "Mifepristone is a potent progesterone antagonist that, in addition to its ability to block glucocorticoid receptors, blocks progesterone receptors...Blockade of progesterone receptors…results in rejection of the developing placenta and death of the embryo. Prolonged ischemia of the decidua and the embryonic placenta causes necrosis [death] of these tissues. Mifepristone also [causes] cervical dilation and liquefaction of the cervical mucus plug. The combined loss of a closed cervix and the protective cervical mucus plug permits contamination of the decidua and the intrauterine necrotic cells with aerobic and anaerobic bacteria from the normal vaginal flora."

have suggested that because RU-486 interferes with the immune response, the bacteria, if present, are then able to flourish, causing a widespread, multi-organ infection in the woman.

The infections are *not* accompanied by a fever, and symptoms match those that are expected after taking the RU-486 regimen (cramping, pain, bleeding, nausea, vomiting), making detection of the fast-spreading infection difficult. Each of the women infected with *C. Sordellii* after RU-486 were dead within five to seven days.

The FDA describes the clinical presentation of *C. Sordellii* infection the following way:

- Rapid onset of influenza like symptoms (nausea, vomiting, and weakness)
- Hypothermia or *absence* of fever
- *Absence* of purulent discharge
- Localized pelvic tenderness may be *absent*
- Elevated hematocrit and marked leukemoid reaction
- Progressive refractory hypotension
- Marked edema with peritoneal and pleural effusions
- Rapidly fatal despite aggressive treatment[150] (emphasis added).

To investigate the nature of the *C. Sordellii* bacteria, the FDA and CDC held the "Emerging Clostridial Disease" workshop on May 11, 2006.[151] Workshop presenters – experts in the fields of pharmacology, immunology, and maternal-fetal medicine – noted that the rapid growth of the *C. Sordellii* bacteria likely forecloses effective treatment;[152] that there is no currently identifiable "window of opportunity" for treatment once a woman is infected, even with major interventions such as hysterectomy;[153] and that antibiotic prophylaxis was unlikely to provide any protection in the RU-486 / *C. Sordellii* context.[154] The fatality rate has been 100% for the women who contracted *C. Sordellii* infection after RU-486.

In an effort to dismiss any association between RU-486 and the *C. Sordellii* deaths, some have promoted the idea that *C. Sordellii* is linked to pregnancy and childbirth, not the abortion pill. However, in five years, five women have died from this infection after taking RU-486. In contrast, the FDA has noted that there were "only five additional cases not associated with

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[149] *See*, Sharon Worchester, *Mifepristone Deaths Raise Unanswered Questions*, Ob. Gyn. News, (October 1, 2005) at 13. (Quoting Dr. James A. McGregor)("Mifepristone has multiple pharmacologic properties that may interfere with innate immune responses to infection, toxin exposures, and inflammatory stimuli.").

[150] Food and Drug Administration "Center Director Briefing" June 27, 2005 (on file with the Subcommittee).

[151] A full transcript for the meeting is available at: http://www.fda.gov/cder/meeting/clostridial/transcript.pdf (last visited October 13, 2006).

[152] Letter to the Editor, James A. McGregor and Ozlem Equiles, *Risks of Mifepristone Abortion in Context*, Contraception 2005, 71: 161.

[153] Public Workshop on Emerging Clostridial Disease," (CDC Conference Center: Atlanta, Georgia, May 11, 2006). Transcript available at http://www.fda.gov/cder/meeting/clostridial/transcript.pdf (last visited October 13, 2006).

[154] *Ibid*.

mifepristone/misoprostol retrieved with a text search of the entire AERS database"[155] of 3.5 million records.[156]

Distinguishing the 100% fatality rate with this infection following RU-486 among women who were otherwise healthy, the FDA noted, "[t]he patients in these 5 [non-RU-486 related] cases had weakened or altered immune function due to chemotherapy and age (neonatal & elderly patients), and use of multiple antibiotics. None of these five cases involved intravaginal product administration and 3 cases had a fatal outcome. *In contrast to these 5 additional cases in [3.5 million] AERS, the 4 U.S. confirmed cases of Clostridium Sordellii infection with medical abortion involved healthy patients and all cases had fatal outcome*"[157] (emphasis added).

A more extensive database search for any reported *C. Sordellii* infections since 1925 found a total of eleven fatal cases related to post-partum/ob-gyn infection or to spontaneous abortion.[158] In contrast with this small number of cases (11 since 1925) five women in five years are known to have died from *C. Sordellii* following RU-486.

Experts studying the immune suppression properties of RU-486 have found that it has the ability to block innate immune response.[159] Lazar had published information as early as 1992

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[155] Memorandum, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, April 12, 2006, From [redacted], Division of Drug Risk Evaluation, Through: [redacted] Division of Drug Risk Evaluation, TO: [redacted] Division of Reproductive and Urologic Products. Subject: Supplementary investigations related to reports of fatal infections associated with mifepristone and misoprostol use for medical abortion. [handwritten note: DFS 4/17/06 Consult #3]

[156] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (May 2, 2006) (on file with Subcommittee).

[157] Memorandum, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, April 12, 2006, From [redacted], Division of Drug Risk Evaluation, Through: [redacted] Division of Drug Risk Evaluation, TO: [redacted] Division of Reproductive and Urologic Products. Subject: Supplementary investigations related to reports of fatal infections associated with mifepristone and misoprostol use for medical abortion. [handwritten note: DFS 4/17/06 Consult #3]

[158] Dennis L. Stevens, M.D., PhD., *Clostridium sordellii: Clinical Settings, Diagnostic Clues and Pathogenic Mechanisms*, Public Workshop on Emerging Clostridial Disease," (CDC Conference Center: Atlanta, Georgia, May 11, 2006). Available at http://www.fda.gov/cder/meeting/clostridial/stevens.pdf (last visited October 13, 2006).

[159] *See,* Jeanette I. Webster and Esther M. Sternberg, *Role of the Hypothalamic-Pituitary-Adrenal Axis, Glucocorticoids and Glucocorticoid Receptors in Toxic Sequelae of Exposure to Bacterial and Viral Products*, Journal of Endocrinology 2004, 181:207-221 ("Natural and synthetic glucocorticoids protect against the lethal effects of many bacterial and viral components...agents that block the hypothalamic-pituitary-adrenal axis, as in…mifepristone…enhance lipopolysaccharide (LPS) and endotoxin lethality and LPS-induced fever. Even the normally endotoxin-nonresponsive C3H/HeJ mice could be made endotoxin sensitive by RU-486."). *See also,* Ralph P. Miech, *Pathophysiology of Mifepristone-Induced Septic Shock Due to Clostridium Sordellii*, The Annals of Pharmacotherapy, September 2005, 39:

> "Mifepristone is a potent progesterone antagonist that, in addition to its ability to block glucocorticoid receptors, blocks progesterone receptors...Blockade of progesterone receptors…results in rejection of the developing placenta and death of the embryo. Prolonged ischemia of the decidua and the embryonic placenta causes necrosis [death] of these tissues. Mifepristone also [causes] cervical dilation and liquefaction of the cervical mucus plug. The

about the increase in fatal septic infection in mice after receiving RU-486, which caused the survival rate to drop dramatically from the control level of 71% to only 15%.[160] Nonetheless, the theory that RU-486 suppresses the immune system was only noted by the FDA as late as 2003,[161] and it wasn't until 2004 that the Agency conducted the minimal inquiry of a literature review to examine the immune suppression properties of RU-486:.

> "The Division of Anti-Infective Drug Products (DAIDP) reviewed the medical literature to examine the potential impact that either or both mifepristone and misoprostol might have on human immune function. They concluded, 'Systemic levels of mifepristone and misoprostol may both influence the host response to infection via their anti-inflammatory effects, respectively. In theory, *these effects may predispose an individual to infection or may predispose an infected individual to a worse outcome*. Such roles are apparently dependent on dose, timing, and rates of uptake and intracellular degradation in different target tissues'"[162] (emphasis added).

Beyond this, there is little more in the thousands of pages of documents provided to the Subcommittee to indicate an extensive FDA examination of the immune suppression properties of RU-486.

In the meantime, women who take RU-486 are exposing themselves to an exponentially greater risk of infection or death as compared to the alternative of surgical abortion. The risk of death from infection is at least ten times greater than surgical abortion during the first eight weeks of pregnancy.[163] In addition to *C. Sordellii* infection, women taking RU-486 have developed other infections following the abortion pill regimen. The FDA has acknowledged 88 reported cases of infection following RU-486.

The most frequent serious adverse event is hemorrhage, where women who lost enough blood as to require transfusions. These cases of massive hemorrhage comprise 12% of the RU-

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> combined loss of a closed cervix and the protective cervical mucus plug permits contamination of the decidua and the intrauterine necrotic cells with aerobic and anaerobic bacteria from the normal vaginal flora."

See also, Sharon Worchester, *Mifepristone Deaths Raise Unanswered Questions*, Ob. Gyn. News, (October 1, 2005) at 13. (Quoting Dr. James A. McGregor)("Mifepristone has multiple pharmacologic properties that may interfere with innate immune responses to infection, toxin exposures, and inflammatory stimuli.").

[160] G. Lazar, *et al.*, *Modification of septic shock in mice by the antiglucocorticoid RU 38486*, 36 Circulatory Shock 180 (1992).

[161] FDA Division of Anti-Infective Drug Products, Report of Medical Officer Consultation (Intravaginal Misoprostol), November 19, 2003, at 4 (on file with the Subcommittee)..

[162] FDA Mifeprex plus Misoprostol Postmarketing Safety Review, November 15, 2004, at 24 (on file with the Subcommittee).

[163] *See,* Michael F. Green, M.D., *Fatal Infections Associated with Mifepristone-Induced Abortion*, Dec. 1, 2005, N. ENGL. J. MED 353;22 *at* 2318. The mortality rate for women who procure a surgical abortion is 0.1 in 100,000 during the first eight weeks of pregnancy, the period for which RU-486 is available for women. Dr. Michael Green, based on usage rates of 460,000 and 4 deaths, suggested that the risk of death from chemical abortion is ten times greater. The rate could be higher, if an accurate numerator is used for the true number of patients who have taken RU-486.

486 AERS.[164] A review of the AERS through September 2005 finds that fifteen women suffered hemorrhages so serious that they lost over half of their entire blood volume and would have died without rapid access to emergency room services.[165]

According to Dr. Donna Harrison, who testified before the Subcommittee at the May 17 hearing *RU-486: Demonstrating a Low Standard for Women's Health?*, "In my experience as an ob-gyn, the volume of blood loss seen in the life-threatening cases is comparable to that observed in major surgical trauma cases like motor-vehicle accidents. This volume of blood loss is rarely seen in early surgical abortion without perforation of the uterus, and it is rarely seen in spontaneous abortion."[166]

As with other adverse events associated with RU-486, no risk factors for hemorrhage have been identified. Rather, they are unpredictable and sporadic.[167]

The proven health risks and demonstrated association with fatal septic infections necessarily prompt urgent consideration of this drug's immediate withdrawal from the market.

V. RECOMMENDATIONS

The high incidence of adverse events has prompted Danco, in cooperation with the FDA, to take steps to alert women and the medical community to the dangers of the drug:[168]

- "Dear Health Care Provider" Letter, April 19, 2002 (warning of danger of ruptured ectopic pregnancies).[169]
- "Dear Emergency Room Director" Letter, November 12, 2004 (warning of infection, heavy bleeding and ruptured ectopic pregnancy).[170]
- "Dear Health Care Professional" Letter, November 12, 2004 (warning of infection, heavy bleeding and ruptured ectopic pregnancy).[171]
- Updated label, December 22, 2004 (reflecting danger of infection, heavy bleeding and ruptured ectopic pregnancy).[172]

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[164] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (May 2, 2006) (on file with Subcommittee).

[165] See *RU-486: Demonstrating a Low Standard for Women's Health? Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Res., Committee on Government Reform*, 109th Cong. (May 17, 2006) (statement of Donna Harrison, M.D.) Available at http://reform.house.gov/UploadedFiles/Harrison%20Testimony%20-%20scan%20test.%20w%20attchmts.pdf.

[166] *Ibid*.

[167] *Ibid*.

[168] See Danco's website, http://www.earlyoptionpill.com/.

[169] Available at http://www.fda.gov/medwatch/SAFETY/2002/mifeprex_deardoc.pdf (last visited October 14, 2006).

[170] Available at http://www.fda.gov/cder/drug/infopage/mifepristone/DearER.pdf (last visited October 14, 2006).

[171] Available at http://www.fda.gov/cder/drug/infopage/mifepristone/DearHCP.pdf (last visited October 14, 2006).

- "Dear Health Care Provider" Letter, July 19, 2005 (warning of the cases of fatal septic shock).[173]
- Updated label, July 19, 2005 (warning of danger of fatal *C. Sordellii* infections).[174]

In light of the significant health risks posed by this drug, the current restrictions, and the letters and label changes subsequent to approval are demonstrably insufficient to protect women from the dangers of RU-486. Rather, the FDA possesses the authority to suspend or withdraw approval of the drug under various provisions. The most important, and perhaps necessary and justified for removing RU-486 from the market, is the Imminent Hazard authority possessed by the Secretary of Health and Human Services.

"Imminent Hazard" is defined and the criteria to be considered are set forth in 21 CFR 2.5:

> (a) Within the meaning of the Federal Food, Drug and Cosmetic Act an imminent hazard to the public health is considered to exist when the evidence is sufficient to show that a product or practice, posing a significant threat of danger to health, creates a public health situation (1) that should be corrected immediately to prevent injury and (2) that should not be permitted to continue while a hearing or other formal proceeding is being held. The imminent hazard may be declared at any point in the chain of events which may ultimately result in harm to the public health. The occurrence of the final anticipated injury is not essential to establish that an imminent hazard of such occurrence exists.
>
> (b) In exercising his judgment on whether an imminent hazard exists, the Commissioner will consider the number of injuries anticipated and the nature, severity, and duration of the anticipated injury.

Under this provision, the Secretary's decision is subject to judicial review, but the courts are deferential to the Secretary's conclusions.[175] Within the context of RU-486, the unpredictability and frequency of serious adverse event and death (discussed in Section III above) warrants withdrawal of this dangerous drug from the market.

The FDA also possesses the authority to unilaterally withdraw approval of a drug under 21 CFR 314.530. RU-486 falls into the withdrawal categories of this provision:

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[172] Available at http://www.fda.gov/cder/foi/label/2004/020687lbl_Revised.pdf (last visited October 14, 2006).

[173] Available at http://www.fda.gov/medwatch/safety/2005/mifeprex_deardoc_071905.pdf (last visited October 14, 2006).

[174] Available at http://www.fda.gov/cder/drug/infopage/mifepristone/DearHCP.pdf (last visited October 14, 2006).

[175] See *Forsham v. Califano*, 442 F. Supp. 203 (D. D.C. 1977)(this case appears to be the only instance in which the "imminent hazard" authority of the HHS Secretary has invoked). See also *RU-486: Demonstrating a Low Standard for Women's Health? Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Res., Committee on Government Reform*, 109th Cong. (May 17, 2006) (statement of O. Carter Snead, Assoc. Professor, University of Notre Dame Law School). Available at http://reform.house.gov/UploadedFiles/Snead%20Testimony.pdf.

(a)(1) A post-marketing clinical study fails to verify clinical benefit

Since its approval, RU-486 has been associated with six known U.S. deaths of healthy women.[176] The safety problems associated with RU-486 are discussed above. Additionally, because women who visit the emergency room arrive with symptoms virtually identical to those associated with miscarriage,[177] deaths within the U.S. following the use of RU-486 may be higher, but unreported.

Moreover, as discussed above, the mortality rate for surgical abortion for the first eight weeks of pregnancy is 0.1 per 100,000.[178] The makers of RU-486 report that 575,000 women have used the drug (based on units shipped, not units prescribed, and based on the assumption that one tablet—rather than the FDA-approved three—is administered to the patient;[179] the actual number of women who have taken the drug may be much lower). Using the figure of 575,000 women having taken RU-486, this works out to a known death rate of approximately 1.39 per 100,000, nearly *14 times* greater than surgical abortion. As noted above, Subpart H drug approval is conditioned on "meaningful therapeutic benefit." The statistics demonstrate that medical abortion is far more dangerous than the existing treatment of surgical abortion, which is proof of a lack of clinical benefit.

(a)(3) Use after marketing demonstrates that post-marketing restrictions are inadequate to assure safe use of the drug product

Experience shows that post-marketing restrictions on RU-486 are inadequate to assure the safe use of the product, because the medical community has ignored them on a widespread basis. As noted earlier in this report, abortion providers routinely use RU-486 beyond the time periods approved by the FDA[180] and with dosing regimens that stray from the FDA's approved

[176] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources, (May 2, 2006) (on file with Subcommittee).

[177] "Dear Emergency Room Director" Letter from Danco Laboratories to emergency room directors, (Nov. 12, 2004), *at* http://www.fda.gov/cder/drug/infopage/mifepristone/DearER.pdf.

[178] Michael F. Green, M.D., *Fatal Infections Associated with Mifepristone-Induced Abortion*, Dec. 1, 2005, N. ENGL. J. MED 353:22 *at* 2318.

[179] *Ibid.*

[180] Some abortion providers (e.g., Planned Parenthood of New York City at www.ppnyc.org/services/factsheets/mifep.htm, Capital Care Women's Center at www.capitalcarewomenscenter.com/services.php, and Camelback Family Planning at www.camelbackfamilyplanning.com/abortionpill.html.), even advertise the availability of RU-486 through 63 days LMP, by which time the rate of incomplete abortion, infection, and other complications rises sharply. In U.S. clinical trials, the failure rate for RU-486 abortions jumps to 17% at 50-56 days LMP, and to 23% at 57-63 days LMP, from 8% at 49 days or less. Irving Spitz *et al*., "Early pregnancy termination with mifepristone and misoprostol in the United States," *New England Journal of Medicine* 1998, 338:1241-47.

regimen.[181] While off-label use of drugs is common, it runs contrary to the entire purpose of the regulatory regime approved for RU-486 under Subpart H.

The FDA is aware of the medical community's refusal to heed the regulations it instated on RU-486. In its own words, the FDA "is aware that…some [physicians] may have chosen to use a modified version of the Patient Agreement form. However, these decisions are made by physicians exercising their own judgment about what is best for their patients**.**"[182]

This is contrary to the detailed Risk Management Program, explained in the FDA memo detailing the drug's approval, which states: "the signed agreement form will be given to the patient for her reference and another kept in the medical records," and "[the prescribing physician] must provide each patient…with a copy of the Medication Guide and Patient Agreement, give her an opportunity to read and discuss both the Medication Guide and the Patient Agreement, obtain her signature on the Patient Agreement and must sign it as well."[183] The FDA determined that these restrictions were critical to the safe use of the drug, and in spite of this, physicians have refused to heed them.

(a)(4) The applicant fails to adhere to the post-marketing restrictions agreed upon

Although the FDA stipulated that the manufacturer have systems in place to track the distribution of RU-486 "to the patient level," and that require physicians to "record the Mifeprex package serial number in each patient's record,"[184] Danco has not provided reliable patient numbers, but rather estimates.[185]

In addition to the FDA requiring patients to sign a Patient Agreement form, the Population Council agreed, as part of the approval process, to "auditing prescribers to ascertain whether they have obtained signed copies of the Patient Agreement forms." It is unclear whether the Population Council, Danco, or any other entity associated with the production of RU-486 has adhered to this requirement.

(a)(5) The promotional materials are false or misleading

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[181] R. Hausknecht, "Mifepristone and Misoprostol for Early Medical Abortion: 18 Months Experience in the United States," *Contraception* 67 (2003): 463-65: "Although the FDA-approved regimen specified a single oral dose of mifepristone 600 mg, many physicians are using a lower dose (200 mg)."

[182] Letter from Patrick Ronan, Associate Commissioner for Legislation Department of Health and Human Services FDA to Hon. Mark E. Souder, (March 16, 2006) (on file with Govt. Reform Subcommittee on Criminal Justice, Drug Policy, and Human Resources).

[183] Memorandum from FDA Center for Drug Evaluation and Research to Population Council 6, (Sept. 28, 2000) (available at http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf).

[184] *Ibid.*

[185] Richard Hausknecht, Medical Director for Danco, described how Danco estimates the usage figures for RU-486: "Denominators… were estimated from sales figures. Although the FDA-approved regimen specified a single oral dose of mifepristone 600 mg, many physicians are using a lower dose (200 mg), …[an] estimated range was based upon Planned Parenthood practices and National Abortion Federation (NAF) polling of their membership practices…[and by] [a]djusting for utilization patterns of providers." *Contraception* 67 (2003): 463-65.

The FDA conditioned approval of RU-486 on tracking its use "to the patient level." In spite of this, the manufacturer estimates the usage of its drug for its promotional materials.[186] This affects the perceived safety of the drug, as the manufacturer may be overstating its actual usage in comparison with the adverse events reported.

Both the "Imminent Hazard" provision and the regulatory provision for approval withdrawal under Subpart H provide sufficient authority for the Administration to remove this dangerous drug from the market.

VI. CONCLUSION

The integrity of the FDA in the approval and monitoring of RU-486 has been substandard and necessitates the withdrawal of this dangerous and fatal product before more women suffer the known and anticipated consequences or fatalities. RU-486 is a hazardous drug for women, its unusual approval demonstrates a lower standard of care for women, and its withdrawal from the market is justified and necessary to protect the public's health.

[186] *Ibid*. *See also*, Letter from David W. Boyer, Assistant Commissioner for Legislation, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources, (May 2, 2006) (on file with Subcommittee); *FDA Announces Mifeprex Not Cause of One of Two Recent Abortion-Related Deaths*, KAISER NETWORK DAILY REPORTS, (April 11, 2006) *at* http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=36534. ("We stand behind the safety profile of the drug, which has been used by approximately 575,000 women in this country since FDA approval in 2000," quoting Cynthia Summers, director of marketing and public affairs at Danco Laboratories, originally in Wall Street Journal, April 11, 2006.)

EXHIBIT 48

Memorandum on RU-486 from HHS Chief of Staff Kevin Thurm to White House Director of Domestic Policy Carol Rasco (May 11, 1994)

Tab 4 Political Issue Discussion

A Judicial Watch Special Report:

The Clinton RU-486 Files

♦

The Clinton Administration's Radical Drive to Force an Abortion Drug on America

Judicial Watch, Inc. ♦ 501 School Street, S.W. ♦ Washington, D.C. 20024

Tel: 202-646-5172 ♦ Fax: 202-646-5199 ♦ www.JudicialWatch.org

Introduction

This Judicial Watch Special Report analyzes newly uncovered documents from the National Archives at the Clinton Presidential Library in Little Rock, Arkansas, describing the Clinton administration's radical drive to introduce the abortion drug RU-486 (mifepristone) into the American marketplace.

The records include the Clinton administration's legal, political and press strategies for rushing RU-486 through the Food and Drug Administration (FDA) processes, despite the manufacturer's historical refusal to permit marketing the drug here. The legal, political and press memos articulate the Clinton administration's views regarding various players in the drug approval and marketing process -- women's groups, members of Congress, public interest groups and the media.

Judicial Watch has engaged in a five-year legal battle with the FDA for release of records under the provisions of the Freedom of Information Act (FOIA), 5 U.S.C. §552, concerning RU-486. We uncovered over 9,300 pages of documents and 840 Adverse Event Reports pertaining to the abortion drug. To date, the deaths of at least six women have been attributed to RU-486. The FDA scheduled a scientific conference for May 11, 2006 in order to study the controversial abortion drug and the circumstances leading to the deaths.

Judicial Watch promotes transparency, integrity and accountability in government, politics and the law. We make aggressive use of open records and open meetings laws as a means to obtain documents with which to educate the American public on the operations of their government and to hold public officials accountable. Judicial Watch also provides technical, research and litigation assistance to public interest groups interested in obtaining information about government activity which may not have the necessary resources or experience to pursue information on their own as part of the Judicial Watch Open Records Project.

Thomas Fitton
President
Judicial Watch, Inc.

April 26, 2006

Questions or comments concerning this report should be directed to:

Christopher J. Farrell
Director of Investigations & Research
Judicial Watch, Inc.
501 School Street, SW -- Suite 500
Washington, DC 20024
Tel: 202-646-5172
cfarrell@judicialwatch.org

The Clinton RU-486 Files:
The Clinton Administration's Radical Drive to Force an Abortion Drug on America

Executive Summary

During a February 2006 research trip to the National Archives at the Clinton Presidential Library, Judicial Watch uncovered new records detailing the Clinton administration's rush to market the abortion drug RU-486 (mifepristone) to American women. The documents include political, legal and press strategy memoranda from Health and Human Services (HHS) Secretary Donna Shalala, FDA Commissioner, Dr. David Kessler, and HHS Chief of Staff Kevin Thurm. Some of the memoranda are addressed to the White House -- in particular, Carol Rasco, the Clinton administration Director of Domestic Policy.

Analysis of the records shows:

- President Clinton ordered HHS and FDA to coordinate and promote the marketing of RU-486 as his first official act in office.
- Within one month, the FDA Commissioner had met with the RU-486 manufacturer and their parent company.
- Official U.S. Government political, economic and diplomatic pressure was brought to bear to strong-arm the companies into changing their policies in order to make the drug available in the United States.
- The FDA was compromised in its role as objective reviewers of the safety and efficacy of the drug.
- The five standard requirements for certifying a drug "safe and effective" were circumvented to rush RU-486 to market.
- Radical, pro-abortion extremists dominated the Clinton administration's "women's health care" agenda and their reckless drive to bring RU-486 to America ultimately cost at least six women their lives and the lives of over 560,000 unborn children.

The Clinton RU-486 Files:
The Clinton Administration's Radical Drive to Force an Abortion Drug on America

* * *

"Hoechst has historically refused to permit Roussel Uclaf to seek marketing approval for RU-486 as an abortifacient in the United States. Both Dr. Kessler [FDA Commissioner] *and I have taken steps to persuade Roussel Uclaf and Hoechst to change their position."*

Donna Shalala
Health & Human Services Secretary
Clinton Administration
November 15, 1993
Confidential Memo to White House

* * *

In February 2006, Judicial Watch uncovered previously confidential files and working papers from the holdings of the National Archives at the Clinton Presidential Library in Little Rock, Arkansas that provide remarkable insight into the Clinton administration's relentless drive to market RU-486 (mifepristone), a drug used to cause abortion, to American women. The documents offer a window into the political strategy, legal theories and media "spin" on the Clinton administration's abortion program.

RU-486 was first developed in France in 1981. It is a manmade steroid designed to work against the hormone progesterone, which is required to promote a baby's proper growth and development. RU-486 works to chemically destroy the unborn child's environment, cutting off nourishment and starving the baby to death in the mother's womb. A second chemical, misoprostol, is then used to create cramping and contractions to expel the dead baby from the mother's womb. The "procedure" must begin within 49 days of conception. The Clinton administration considered this method of abortion part of "women's health care." President Clinton thanked the maker of RU-486 in writing, "On behalf of the government of the United States and for the women of America. . ."[i]

On January 22, 1993, in his first official act, President Clinton issued a memorandum directing HHS Secretary Donna Shalala to promote the testing and licensing of RU-486 in the United States. (See Tab A)

Abortion was a key domestic policy item for President Clinton. RU-486 was just one part of the overall strategy for his administration's agenda. For example, in a

National Archives document entitled, "President William J. Clinton -- Eight Years of Peace, Prosperity and Progress," the first "accomplishment" listed reads:

> **Abolished Restrictions on Medical Research and the Right to Choose** As his first executive actions, President Clinton revoked the Gag Rule, which prohibited abortion counseling in clinics that receive federal funding to serve low-income patients. He also revoked restrictions on a woman's legal right to privately funded abortion services in military hospitals, restrictions on the import of RU-486, and restrictions on the award of international family planning grants (the "Mexico City Policy"). The President also lifted the moratorium on federal funding for research involving fetal tissue, allowing progress on research into treatments for Parkinson's disease, Alzheimer's, diabetes and leukemia. (Executive Memoranda, 1/22/93)[ii]

The tone was set for the Clinton administration's drive towards promoting abortion as "health care." Shalala and FDA Commissioner, Dr. David Kessler, engaged in a political, legal and economic campaign to force the French pharmaceutical firm, Roussel Uclaf, and their German parent corporation, Hoechst, A.G., to file a "new drug application" (NDA) with the FDA, and begin marketing RU-486 to American women.[iii]

In April 1993, the FDA brokered a meeting between Roussel Uclaf and the Clinton administration's anointed abortion proponent, the Population Council, a non-profit organization that conducts research on so-called "reproductive health issues." Roussel Uclaf and the Population Council already had an existing contractual relationship concerning provision of abortifacients (substances that induce abortion) for various clinical trials.[iv] It is difficult to understand the FDA's role in bringing the parties together, other than to continue to bring official U.S. government pressure on Roussel Uclaf and to designate the Population Council as the Clinton administration's abortion drug development and marketing proxy.

The Population Council claims to be " . . . an international, nonprofit, nongovernmental organization, seeks to improve the well-being and reproductive health of current and future generations around the world and to help achieve a humane, equitable, and sustainable balance between people and resources."[v] The organization was founded by John D. Rockefeller III in 1952. In 2005, they projected spending over $71 million in 70 countries around the world. Their work is funded by governments, foundations, individuals and "multilateral organizations."[vi]

According to the Clinton RU-486 files, Roussel Uclaf made the decision to use the Population Council as the administration's surrogate for forcing RU-486 on America.

There is no mention in the memoranda of Planned Parenthood or the National Abortion and Reproductive Rights Action League (NARAL). There is no mention of public disclosure, discussion, competition or bidding. One might imagine a selection process or staff discussion of the relative pros and cons for selection of another abortion group, but there is no evidence of any such discussion or consideration. In a memo by HHS Chief of Staff Kevin Thurm (discussed in detail below), the Clinton administration seems to have been predisposed to using the Population Council to carry out their abortion plans based on an existing relationship of the abortion non-profit with the maker of RU-486.

Roussel Uclaf repeatedly sought total U.S. government-sponsored indemnification from any damages it might incur by bringing RU-486 to the U.S. marketplace. Roussel Uclaf President, Dr. Edouard Sakiz, specifically expressed concerns over liability actions against his firm "if a woman had an incomplete abortion and delivered a deformed fetus." Dr. Sakiz was also particularly concerned about "consequential damages," such as the economic costs from boycotts. The Clinton administration's fervent commitment to making RU-486 part of the American abortion industry is demonstrated through Dr. Sakiz's reservations concerning legal and economic exposure. The Clinton administration's near-obsession with introducing a "safe and effective" abortion drug is revealed in Shalala's confidential memo to the White House of November 15, 1993:

> "Dr. Sakiz's view was that if the United States Government wanted RU-486 to be marketed in the United States, it should compensate Roussel Uclaf for any damages that the company might suffer from complying with the United States Government's request."

(See Tab B)

Dr. Sakiz was saying, in other words, "If <u>you</u> want it so badly, <u>you</u> pay the consequences." The Clinton administration was attempting to trump a business decision of the pharmaceutical company while exposing the corporation to risk for abiding by a U.S. government request.

Even Clinton FDA Commissioner Kessler understood and memorialized the controversy over the administration's aggressive efforts to introduce RU-486 when he wrote in a September 30, 1993 memorandum to Shalala:

> " . . . other Congressional members have written to Hoechst expressing their strong opposition to the marketing of RU-486 in this country. This, and the well-publicized activities of anti-abortion groups, have provided Hoechst and Roussel Ucalf with evidence that the U.S. population

> lacks cohesiveness on this issue and that the abortion debate continues."

(See Tab C)

The Clinton administration realized that attempting to enact blanket indemnification by the U.S government of a foreign corporation for an abortion drug was politically and practically impossible. According to the Clinton RU-486 files, Dr. Sakiz still went ahead and committed to negotiating with the Clinton administration surrogates – the Population Council – agreeing:

- To license RU-486 to the Population Council which would conduct a clinical trial involving 2000 women pursuant to an investigational new drug application;
- The Population Council would ultimately submit an NDA to the FDA based on the results of the clinical trial and on other studies conducted by Roussel Uclaf; and
- The Population Council, with the concurrence of Roussel Uclaf, would chose a new manufacturer for the drug, and that Roussel Uclaf would transfer its technology for making the drug to that manufacturer because Roussel Uclaf did not want to manufacture the drug for sale in this country. [Emphasis added.]

(See Tab B)

According to the Clinton RU-486 files, over the next few months Roussel Uclaf reiterated its desire for protective federal legislation providing blanket indemnification from the use of RU-486. Roussel Uclaf did not anticipate any profit from selling RU-486 in the United States; and was only entering the American market at the insistence of the Clinton administration. FDA representatives told Roussel Uclaf that such protection was extremely unlikely.

In a September 30, 1993 memorandum to Shalala, FDA Commissioner Kessler recounts a conversation he had with Jim Boynton, legal counsel for the Population Council, concerning the Roussel Uclaf indemnification legislation. Kessler pointed out the recent passage of the Hyde Amendment (restricting federal funds for abortion), and that with one exception (swine flu event), the United States had never agreed to indemnify any drug manufacturer. Apparently sensing that it might be perceived as inappropriate for the FDA commissioner to be discussing indemnification with a drug company representative for a supposedly safe drug, Kessler tried to cover his tracks. Kessler wrote that he, ". . . further explained that it would go far beyond FDA'S

appropriate role to seek such protection for a drug company." [Emphasis added.] Nonetheless, the FDA offered to advance the idea within HHS.

Not satisfied with the denials of indemnification from the FDA and HHS, in September 1993 Roussel Uclaf hired legal counsel (reportedly, Lester Hyman and John Hoff of the firm Swidler & Berlin) to lobby the federal government for indemnification "at levels higher than the FDA" – presumably from President Clinton and other pro-abortion advocates in the Congress, such as Rep. Ron Wyden and Rep. Henry Waxman. Concerned with these moves, HHS Chief of Staff Kevin Thurm and HHS General Counsel Harriet Rabb initiated a meeting with attorneys from Swidler & Berlin. During that meeting Roussel Uclaf's lawyer suggested that the United States could exercise its statutory powers of eminent domain and seize the patent for RU-486 for the abortifacient uses of the drug.[vii]

Meanwhile, the Population Council and Roussel Uclaf pressed forward with licensing details, and simultaneously made plans to sway the leadership of Hoechst to allow their subsidiary to enter into an agreement with the Population Council. Shalala's confidential memo to the White House warns, ". . . we do not think the negotiations will be successfully concluded without pressure on Roussel Uclaf/Hoechst."[viii]

Shalala suggested the Clinton administration bring the force of the United States Government to bear on the Hoechst and Roussel Uclaf corporations. She also went on to suggest that the United States exercise its international diplomatic and economic pressure on the German and French governments, as a means of further "influence" against the corporations. In a November 15 confidential memo to the White House, Shalala wrote: "The French and German governments might be displeased to learn that their companies are not accommodating a request made by the United States Government."

While the Clinton administration pondered exercising the full economic and diplomatic weight of the United States Government to advance its abortion agenda, it is important to note that Roussel Uclaf was willing to give a royalty-free license to any major U.S. pharmaceutical company – but no U.S. company would take the license.

The Clinton RU-486 files show specualtion among administration officials concerning delays in the negotiations between Roussel Uclaf and the Population Council. The pending retirement of the chief executive officer of Hoechst, Professor Wolfgang Hilger, was discussed in Kessler's September memo, noting that Prof. Hilger was "very staunchly Catholic." There was also a discussion of the likelihood of an international foundation being created by the drug's inventor, Dr. Etiene Balieu, for broader marketing opportunities. Apparently the Clinton administration was concerned about competition from an abortion drug "insider."[ix]

Just as the name of the Population Council "appeared" in the Clinton administration's confidential memos without a trace of how it became the administration's surrogate, so too does the recommendation for Felix Rohatyn to serve as an "expert advisor."[x]

After a review of the economic, political and diplomatic issues involved in strong-arming Hoechst and Roussel Uclaf, Dr. Kessler advanced Mr. Rohatyn's name by concluding with a political point: "We think that someone familiar to these circles would advance the Administration's goal to bring a safe and effective abortifacient to the U.S. market." Again, there is no discussion, alternatives or explanation offered for this appointment. The question of appointment of an "expert advisor" for the U.S. government is raised and answered in the space of one paragraph.

In a remarkable admission that the FDA had been thoroughly politicized in the Clinton administration's radical drive for RU-486, the agency's commissioner, Dr. Kessler, wrote in his September memo, " . . . the FDA cannot take this issue too far without compromising its role as objective reviewers of the safety and efficacy of the drug."

The Clinton RU-486 file offering the most comprehensive treatment of the administration's strategic campaign to introduce RU-486 to the American market is a memorandum dated May 11, 1994 from HHS Chief of Staff Kevin Thurm to the White House – in particular, Carol Rasco, Director of the Clinton administration Domestic Policy Council. (See Tab D)

Thurm's memo details three issues submitted for decision by the President:

- Whether the President is willing to write a letter to the maker of RU-486, asking that the U.S. patents for the drug be assigned to a non-profit entity in this country [Population Council].

- If the negotiations between Roussel Uclaf and the Population Council fail, and the "only" available option is the "gift offer," is the U.S. Government willing to accept the RU-486 patent rights, and under what conditions?

- If the government is not willing to accept the patent rights, what will be the basis for that decision, and how will it be communicated to the American public?

Thurm develops and discusses each of the factors bearing on the subject in a series of tabs and exhibits to his memo. He provides a history and background tab recounting the Clinton administration's position on RU-486; a tab discussing legal issues;

a brief marketing study addressing timing, administration, and abortion proxies; political considerations; and finally, a discussion of press strategies and concerns.

Thurm explains that on April 26, 1994, the Board of Roussel Uclaf passed a resolution authorizing the assignment of RU-486 patent rights to either the U.S. Government or to a non-profit organization. If the rights were to go to a non-profit organization [Population Council], then Roussel Uclaf demanded a letter from the President of the United States requesting RU-486 on behalf of the women of the United States. President Clinton signed exactly such a letter on May 16, 1994. (See Tab E)

President Clinton's extraordinary letter is direct documentary evidence of his personal intervention as a politician, and clear evidence that the RU-486 patent rights would never have been assigned to the Population Council without his compliance with Roussel Uclaf's demands.

President Clinton's RU-486 request letter to Dr. Edouard Sakiz of Roussel Uclaf claims that it is important for the women of the United States to have "safe and effective medical treatments." Under that rubric, President Clinton writes that he "understands" Roussel Uclaf has been in negotiations with the Population Council. Of course, the Population Council had been serving as a Clinton administration abortion "front" for several months. President Clinton closes his RU-486 request letter by stating: "On behalf of the government of the United States and for the women of America, I thank you for your work."

Thurm's memo specifically addresses the requirements for RU-486 clinical trials and the Population Council's requirements for marketing application for the FDA. The significance of speedy approval and abbreviation of various timelines is a theme throughout his analysis. Not surprisingly, the Clinton administration's radical drive to bring RU-486 to the American market manifested itself in other ways, once the patent rights were obtained by the Population Council. For example, the five standard requirements for certifying a drug "safe and effective" were circumvented to rush RU-486 to market.[xi] Probably the most reckless act by the FDA was the waiver of the normal requirement for random, double-blind, control tests for new drugs. The FDA's expedition in this process was justified with language reserved for drugs developed to cure life-threatening conditions. Certainly, pregnancy is not a disease, nor is it likely to be life threatening – so how could they have twisted the rules so dramatically? What political pressure was brought to bear?

The "political issue discussion" tab to Thurm's memo offers a glimpse into the Clinton administration's abortion politics techniques. The Clinton administration steadfastly continues the manipulation of language that seeks to forever separate the words "kill," "baby" and "abortion." Thurm states: "It is, therefore, extremely important that the decision concerning RU-486 be placed in the context of promoting women's

health and maintaining the close relationship of the administration to these ["pro-choice" and women's groups] groups."

The Clinton administration wanted a quick victory on RU-486 and was deeply concerned that RU-486 might remain a "front burner" issue through the 1996 presidential election. They were particularly sensitive to the prospect of prolonged, intense, public attention and debate on RU-486. Thurm advised political caution concerning unintended consequences, allowing " . . . Republicans and others opposed to the administration to focus attention on this decision and its aftermath."

The Clinton press strategy documents discuss the ramifications of accepting or rejecting the gift of the RU-486 patents. Acceptance of the patent gifts was relegated to Secretary Shalala "on behalf of American women," but specifically as a means of "insulating the White House." While seeking insulation, the press memo stresses the need to credit President Clinton for keeping his campaign promises and giving a major "reproductive rights victory" to American women. The memo also contains a disturbing directive:

> " . . . there should also be a concerted effort on the part of HHS Public affairs team to place stories that outline the hurdles that must be overcome to shield the Administration against fallout from our allies in the event efforts to get RU-486 to the market become stalled in bureaucratic process, in Congress or for other reasons."[xii]

If the Clinton administration's RU-486 strategy failed all together, it appears the press response included a calculated scenario for resorting to lying to the American public. Working through the various scenarios, the author of the memo offers an "alternative":

> " . . . another potential argument we could embrace is the position that we wanted more than the rights they were willing to grant because our interest in this drug goes beyond the issue of abortion, the need for which we are committed to making as rare as possible."[xiii]

Still worried about potential fallout and damage with abortion proponents and allied political groups, the press memo ends stating:

> "Without a doubt, a 'no' will subject the Administration to a firestorm of protest by pro-choice and women's groups; and there will be few natural political allies vocally defending this decision, particularly in light of the relative difficulty of explanation."[xiv]

Beyond the Clinton Files -- RU-486 in 2006

As Judicial Watch reviewed the Clinton RU-486 files, documenting the extraordinary lengths the administration went to rush the abortion drug to U.S. markets, the earliest correspondence on file at the Archives caught our attention and, in hindsight, provided some perspective for examining RU-486 matters in 2006. (See Tab F)

The file contained a handwritten letterhead note from Betsey Wright, President Clinton's former Chief of Staff, and the White House staff member charged with covering-up "bimbo eruptions." The note reads: "To Carol Rasco. This just got forwarded to me. Please handle. BW 3/9/93." There is an additional notation that reads: "cc for Shalala on Tues. MK," with the name Shalala circled and a line drawn to the words "To handle."[xv]

Betsey Wright's note was attached to a letter dated January 6, 1992, from Ron Weddington, an attorney that served as co-counsel in the infamous *Roe v. Wade* lawsuit. Weddington attached an "open letter" to President-elect Clinton. Weddington's letter recommends that the new president should, " . . . start immediately to eliminate the barely educated, unhealthy and poor segment of the country . . ." and that the " . . . government is going to have to provide vasectomies, tubal ligations and abortions . . . RU-486 and conventional abortions."[xvi]

Weddington states: "Condoms won't do it. Depo-Provera, Norplant and the new birth control injection being developed in India are not a complete answer, although the savings that could be effected by widespread government distribution and encouragement of birth control would amount to billions of dollars."

The full text of Weddington's letter is a breathtakingly arrogant exegesis on the abortion lobby's culture of death. As disturbing as the Weddington letter is to read, what is more disturbing is the fact that Betsey Wright, one of President Clinton's closest confidantes, tasked Donna Shalala to "handle" it along with the Director of the White House Domestic Policy Council, Carol Rasco. Weddington's ravings were not relegated to a file for unsolicited constituent correspondence. On the contrary, the Weddington letter is, chronologically and philosophically, the foundation document for the Clinton RU-486 files.

Today we are faced with the horrible results of the political and "health care" campaign to put RU-486 on the market. Since RU-486 was approved for use in the United States in September 2000, at least six women have died after taking the abortion drug. Only after the death of 18 year old Holly Patterson, on September 17, 2003, did the media and the FDA begin to pay attention to the dangers of RU-486.

In November 2004, following the third woman's death, the FDA elected to "strengthen the warning notice," a step that may have provided some sort of "informational" or disclaimer insulation for the FDA, but a tactic that certainly did not make RU-486 any safer for women.

Planned Parenthood, which had ignored the FDA's warnings concerning how to administer the drug regimen, played a role in the deaths of four women as the "procedure" provider. The FDA has determined that the four California women who died after taking RU-486 all suffered from a highly lethal bacterial infection -- Clostridium sordellii. The bacterium flourishes in the uterus and then enters the bloodstream, eventually leading to toxic shock.

It is quite likely that more women have died from RU-486 and their deaths have gone unreported because doctors, medical examiners and coroners are not obligated to forward reports dealing with RU-486 side effects to the FDA. This is particularly true in cases where local health officials may not associate a death with an RU-486 abortion, especially if the woman's death occurs several days or even weeks later.

Even abortion providers now have low regard for the safety of RU-486. Dr. Warren Hern, an abortionist in Denver, Colorado has stated: "I think surgery should be the procedure of choice." Pills, he said, "are a lousy way to perform an abortion." He is not alone. Dr. Damon Stutes, an abortionist from Reno, Nevada reluctantly agrees with Pro-Life critics of RU-486, stating, "the truth is the truth," and that, "The complications from RU-486 far exceed the complications of surgical abortion." [xvii]

It seems that the federal government has finally come to grips with the growing number of deaths attributed to the use of RU-486 and is prepared to take some action, however late. The government will convene a scientific conference at the Center for Disease Control in Atlanta, Georgia on May 11, 2006. More than two dozen scientists and doctors will make presentations concerning the deadly bacterial infections that killed the California women mentioned above.

Conclusion

Judicial Watch hopes that this special report on the Clinton RU-486 files has provided the reader with sufficient documentary evidence from primary sources to illuminate the Clinton administration's rush to achieve part of its abortion agenda through bringing RU-486 to America. Armed with the long-delayed facts from Clinton insider memoranda, the reader is now equipped to evaluate policy and hold public officials accountable.

On September 28, 2000, the day RU-486 was approved for U.S. markets, the FDA Commissioner, Dr. Jane E. Henney, said in an interview, "Politics had no role in this

decision."[xviii] The public now has copies of the the Clinton RU-486 files that unequivocally say otherwise.

Endnotes

[i] See Tab E: Letter from President William J. Clinton to Dr. Edouard Sakiz, Chaiman of Roussel Uclaf, dated May 16, 1994.

[ii] See: http://clinton5.nara.gov/media/pdf/eightyears.pdf

[iii] Hoechst had a historical reason for wanting to keep a low profile concerning RU-486. Hoechst was part of a cartel connected to the infamous I.G. Farben Chemical Company, the makers of Zyklon-B -- the cyanide gas used in Nazi death camps. In 1999, Hoechst merged with another European pharmaceutical company to form Aventis.

[iv] Copies of the Roussel Uclaf – Population Council contract were not available from the Archives.

[v] See: http://www.popcouncil.org/about/index.html

[vi] See: http://www.popcouncil.org/mediacenter/PC_Key_Facts.html

[vii] See Tab C: FDA Commissioner Kessler's Memorandum to HHS Secretary Shalala, dated September 30, 1993.

[viii] See Tab B: HHS Secretary Shalala's Confidential Memorandum to White House Director of Domestic Policy Carol Rasco, dated November 15, 1993.

[ix] See Tab C, pages 4-5.

[x] Felix Rohatyn is a Wall Street investment banker and served as President Clinton's Ambassador to France from 1997 to 2000.

[xi] Donna J. Harrison, M.D., "Dangerous Medicine," *The New York Times*, November 19, 2004.

[xii] See Tab D: HHS Chief of Staff Kevin Thurm's Memorandum to White House Director of Domestic Policy Carol Rasco, Subject: RU-486, dated May 11, 1994; Tab 5: Press Strategies and Concerns.

[xiii] *Ibid.*

[xiv] *Ibid.*

[xv] See Tab F: Clinton Transition Team Director of Public Outreach Betsey Wright's correspondence file Re: RU-486 from Mr. Ron Weddington, dated 3/9/93.

[xvi] *Ibid.*

[xvii] Gardiner Harris, "Some Doctors Voice Worry Over Abortion Pill's Safety," *The New York Times*, April 1, 2006.

[xviii] Gina Kolata, "U.S. Approves Abortion Pill; Drug Offers More Privacy, and Could Reshape Debate, *The New York Times*, September 29, 2000.

Tab A

THE WHITE HOUSE

WASHINGTON

January 22, 1993

MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

SUBJECT: Importation of RU-486

In Import Alert 66-47, the Food and Drug Administration ("FDA") excluded the drug Mifepristine -- commonly known as RU-486 -- from the list of drugs that individuals can import into the United States for their "personal use," although the drugs have not yet been approved for distribution by the FDA. (See FDA Regulatory Procedures Manual, Chapter 9-71.) Import Alert 66-47 effectively bans the importation into this Nation of a drug that is used in other nations as a nonsurgical means of abortion.

I am informed that in excluding RU-486 from the personal use importation exemption, the FDA appears to have based its decision on factors other than an assessment of the possible health and safety risks of the drug. Accordingly, I hereby direct that you promptly instruct the FDA to determine whether there is sufficient evidence to warrant exclusion of RU-486 from the list of drugs that qualify for the personal use importation exemption. Furthermore, if the FDA concludes that RU-486 meets the criteria for the personal use importation exemption, I direct that you immediately take steps to rescind Import Alert 66-47.

In addition, I direct that you promptly assess initiatives by which the Department of Health and Human Services can promote the testing, licensing, and manufacturing in the United States of RU-486 or other antiprogestins.

You are hereby authorized and directed to publish this memorandum in the Federal Register.

William J. Clinton

Tab B

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

NOV 15 1993

~~CONFIDENTIAL~~

file

DATE: 4/14/04

MEMORANDUM FOR CAROL RASCO

The purposes of this memorandum are: (1) to inform you of the Department's progress in implementing the President's directive of January 22, 1993, to "assess initiatives by which the Department of Health and Human Services can promote the testing, licensing, and manufacturing in the United States of RU-486 or other antiprogestins;" and (2) to outline the necessary next steps to accomplish the President's directive.

Background: You may recall that RU-486 is manufactured by the French firm Roussel Uclaf and is approved to induce abortions in France, the United Kingdom, and Sweden. Roussel Uclaf has stated that it can act in the United States only with the approval of its parent company, Hoechst AG, a German firm. Hoechst has historically refused to permit Roussel Uclaf to seek marketing approval for RU-486 as an abortifacient in the United States.

Both Dr. Kessler and I have taken steps to persuade Roussel Uclaf and Hoechst to change their position. In February Dr. Kessler met with Dr. Edouard Sakiz, the President of Roussel Uclaf, to discuss the availability of RU-486 in the United States for research and marketing. In March I wrote to Professor Wolfgang Hilger, President of the Board of Hoechst, to ask him to permit Roussel Uclaf to begin any necessary testing of RU-486 in the United States in preparation for filing a new drug application with the FDA. Later in March there were press reports that Roussel Uclaf would respond to the requests of the Clinton Administration to make RU-486 available in this country and that testing of the drug would begin approximately two months later (i.e., in May).

In April 1993, FDA arranged a meeting between Roussel Uclaf and the Population Council, a non-profit corporation that conducts research on reproductive health issues. The meeting's purpose was to facilitate an agreement between those parties to work together to test RU-486 and file a new drug application for the drug. The Population Council was identified as the most likely group to work with Roussel Uclaf because of an existing contract between these two parties that required Roussel Uclaf to give the Population Council sufficient amounts of the drug for the Population Council to conduct clinical trials. The contract also appeared to require Roussel Uclaf to license the drug to the Population Council if Roussel Uclaf were unwilling to sell the drug in the United States.

At the April meeting, Dr. Edouard Sakiz, President of Roussel Uclaf, raised the issue of federal legislation to indemnify

Roussel Uclaf from any damages it might incur by permitting RU-486 to be marketed in the United States. Dr. Sakiz was worried about product liability actions against Roussel Uclaf if a woman had an incomplete abortion and delivered a deformed fetus. Dr. Sakiz was also concerned about consequential damages, such as the economic costs from boycotts of other Roussel Uclaf or Hoechst products, or bombings of Roussel Uclaf/Hoechst facilities by right-to-life groups. Dr. Sakiz's view was that if the United States Government wanted RU-486 to be marketed in the United States, it should compensate Roussel Uclaf for any damages that the company might suffer from complying with the United States Government's request.

Dr. Sakiz was clearly informed at the April meeting that such legislation would never be enacted and that the FDA would not support Roussel Uclaf in seeking it.

Despite being told that there was no possibility of obtaining federal legislation to protect Roussel Uclaf from consequential damages or product liability suits, Dr. Sakiz committed Roussel Uclaf to negotiate with the Population Council to bring RU-486 onto the United States market. Specifically, at the April meeting Roussel Uclaf and the Population Council agreed:

- That Roussel Uclaf would license RU-486 to the Population Council, which would conduct a clinical trial involving 2000 women pursuant to an investigational new drug (IND) application;

- That the Population Council would ultimately submit a new drug application (NDA) to FDA, based on the results of the clinical trial and on other studies that have been conducted by Roussel Uclaf; and

- That the Population Council, with the concurrence of Roussel Uclaf, would choose a new manufacturer for the drug, and that Roussel Uclaf would transfer its technology for making the drug to that manufacturer because Roussel Uclaf does not want to manufacture the drug for sale in this country.

It was then left for the Population Council and Roussel Uclaf to revise the terms of their contract, while Roussel Uclaf began sending scientific information to FDA and the Population Council. A tentative goal of September 15 was established for concluding the contract negotiations. As of late July 1993, the Population Council thought that the negotiations were proceeding smoothly, though slowly.

CURRENT STATUS

On August 2, 1993, the Population Council's lawyer notified FDA that **Roussel Uclaf had recently reasserted its demand for protective federal legislation.** Roussel Uclaf insisted that the Population Council obtain a commitment from the United States Government that: 1) legislation would be enacted making it a crime for any person to hurt or harass any doctor administering RU-486, their patients, or the drug's manufacturers, distributors, and salespersons; 2) the Department of Justice publicly commit to enforce this law, if enacted; 3) legislation would be enacted indemnifying Roussel Uclaf for any product liability exposure resulting from the use of RU-486 in this country, or, as an alternative, a prohibition of any product liability actions against Roussel Uclaf for RU-486; 4) as part of any legislation, indemnification for consequential damages.

In exchange Roussel Uclaf would give the Population Council a royalty-free license because it has decided to forego any profit from entering the United States market. **In short, Roussel Uclaf's position is that it should not incur any liability exposure as a result of making RU-486 available in this country** as an abortifacient because it does not anticipate any profit from selling RU-486 for that use in the United States and is entering the American market only at the request of the United States Government. Roussel Uclaf remains willing to exploit its patent for non-abortifacient uses of RU-486, should any other use be found to be safe and effective.

FDA advised the Population Council's lawyer that it could not make a commitment to seek such legislation and that its enactment was extremely unlikely, both for political reasons and because the United States had never agreed to indemnify any drug manufacturer, with the exception of the swine flu precedent. The FDA also communicated that seeking such protection for a drug company far exceeded FDA's appropriate role, but that the agency would discuss the situation with the Department.

In mid-September Roussel Uclaf hired legal counsel, Swidler and Berlin, to lobby the federal government at levels above FDA to obtain the legislation described above. On October 5, Kevin Thurm, the Department's Chief of Staff, and Harriet Rabb, the Department's General Counsel, met with lawyers from Swidler and Berlin to discuss the situation. The Department initiated the meeting to assess how the United States Government might facilitate successful completion of the negotiations between Roussel Uclaf and the Population Council. At that meeting, the company reiterated its concerns about obtaining indemnification for potential losses and was again told emphatically that the Department would not support its efforts to obtain federal legislation. Roussel Uclaf's lawyer then suggested that the

United States could exercise its statutory powers of eminent domain and take over the patent for RU-486 insofar as it covers abortifacient uses of the drug.

The Population Council appears to be attempting to meet those demands of Roussel Uclaf that do not require the enactment of federal legislation. We have been advised by the Population Council that they sent a proposed licensing agreement to Roussel Uclaf on October 11, although we do not know whether Roussel Uclaf and Hoechst will find this proposal acceptable. In addition, the Population Council's President recently met with the President of Roussel Uclaf, and is planning to send a delegation to Germany during the first few weeks of November in the hope that if Hoechst understands that the Population Council is a serious, credible organization, Hoechst will withdraw its objections and permit Roussel Uclaf to enter into an agreement with the Population Council. Despite these moderately positive developments, we do not think that the negotiations will be successfully concluded without pressure on Roussel Uclaf/Hoechst.

Moreover, we have learned that Hoechst is interested in using an American venture capitalist group as a partner for the Population Council; this group is thought to be able to secure funds sufficient to indemnify Hoechst at the level it desires. However, it is our understanding that the Population Council appears unwilling to work with this group. This issue has further complicated the negotiations.

AVAILABLE OPTIONS TO MOVE FORWARD NEGOTIATIONS

The negotiations between Roussel Uclaf and the Population Council have not been successfully concluded because of the insistence of Roussel Uclaf and Hoechst that they be protected from all economic harm if they permit RU-486 to be marketed in this country. There are two options for moving forward the stalled negotiations:

One option is to enlist the aid of Felix Rohatyn, or someone of comparable stature, to negotiate with Roussel Uclaf and Hoechst on behalf of the United States Government. The negotiations require a person with extensive experience in the international business community, especially France and Germany. In addition the person must understand the pharmaceutical industry and have the standing to participate in high-level discussions that might involve appropriate ambassadors, as well as the Health Ministers in France and Germany.

A second option is for the United States to exercise its statutory powers of eminent domain and take over the patent for RU-486, insofar as it covers the abortifacient use of the drug. The Government could then contract with a company to manufacture

and distribute the drug. As noted above, this option was suggested by Roussel Uclaf's lawyers in their October 5 meeting with the Department's Chief of Staff and is clearly the company's preferred approach. While the United States government has the legal authority to take over the patent, such an approach is rare and in this case is politically complex. Although legal, there are particular concerns about the political viability of this approach and the willingness of Congress to permit such an action to stand. We note that Roussel Uclaf did not demand that the governments of France, England, or Sweden take such steps.

NEXT STEPS

Unless you object, the Department plans to engage the services of Felix Rohatyn or someone comparable as a negotiator. This negotiator would require the State Department's support in making appropriate diplomatic contacts, both with the United States Ambassadors to France and Germany, the French and German Ambassadors to this country, and other high-level officials in France and Germany, such as the respective Health Ministers. The purpose of such contacts would be to assess the situation and determine what measures the United States could take to persuade Roussel Uclaf and Hoechst to make RU-486 available in the United States. The French and German governments might be displeased to learn that their companies are not accommodating a request made by the United States Government. In addition, a negotiator of Felix Rohatyn's caliber might identify means other than federal legislation to satisfy Roussel Uclaf's and Hoechst's concerns.

In order for the negotiator to succeed, the Department and the Administration must be unequivocal in the position that taking over the patent for RU-486 is not an option. To avoid any ambiguity on this point, the negotiator should have a letter signed by the Secretary of Health and Human Services making clear on behalf of herself and the Administration that the United States government will not take over the patent. In addition the letter should request on behalf of the Administration that Hoechst and Roussel Uclaf conclude negotiations for the entry of RU-486 onto the U.S. market expeditiously. Roussel Uclaf will have every incentive to delay the negotiations if it thinks that the United States will ultimately take over the patent. It is the Department's position that this option should be unambiguously rejected, not only because it is controversial, but because its continued existence will make it impossible for the negotiator to obtain any other agreement.

Donna E. Shalala

Tab C

Food and Drug Administration
Rockville MD 20857

September 30, 1993

NOTE TO: The Secretary

FROM: The Commissioner of Food and Drugs

SUBJECT: RU-486

On January 22, 1993, President Clinton issued a memorandum directing you to assess initiatives to promote the testing, licensing, and manufacturing in the United States of RU-486 (mifepristone).[1] The Agency has had ongoing dialogue with Roussel Uclaf to get a marketing application submitted to FDA for the drug. Both you and the FDA are on record as stating that if RU-486 is a safe and effective alternative to surgical abortion, then women in the U.S. should have access to that drug. The President also directed you to reassess whether RU-486 qualifies for importation under FDA's personal use importation policy.[2]

I. Current Marketing of the Drug

RU-486 is manufactured by the French firm Roussel Uclaf and it is approved to induce abortions in France, the United Kingdom, and Sweden. Roussel Uclaf has stated that it can act in the United States only with the approval of its parent company, Hoechst AG. Hoechst has historically refused to permit Roussel Uclaf to seek marketing approval for RU-486 as an abortifacient in the United States. Both you and I have asked Hoechst to permit Roussel Uclaf to file a new drug application (NDA) for the drug. Hoechst remains adamant in its refusal. While some members of Congress have written to Hoechst urging the company to

[1] Although there are several investigational new drug applications (INDs) on file with FDA for RU-486 for other uses, including Cushing's syndrome, diabetes, meningioma, and breast cancer, Roussel Uclaf will not pursue marketing applications for these indications until the abortion issue is resolved. FDA representatives have met with representatives from the National Institutes of Health (NIH) to discuss initiatives to promote the testing in the United States of RU-486 and other antiprogestins. NIH is limited in what it can do by the restrictions placed on its appropriation by the Hyde Amendment.

[2] In accordance with the President's January 22 memorandum, FDA has reassessed whether RU-486 might qualify for importation under FDA's personal use importation policy and whether the import alert should be rescinded. There are significant public health implications associated with rescinding the import alert, especially related to whether the drug could be safely used under these circumstances; the availability of counterfeit RU-486 on the world market for which the Agency cannot attest to purity, quality, or safety; and the fact that Roussel Uclaf's RU-486 is so tightly controlled as to be unavailable for personal importation even if the import alert were to be rescinded. The Agency submitted its recommendation on this issue to PHS on July 14, 1993. Because the import alert has been challenged by a woman who attempted to bring a small quantity of RU-486 into the country, the Agency is working with the Department on an appropriate response to this ongoing litigation.

submit a marketing application for RU-486, other Congressional members have written to Hoechst expressing their strong opposition to the marketing of RU-486 in this country. This, and the well-publicized activities of anti-abortion groups, have provided Hoechst and Roussel Uclaf with evidence that the U.S. population lacks cohesiveness on this issue and that the abortion debate continues.

II. Summary of Discussions with Roussel Uclaf Regarding Testing of the Drug

In April 1993, FDA arranged a meeting between Roussel Uclaf and the Population Council to attempt to get those parties to agree to work together to test RU-486 and file a new drug application for the drug. The Population Council was identified as the most likely group to work with Roussel Uclaf because the Population Council had a contract with Roussel Uclaf which required Roussel Uclaf to give the Population Council sufficient amounts of the drug so that the Population Council could conduct clinical trials. The contract also appeared to require Roussel Uclaf to license the drug to the Population Council if Roussel Uclaf was unwilling to sell the drug in the United States. A copy of that contract, which must remain confidential, is attached.

At the April meeting, Dr. Edouard Sakiz, president of Roussel Uclaf, raised the issue of federal legislation to indemnify Roussel Uclaf from any damages it might suffer from permitting RU-486 to go onto the United States market. Dr. Sakiz was worried about product liability actions against Roussel Uclaf if a woman had an incomplete abortion and a deformed fetus. Dr. Sakiz was also concerned about consequential damages, such as the economic costs from boycotts of Roussel Uclaf (or Hoechst) products, bombings of Roussel Uclaf/Hoechst facilities, etc. by right-to-life groups. Dr. Sakiz's view was that if the United States Government wanted RU-486 on the U.S. market, then the United States Government should make Roussel Uclaf whole for any damages Roussel Uclaf might suffer because it had agreed to the United States Government's request.

Dr. Sakiz was told quite clearly at the April meeting that such legislation would never be enacted and the FDA would not support Roussel Uclaf in its advancement of that idea.

Despite being told that there was no possibility of obtaining favorable legislation, Dr. Sakiz committed Roussel Uclaf to go forward with the Population Council to bring RU-486 onto the United States market. Specifically, at the April meeting Roussel Uclaf and the Population Council agreed:

- That Roussel Uclaf would license RU-486 to the Population Council, which would conduct a clinical trial involving 2000 women pursuant to an investigational new drug (IND) application;

- That the Population Council would ultimately submit an NDA to FDA, based on the results of the clinical trial and on other studies that have been conducted by Roussel Uclaf; and

- That the Population council, with the concurrence of Roussel Uclaf, would choose a new manufacturer for the drug, and that Roussel Uclaf would transfer its technology for making the drug to that manufacturer, because Roussel Uclaf does not want to manufacture the drug for sale in this country.

It was then left for the Population Council and Roussel Uclaf to revise the terms of their contract, while Roussel Uclaf began sending scientific information to FDA and the Population Council. The contract negotiations continued from sometime after the April meeting until recently. As of late July 1993, the Population Council thought the contract negotiations were proceeding smoothly, though slowly. In those negotiations the Population Council was represented by Jim Boynton of Christy and Viener and Roussel Uclaf was represented by Joe Orsini, its corporate council in Paris.

On August 2, 1993, Jim Boynton, the Population Council's lawyer, notified FDA that Roussel Uclaf had recently demanded that the Population Council obtain a commitment from the U.S. Government that the U.S. would enact legislation that would protect all persons who had anything to do with RU-486. This was described as similar to "right-to-access" legislation that would make it a crime for any person to hurt or harass any doctor administering RU-486, their patients, and the manufacturers, distributors, and salespersons for the drug. Roussel Uclaf also demanded that the Department of Justice promise to expend its resources to enforce this law, if enacted. Roussel Uclaf also asked for legislation that would indemnify Roussel Uclaf against any product liability exposure as a result of the use of RU-486 in this country or, as an alternative, that would ban any product liability actions against Roussel Uclaf for RU-486. Finally, Roussel Uclaf asked for legislation that would indemnify Roussel Uclaf against consequential damages. Roussel Uclaf's principal assertion is that it is willing to give the Population Council a royalty-free license, because it has decided (given a push by Hoechst), that it will forego any monetary gain from entering the U.S. market. In short, because Roussel Uclaf does not expect to make any money off of RU-486 in the U.S. market, and sees itself as permitting RU-486 to enter the U.S. market only because asked to do so by the United States Government, then it should not incur any liability exposure on account of the drug.

FDA advised Mr. Boynton that the FDA could not make a commitment to seek such legislation, pointing out that Congress had recently reenacted the Hyde Amendment and that other than the swine flu situation, the United States had never agreed to indemnify any drug manufacturer. The FDA further explained that it would go far beyond FDA's appropriate role to seek such protection for a drug company. The FDA offered to advance the idea within the Department, but was advised by Mr. Boynton that the answer given was sufficient.

In mid-September, Roussel Uclaf hired legal counsel (allegedly, Lester Hyman and John Hoff of Swindler and Berlin) to lobby the federal government at levels above FDA to obtain legislation protecting the company from potential losses, as described above.

III. Analysis

The FDA's principle objection to Roussel Uclaf's request for indemnification and related relief has been pragmatic--we did not (and do not) think Congress would ever pass such legislation. Having said that, we also think that there are other policy reasons for refusing to seek indemnification of a drug manufacturer, for example:

- It would create an unacceptable precedent for any manufacturer of a significant vaccine or drug to seek indemnification as a condition for bringing the product to market. There is little basis to distinguish RU-486 from a breakthrough AIDS drug or unique vaccine. The swine flu indemnification plan proved very problematic for the United States Government.

- If public health problems were to occur post-approval, the interest of the United States as an indemnifying party would be to disprove that problems had occurred, while FDA's obligation would be to objectively investigate and take appropriate actions to protect the public health. This would be an untenable conflict for the United States Government.

Roussel Uclaf's liability and boycott concerns should not be underestimated. Because Roussel Uclaf is willing to give the Population Council a royalty-free license, it wants to eliminate any potential for expenses due to the drug's introduction into the United States market. Roussel Uclaf has also expressed its willingness to give a royalty-free license to any other major U.S. pharmaceutical company, but has found no company willing to take the license. Roussel Uclaf could, possibly, sell the drug to the Population Council (or to others) but it appears unwilling to do so, perhaps because the drug may have important other therapeutic benefits in the future, and it may want to maintain the right to sell to those markets. However, Hoechst may be willing to simply abandon the patent or give it to the United States.

There are some that suggest that Roussel Uclaf is simply playing a delaying game--waiting until the very staunchly Catholic Hoechst CEO (Prof. Wolfgang Hilger) retires in April 1994--so that then Roussel Uclaf would be free to exploit the drug in the United States and elsewhere for all uses. Others suggest that Roussel Uclaf does not want to reach agreement with the Population Council, but is merely stalling until an international foundation is created by Dr. Etienne Balieu, the inventor of the drug and a former Roussel Uclaf employee, to which Roussel Uclaf could then sell the rights to the drug.

The speculation is fueled by the essentially unanswered question--as to why Roussel Uclaf is willing to manufacture and sell RU-486 to some markets (England, France, and Sweden) but not to others (e.g., the United States). The common thinking is that Hoechst is only willing to permit Roussel Uclaf to sell RU-486 in a country when Hoechst is forced to do so politically, and, therefore, the only way to get RU-486 onto the U.S. market is to exercise political pressure on Roussel Uclaf and on Hoechst.

This thinking appears borne out by the circumstances here--Roussel Uclaf was willing to come to the table (at FDA) when it had received pressure from President Clinton (the January 23, 1993, Executive Order), you (your March 12, 1993, letter to Prof. Hilger at Hoechst), and FDA, but that since that pressure has waned the incentive to come to an agreement has also waned.

Another possibility is that the Population Council is simply attempting to reach an agreement that leaves Roussel Uclaf with too little, and that if the Population Council were willing to settle for less (e.g., the ability to study, but not to market the drug or to indemnify Roussel Uclaf) then a deal could be reached.

IV. Recommendation for Expert Advisor

This situation calls for someone of Felix Rohatyan's caliber for several reasons. At the outset, we must make it clear that the FDA cannot take this issue too far without compromising its role as objective reviewers of the safety and efficacy of the drug. But equally as important is the fact that this is an issue where business and politics intersect quite dramatically. Because of the abortion debate, Roussel Uclaf is left alone to promote its drug. Other major U.S. drug manufacturers have, to date, refused to join forces with Roussel Uclaf--either by agreeing to go forward with their own abortifacient drug products, or by agreeing to be the manufacturer or distributor of RU-486. Therefore, Roussel Uclaf feels isolated (and vulnerable) by the U.S. demands. It will take an experienced person, familiar with the drug industry, to sort out these issues.

Second, there are pragmatic, economic concerns to be faced. Roussel Uclaf's concerns about indemnification are realistic concerns that need to be satisfied. Someone with extensive experience in the business community (in France and Germany as well as in the United States) will have a better understanding of the various ways this concern can be overcome.

Finally, there are diplomatic issues that may need to be addressed. It may be that France and Germany would be unhappy to learn that their companies were not accommodating a request made by the United States Government. The U.S. Ambassadors to France and Germany will

need to be consulted on these issues, and your counterparts in France and Germany may also need to be involved. We think that someone familiar to these circles would advance the Administration's goal to bring a safe and effective abortifacient to the U.S. market.

Mary Pendergast
for David A. Kessler, M.D.

Attachment: Contract

cc: Dr. Philip Lee
Mr. Kevin Thurm

THE WHITE HOUSE

WASHINGTON

January 22, 1993

MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

SUBJECT: Importation of RU-486

In Import Alert 66-47, the Food and Drug Administration ("FDA") excluded the drug Mifepristine -- commonly known as RU-486 -- from the list of drugs that individuals can import into the United States for their "personal use," although the drugs have not yet been approved for distribution by the FDA. (See FDA Regulatory Procedures Manual, Chapter 9-71.) Import Alert 66-47 effectively bans the importation into this Nation of a drug that is used in other nations as a nonsurgical means of abortion.

I am informed that in excluding RU-486 from the personal use importation exemption, the FDA appears to have based its decision on factors other than an assessment of the possible health and safety risks of the drug. Accordingly, I hereby direct that you promptly instruct the FDA to determine whether there is sufficient evidence to warrant exclusion of RU-486 from the list of drugs that qualify for the personal use importation exemption. Furthermore, if the FDA concludes that RU-486 meets the criteria for the personal use importation exemption, I direct that you immediately take steps to rescind Import Alert 66-47.

In addition, I direct that you promptly assess initiatives by which the Department of Health and Human Services can promote the testing, licensing, and manufacturing in the United States of RU-486 or other antiprogestins.

You are hereby authorized and directed to publish this memorandum in the Federal Register.

William J. Clinton

Tab D

MAY 11 1994

TO: Carol Rasco

FROM: Kevin Thurm

SUBJECT: RU 486

Background

Roussel Uclaf, a French subsidiary of the German company, Hoechst, holds two United States patents for its product, RU 486, which has abortifacient and potentially scores of other medical uses. The French company has engaged the Population Council, a not-for-profit organization, in over 14 months of negotiations designed to transfer Roussel Uclaf's United States patent rights to the Population Council which would then take steps to bring RU 486 to market in this country. Those negotiations are on-going.

On May 9, 1994, Roussel Uclaf wrote a letter to Secretary Shalala stating the company's wish, instead, to offer the RU 486 United States patent rights to the American government insofar as the abortifacient and other gynecological uses are concerned. The company proposes voluntarily to assign its patent rights, as so limited, to the government free of charge, asking nothing in return.

Were the government willing to accept the "gift" offer, negotiations with the Population Council would be discontinued, and the patents, as so delimited, would be made available for assignment to the United States.

Alternatively, Roussel Uclaf has advised that should its bilateral negotiations with the not-for-profit be resolved, the deal cannot be finally closed unless and until the President of the United States writes a letter to the French company asking, on behalf of the women in America, that the patents be assigned to a non-profit entity in this country.

Roussel Uclaf strongly favors the gift to the government arrangement. Your advisors strongly favor the bilateral arrangement and have taken steps consistently and firmly to so insist.

Issues for Decision

One: Whether the President is willing to write a letter to the manufacturer of RU 486 asking that the United States patents for that product be assigned to a not-for-profit entity in this country. A suitable letter might read as follows:

> It is important for the health of women in the United States that they have access to the widest possible range of safe and effective medical treatments. In support of

> that goal, in January 1993, I asked the Secretary of Health and Human Services to promote the testing and licensing of mifepristone [RU 486] and other antiprogestins in the United States.
>
> To permit the appropriate testing, development and distribution of RU 486 in the United States, I ask that your company give its mifepristone patent rights in the United States to a non-profit organization that would take all necessary steps to file a new drug application with the Food and Drug Administration [FDA], so that the FDA can determine whether the drug is safe and effective for use in the United States.

Two: If the bilateral negotiations between Roussel Uclaf and the not-for-profit entity fail, and the only option then currently on the table is the gift offer, is the government of the United States willing, and if so, under what conditions, to accept the offer of the patent rights for RU 486?

Three: If the government is not willing to accept the offer of the patent rights, on what is that decision to decline based, and how will it be communicated to the American people?

* * * * * * * * * * * * * * *

The following tabs set forth discussion of the various factors that may be brought to bear on the decision-making:

Tab 1:	History and background of RU 486 in this Administration
Tab 2:	Legal issues
Tab 3:	Bringing RU 486 to market [timing, available entities, administrative hurdles]
Tab 4:	Political considerations
Tab 5:	Press strategies and concerns

The following documents are attached for your reference;

Exhibit 1:	The President's Memorandum of January 22, 1993
Exhibit 2:	Roussel Uclaf's May 9, 1994 letter to Secretary Shalala attaching a draft offer of the gift
Exhibit 3:	Roussel Uclaf's draft letter to the President
Exhibit 4:	Minutes in French and translation of the April 26, 1994 Roussel Uclaf board meeting setting out the need for a letter from the President

BACKGROUND

Roussel Uclaf, a French subsidiary of the German company, Hoechst, holds two United States patents for its product RU 486, which has abortifacient and various other medical uses. The patents will expire in the years 2000 and 2001. Hoechst, the parent company, is co-owned by the Celanese Corporation, whose direct or indirect product lines include Nike sneakers and seat belts; the company does about $8 billion worth of business per year in the United States.

On January 22, 1993, the President directed the Secretary to "assess initiatives by which the Department of Health and Human Services can promote the testing, licensing, and manufacturing in the United States of RU 486 or other antiprogestine" (Exhibit 1). Within the month, the FDA, through Commissioner David Kessler, requested both Roussel Uclaf and Hoechst to expedite the process and met with representatives of Roussel to discuss issues. In March 1993, Secretary Shalala wrote to the president of Hoechst urging him to eliminate all corporate barriers to introduction of RU 486 in the United States.

Roussel Uclaf identified the Population Council, a non-profit organization based in New York, as the most likely vehicle through which to produce, distribute and test RU 486; the two parties have a 1982 contract which gives the Population Council some limited rights to license Roussel Uclaf product in this country.

Over the past fourteen months, the two parties have conducted on-again/off-again negotiations over a distribution scheme, liability insurance (product and damage to property), and insurance for lost profits due to economic boycotts of non-related products. During these talks, Roussel, in addition to the three main issues, occasionally raised subsidiary matters; these bumps in the road served to delay the negotiations (some believe that Roussel was in a holding pattern in anticipation of corporate leadership changes in January and April of this year). In several newspaper stories on this issue during this period, representatives of the two parties have been quoted saying they expected a deal shortly. Obviously this has yet to materialize.

Last fall, lawyers representing Roussel Uclaf met with HHS officials to discuss ways the federal government might help the negotiations. Over a series of meetings, the corporation's lawyers presented a variety of requests, including whether the Administration would seek legislation indemnifying Roussel for all potential damages or would seize the patents. HHS officials repeatedly told Roussel's lawyers that neither was a possibility, and that the deal should be done through the private parties.

On April 14, 1994, the Secretary, along with other HHS officials, met with representatives of the two parties, including Professor

Ernst Afting (current CEO of Roussel), Dr. Edouard Sakiz (past CEO and current Board Chair of Roussel), and Margaret Carlson (head of the Population Council). The Secretary stated that the U.S. government would neither seek legislation indemnifying Roussel nor seize the patents. She made clear to the parties the importance she attached to the introduction of the product in the U.S. through an agreement between them. She ended the meeting by imposing a May 15, 1994 deadline for successful completion of their negotiations.

In light of this deadline and hearings scheduled by Congressman Ron Wyden for 10:00 a.m. on May 16 to obtain a status report, the parties have continued their negotiations. Although many issues have been resolved, some remain: the extent of insurance coverage for product liability and damage to property, and a "pull the plug" option which would give Roussel the authority to require the Population Council to withdraw the product from the market if the potential liability from all lawsuits exceeded a specified amount.

On April 26, 1994, the Board of Roussel Uclaf passed a resolution authorizing under certain circumstances the assignment of patent rights to either the United States government or to a non-profit organization (Exhibit 4). If the rights are to be given to a non-profit, the President of the United States must so request by letter on behalf of the women of the country (see draft letter in cover memo).

By letter of May 9, 1994, Roussel notified the Secretary that it was prepared to assign the patent rights (for abortifacient and other gynecological uses) to the government and attached a draft letter to the President from Professor Afting, the president and CEO of Roussel (Exhibits 2 and 3). This draft letter closely mirrored an earlier informal draft discussed with Kevin Thurm, Harriet Rabb and David Kessler during the prior week.

Discussions between the parties are scheduled to continue through the end of the week. If the private arrangement is not concluded, we must be prepared to have an answer to Roussel's letter which we believe the company would send (or at least publicize). There is some "buzz" among pro-choice and women's groups about this issue so there is a chance developments will leak before the deal is finished or the letter is formally sent.

LEGAL ISSUES DISCUSSION

I. **Gift Acceptance.** The first question is whether the government should insist that any gift be for all known medical uses, not just abortifacient and gynecological [including, perhaps, "morning after"] uses. On the one hand, the broader rights may make the patent more attractive to potential licensees. On the other hand, some potential licensees may be appropriate repositories of the government's patent rights for the designated uses, but not the full range of known medical uses. Finally, the burden of testing and bringing forward the product for abortifacient and gynecological uses may be more than enough obligation. The responsibility of pursuing research and testing on all the known medical uses to bring the promising ones to fruition may be more than the government and any licensee want to assume.

The Secretary has statutory authority to accept a gift, such as a patent, on behalf of HHS's Public Health Service. Alternatively, the directors of the national research institutes at HHS's National Institutes of Health (NIH) have statutory authority to accept gifts to support the activities of their institutes. Each option has pluses and minuses.

A. Secretarial gift acceptance. Because patents are intangible property, by statutory directive, the evidence of the gift (in this case, the original patent assignments), must be lodged with the Department of the Treasury. Treasury has the discretion to hold the property or liquidate it at HHS's request. There is unlikely to be a problem raised by Treasury, but, to date, that Department has had no part in the RU 486 issue and must be consulted should this route be chosen.

B. NIH gift acceptance. No involvement of Treasury is required. Gifts to NIH institutes must be made to support the activities of the receiving institute - so a showing of such purpose would have to be made. This is not likely to pose a problem, but no work has been done to identify a likely institute recipient or to prepare the gift justification.

Finally, with regard to gift acceptance, since Roussel Uclaf is an entity doing business with HHS, including specifically the Public Health Service and its components, the government will have to be sure that accepting the gift does not give rise to a public perception concern. There is no ethical impediment to accepting gifts from entities so positioned, but care must be taken to weigh the benefits and consequences so that the public can be assured that no favor has been curried or promised. In fact, it has not.

II. **Transfer of the Gift.** Roussel Uclaf has offered to assign its rights to the abortifacient and gynecological patent uses to the government. Were the United States to accept the assignment

from Roussel Uclaf, the government would in turn find a licensee or licensees willing and able to take responsibility for obtaining FDA approval and bringing the product to market. Although it is conceivable that the government could perform these tasks itself, only the Department of Defense now manufactures drugs on a large scale.

Since, by law, federal agencies are authorized to grant licenses in federally owned patents, were the government to have the patents by assignment, subsequent licensing arrangements are possible. Additionally, patent law provides the patent owner (or, in this case, the patent assignee) with the right to sue for patent infringement. Such capacity to bring suit could be consequential if counterfeit product began to appear in the United States.

III. **Licensing the United States Patent Rights.** Government agencies are authorized by law to grant non-exclusive, exclusive or partially exclusive licenses under federally-owned patents. Licenses to PHS-owned inventions are negotiated by the NIH Office of Technology Transfer in accordance with government-wide regulations.

Under the regulations, non-exclusive licenses can be given by the government relatively easily and directly to any applicants, generally speaking, whose capacity to act responsibly regarding the license has been demonstrated.

Exclusive or partially exclusive licenses are subject to a different, but not much more difficult process. Notice of the patent's availability must be published in the Federal Register, and a sixty day period for filing written objections must be allowed. No less than three months after the date of publication, and after consideration of any objections received, an exclusive or partially exclusive license may be granted. In that event, the agency must make determinations regarding the necessity for an exclusive license, rather than a nonexclusive one, the effect of the license on competition, and whether small business firms have been given first preference in accordance with the statute and regulations.

If and once the United States accepts the gift, it will be critically important that some bidder(s) come forward seeking a license to bring the product to market. Roussel Uclaf's efforts to shop this product around to United States pharmaceutical companies to get one or more to take up the responsibility of bringing RU 486 to market have been unsuccessful. Roussel Uclaf reports that the reluctance reflects other companies' unwillingness to bear (i) the product liability risks associated with the abortifacient or (ii) the political pressure from anti-abortion forces.

IV. **Possible United States Tort Liability.** The likelihood of United States tort liability depends, in large measure, on the

government's role in bringing RU 486 to market. Through sovereign immunity, the United States government is not subject to liability except to the extent that it consents to be sued. The Federal Tort Claims Act (FTCA) is a statutory limited waiver of sovereign immunity and, thus, acts as consent to being sued. Under the FTCA, the government is liable for personal injury caused by the negligent or wrongful act or omission of a Federal employee under circumstances where the government, if a private party, would be liable to the plaintiff. It would be unlikely for a court to allow a suit to go forward against the government under the FTCA if the government merely performed the "discretionary functions" of accepting a gift, licensing the patents, and acting on an application for FDA to approve a drug.

However, were the government to become enmeshed in facilitating or playing a direct role in the transfer of the technical background information that makes it possible actually to make RU 486, for example, the government risks being drawn into liability. An approach which limits the government's role in bringing RU 486 to market, while solving the lion's share of the potential government liability risk, creates other problems. Without the backup technical "know how," it would be years before any government licensee could create the product. Since it is unlikely that a licensee would bid for these patent rights without the actual prospect of bringing the product into existence, the United States could be left holding the patents with no licensee willing to step up and take them.

Alternatively, if a European or other off-shore manufacturer made the product in a fashion that meets FDA standards, the product is potentially importable by a government licensee. One wrinkle on this process results from the technology transfer regulations referenced above which note that normally, licensees of United States patents have to agree that the product will be produced substantially in the United States.

In short, to the extent the government refuses to become involved in actually transferring the technology, tort liability is kept at bay. But licensees may be kept at bay as well, leaving the government holding the patents with no prospect of bringing RU 486 to the women in America.

BRINGING RU 486 TO MARKET

A. Direct Patent Transfer to Population Council

If Roussel Uclaf agrees to license its patent rights in RU 486 to the Population Council, the Population Council would then have to take the following steps:

o Locate a drug manufacturer that would be willing to manufacture RU 486 for the United States market (we are advised that such a manufacturer has been identified by the Population Council).

o Obtain information from Roussel Uclaf on how Roussel Uclaf manufactures RU 486 and on its testing of the drug, so that the new manufacturer could follow parallel processes and the Population Council could refer to Roussel Uclaf's animal and human testing of RU 486 in any submission to the Food and Drug Administration. If Roussel Uclaf provides this information and technology transfer, it will significantly shorten the amount of time it will take to bring the drug to the United States market (assuming the drug is found to be safe and effective by FDA). With Roussel Uclaf's information, it might take six to twelve months for the Population Council's manufacturer to begin production of the drug, and for the Population Council to file its marketing application with the FDA. If Roussel Uclaf refuses to provide such information, it will take the Population Council eighteen months to two years to begin production, and up to five years to repeat the animal and human tests that show whether the drug is safe and effective.

Roussel Uclaf has stated that they will transfer the technology to the Population Council, but we do not consider this a strong assurance.

o Begin some clinical testing of the drug in the United States. Clinical trials, though not absolutely necessary for FDA approval, would permit women in the United States to have access to the drug, and for United States physicians to become familiar with the drug, while the Population Council prepared its marketing application for the FDA.

If Roussel Uclaf were to provide French-made RU 486 to the Population Council for the clinical trials, such trials could begin in the United States in approximately six months (five months for the Population Council to design its trials and find physicians willing to do the trials, and one month for FDA approval). If Roussel Uclaf were not willing to provide the drug for clinical trials, such trials would have to wait until (1) the Population Council's manufacturer could begin production of the drug, and (2) either Roussel Uclaf gave the Population Council its animal studies or the Population Council did its own animal studies.

Roussel Uclaf has stated that it would provide the French-made RU 486 to the Population Council for the clinical trials, but again we do not consider this a strong assurance.

o File a marketing application with the FDA. As indicated above, if Roussel Uclaf provides information and transfers its technology to the Population Council, a marketing application could be filed with the FDA within six to twelve months. FDA review would take no longer than six months. Many of the scientific decisions on the proper use and distribution of the drug have already been considered by the FDA, based on information already provided to FDA by Roussel Uclaf and the Population Council. Roussel Uclaf would not need to finish its United States clinical trials before filing a marketing application with FDA; such trials could be used to refine the use of the drug at a later time.

B. Patent Transfer to the United States

If Roussel Uclaf gives its patents to the United States, the United States would have to take the following steps:

o The United States would have to determine the scope of the rights given to the United States -- are the rights only in the abortifacient and other gynecological uses of the drug, or in all uses of the drug (e.g., gynecological uses, Cushing's disease, breast cancer).

o The United States would then need to transfer its rights in the patents to a third party. This process is discussed at Tab 2, and would take at least six months.

o The license holder would then need to take all of the steps outlined above, i.e., find a manufacturer, conduct the necessary tests, and file a marketing application with the FDA. The length of time these steps will take depends on whether Roussel Uclaf is willing to transfer its information, technology, and the drugs necessary for clinical trials to the license holder. Roussel Uclaf has advised the government that it would provide the information and French-made RU 486 for clinical trials to the United States' licensee, but it could change its mind.

It is difficult to determine whether the United States's license holder would take appreciably longer to bring RU 486 to market than the Population Council would need if the Population Council received a direct transfer of rights from Roussel Uclaf. Obviously, if the United States licensee is the Population Council, little time will be lost above that associated with the transfer of the patent rights from the United States to the Population Council. If another group becomes the United States's

licensee, that group might be able to bring the drug to the United States market slightly faster than the Population Council (if the group chosen was very familiar with the drug, had a good manufacturing facility, the cooperation of Roussel Uclaf, experience in FDA marketing applications, and excellent contacts with United States physicians) or much slower (if the group falls short on any factor).

We anticipate that if Roussel Uclaf gives its patent to the United States, it will add at least six months, and quite possibly twelve to eighteen months, onto the time needed to bring the drug to the United States market. This estimate excludes any additional time generated by litigation (see Tab 2).

POLITICAL ISSUE DISCUSSION

In viewing the various options, it is important to place them in a broader political context, particularly as they relate to health care reform, given the likelihood that Congress will narrow the current Health Security Act provisions that provide for abortions under pregnancy-related services.

Because of this situation with the Health Security Act, the introduction of RU 486 will be of greater significance to the pro-choice and women's groups. If the Administration is viewed as closing the door or rejecting an apparently reasonable offer on RU 486, then the path toward reaching a non-confrontational agreement with the advocates on the Health Security Act could become much more difficult. It is, therefore, extremely important that the decision concerning RU 486 be placed in the context of promoting women's health and maintaining the close relationship of the Administration to these groups.

With regard to other political considerations, the acceptance of RU 486 by the federal government, as opposed to by a private non-profit organization, would most certainly lead to a floor amendment on the Labor, HHS appropriations bill, or other legislative vehicle to prohibit federal funds from being used in conjunction with RU 486. It is difficult to predict the exact nature of the amendment. However, in the last Congress, Representatives Dornan, Dannemeyer, Lent, Bartlett, Bunning and Hunter co-sponsored a bill to prohibit federal funds from being used for clinical studies of RU 486 as an abortifacient. Given the likelihood of another Hyde-type amendment on the House and Senate floors this year, as well as the expected abortion-related amendments on health care reform, the members of the House and Senate will be frustrated at having to face another abortion-related vote (on RU 486 appropriation limits). The outcome of such a vote is difficult to predict.

To date, we have worked very cooperatively with Congressman Ron Wyden, the chief Congressional advocate in providing access to RU 486 to women in this country. We expect to be able to continue this close working relationship through the upcoming hearing on May 16. Because Congressman Wyden has postponed past hearings, and is very frustrated by the fourteen months of negotiations, it is unlikely that he would be willing to postpone the May 16 hearing. He is convinced that Roussel Uclaf and Hoechst have been stalling for time, and that it is important to remain firm on the hearing date in order to force agreement or to make it clear to the American public that the companies have no intention of providing RU 486 to the American market.

Finally, regardless of the precise wording of the President's January 22, 1993 memorandum, the expectation it created among the pro-choice and women's groups is that the federal government will do everything possible to get RU 486 introduced in this country. Leaders of these groups will be concerned with Administration action on health care reform and other issues, including the choice to replace Justice Blackmun. Saying "no" to a facially reasonable offer by Roussel Uclaf weakens our political base and may subject the President to criticism that he is not sticking to his original position.

Given the expression of Presidential support for RU 486 in January 1993, a "yes" adds marginal political cost (separate from issues like health care reform). For 1996 purposes, we probably lose few friends and anger few voters not already positioned on this or related issues.

A "yes", however, also means the Administration will have this issue on its front burner for a significant period of time. Anticipated floor amendments in Congress, rallying at HHS or other government buildings by pro-life groups, and the necessarily public process to secure licensees will provide ample opportunity for Republicans and others opposed to the Administration to focus attention on this decision and on its aftermath.

LIST OF MEMBERS INTERESTED IN THE RU-486 ISSUE

HOUSE

Ron Wyden
Henry Waxman
Michael McNulty (D-NY)
Jim Bunning (R-KY)
Robert Dornan (R-CA)
Duncan Hunter (R-CA)

SENATE

Carol Moseley Braun (D-IL)
Paul Simon (D-IL) (wrote on behalf of constituent)
John Breaux (D-LA) (wrote on behalf of constituent)

BACKGROUND

For five years Wyden has been by far the most active and vocal Member on RU-486. He has held numerous hearings and cosponsored a bill with Waxman in the last Congress to overturn the FDA import ban. Also in the last Congress, 6 Republicans (Dornan, Dannemeyer, Lent, Bartlett, Bunning, and Hunter) cosponsored a bill to prohibit federal funds from being used for clinical studies of RU-486 as an abortifacient. No one in the Senate is consistently active on this issue.

Obviously, the womens' caucus will be interested in any actions taken on Ru-486 as will the pro-life caucus (especially Hyde, Helms, and C. Smith). However, in the last four years the Department has not received RU-486 letters from either group.

Very little mail has been received by the Clinton Administration on RU-486. A typical letter is the attached C. Moseley-Braun letter inquiring as to the status of the President's Directives.

In the Bush Administration a typical letter is the attached California delegation letter on RU-486 as an important option for American women. Also, letters often stressed the importance of allowing research on RU-486 to go forward in areas of breast cancer, glaucoma, Cushing's disease, etc.

Please let me know if I can get additional information for you.

PRESS ISSUES DISCUSSION

If negotiations with the Population Council collapse, the Clinton Administration will be left with two possible courses of action. The following is an examination of the public relations ramifications of both choices:

If the Administration decides to accept the gift of the patent from Roussel Uclaf, for purposes of insulating the White House, it should be accepted by Secretary Donna Shalala at the direction of the President of the United States and on behalf of the women in America. This could be done in a press conference on Friday, May 13, 1994, with up to four principals: Secretary Shalala, Roussel Uclaf President, Population Council (if they would agree to run the clinical trials) and possibly Congressman Ron Wyden (who has been pushing this issue on Capitol Hill).

It would be made very clear that this step is the result of the process that was set in motion by President Clinton's memorandum of January 22, 1993, and that it is being taken because it was impossible for Roussel Uclaf to come to closure with a private sector entity. Because a non-surgical (and sometimes safer) abortion alternative would thus be available to women in the United States (as it is to many women in Europe), accepting the patent gift should be touted as a reproductive rights victory for American women and another example of the Clinton Administration's commitment to deliver on its promises. However, Secretary Shalala's remarks would be tempered by caution about the long and difficult road ahead and the potential roadblocks to bringing RU 486 to the marketplace.

While it should not be a part of the formal press conference, there should be a concerted effort on the part of the HHS Public Affairs team to place stories that outline the hurdles that must be overcome to shield the Administration against the fallout from our allies in the event efforts to get RU 486 to market become stalled in bureaucratic process, in Congress or for other reasons.

Because the Clinton Administration would actually be in possession of the RU 468 patent for a period of time while the licensing process moves foreward, during that time, the Administration may well be the focus of protest by conservative organizations that have become increasingly vocal and militant. These groups have suffered recent setbacks in court (e.g. a ruling that has imposed massive fines and barred them from physically blocking access to abortion facilities). They would welcome an extremely high visibility focal point for their activities. Protest marches in front of the White House and HHS are imaginable, and the conservative talkshow circuit would help to sustain the furor. This could go on while other abortion-related issues are before Congress, including debate on the Health Security Act and the FY 1995 enactment of the Hyde

Amendment. In the worst case, it could put the abortion issue centerstage, with the Clinton Administration as a high-profile player right up through the kick-off of the 1996 re-election campaign.

It would also be necessary to recruit a cadre of lawmakers, pro-choice and women's advocates willing and able to speak up for the Administration over the course of this heated debate. That is critically important for holding our own on the conservative talkshow circuit.

If the Administration decides to reject the gift of the patent from Roussel Uclaf, news of that decision should be disclosed in a press conference on Friday, May 13, 1994, by Secretary Shalala and FDA Commissioner David Kessler. It will be necessary to construct a rationale for why that course of action is better than the alternative one for American women. The argument will have to be that giving the patent to the United States government does not speed the drug to the American marketplace. In fact, it does just the opposite. Administrative regulatory process and the potential for legislative stonewalling could be very time consuming and could ultimately prevent the women in America from gaining access to
RU 486.

We should also highlight in the Secretary's statement the unprecedented nature of what Roussel Uclaf was attempting to position the United States to do. Never before has a patent been accepted by the government. The novelty of the situation makes the issue potentially more likely to be tied up in litigation or legislative maneuvering. One of the speakers would provide details of the formidable obstacles that may delay or even prevent the United States from moving the drug onto the market.

If Roussel Uclaf is willing to grant the United States patent rights for using RU 486 only for abortifacient and other gynecological purposes, another potential argument we could embrace is the position that we wanted more than the rights they were willing to grant because our interest in this drug goes beyond the issue of abortion, the need for which we are committed to making as rare as possible.

We would stress that a private sector deal is the only viable option for getting RU 486 quickly through clinical trials and into the market place. We should outline in detail all that the Population Council did to try and close the deal during the 14-month negotiations with Roussel Uclaf. The message, either implicitly or explicitly, is that Roussel Uclaf does not really want to close a deal with an entity that clearly has the potential to bring RU 486 to the marketplace because the company fears pressure from American conservatives.

Our position should be publicly to challenge Roussel Uclaf to go back to the bargaining table with the Population Council or to open negotiations with another entity; to stop playing games; and to get serious about responding to the request that President Clinton made of them almost a year and a half ago.

Without a doubt, a "no" will subject the Administration to a firestorm of protest by pro-choice and women's groups; and there will be few natural political allies vocally defending this decision, particularly in light of the relative difficulty of explanation.

* * * * * * *

It should be noted that Roussel Uclaf has already begun, informally, to circulate word of its potential offer to the United States. Many representatives of the pro-choice community already know about the potential gift offer. We may be forced to confront a news account of the issue prior to the Congressional hearings on May 16, 1994. Such a story will, undoubtedly, be presented from the Roussel Uclaf perspective as opposed to the Administration's point of view.

THE WHITE HOUSE

WASHINGTON

January 22, 1993

MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

SUBJECT: Importation of RU-486

In Import Alert 66-47, the Food and Drug Administration ("FDA") excluded the drug Mifepristine -- commonly known as RU-486 -- from the list of drugs that individuals can import into the United States for their "personal use," although the drugs have not yet been approved for distribution by the FDA. (See FDA Regulatory Procedures Manual, Chapter 9-71.) Import Alert 66-47 effectively bans the importation into this Nation of a drug that is used in other nations as a nonsurgical means of abortion.

I am informed that in excluding RU-486 from the personal use importation exemption, the FDA appears to have based its decision on factors other than an assessment of the possible health and safety risks of the drug. Accordingly, I hereby direct that you promptly instruct the FDA to determine whether there is sufficient evidence to warrant exclusion of RU-486 from the list of drugs that qualify for the personal use importation exemption. Furthermore, if the FDA concludes that RU-486 meets the criteria for the personal use importation exemption, I direct that you immediately take steps to rescind Import Alert 66-47.

In addition, I direct that you promptly assess initiatives by which the Department of Health and Human Services can promote the testing, licensing, and manufacturing in the United States of RU-486 or other antiprogestins.

You are hereby authorized and directed to publish this memorandum in the Federal Register.

William J. Clinton

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ROUSSEL UCLAF

Professeur Daniel-Ghislain Affling
Président du Directoire

Paris, May 9, 1994

Honorable Donna SHALALA
Secretary of Health and Human Services
Room 615 F
Hubert Humphrey Building
200 Independence Avenue SW
WASHINGTON, D.C. 20201
USA

Attention : Mr. Kevin THURM

Dear Secretary Shalala,

Following various meetings with your Staff and with FDA officers, the latest on May 6, 1994 with Dr. Kessler, we would like to confirm that we are ready to assign our US patent rights on RU 486 in accordance with the attached draft letter from us to the President of the United States of America.

This document is substantially similar to the draft that was given to Mr. Kevin Thurm, on April 29, 1994, by our counsel Lester Hyman, to allow a review of the situation by your Administration.

Of course we will continue to work with you and all relevant people in a constructive spirit and we look forward to meet you personally by the end of this week, as planned.

Sincerely,

Pr. E-G. AFTING
President & CEO

cc. Dr. KESSLER

55, Boulevard des Invalides 75325 Paris Cedex 07
Tél. 01 40 62 40 00 Fax 01 40 62 46 01 Télex 200 772 F

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ROUSSEL UCLAF

DRAFT

Paris, May ..., 1994

Honorable William J. CLINTON
President of the United States
The White House
1600 Pennsylvania Avenue NW
WASHINGTON, D.C. 20500
USA

Attention : Ms. Nancy HERNREICH

Dear Mr. President,

You have requested that ROUSSEL UCLAF allow the RU 486 compound to be used in your country.

We have been working to react to that request in a responsible manner.

I now am pleased to inform you that we have decided to contribute mifepristone (RU 486) for abortifacient purposes (and other gynecological uses) to the people of the United States of America, completely free of charge, by voluntarily assigning our relevant patent rights to the US Government.

This an unconditional gift, we ask for nothing in return.

Sincerely,

Pr. E-G. AFTING
President & CEO

35, Boulevard des Invalides 75323 Paris Cedex 07

PROJET 09.05.94

ROUSSEL UCLAF
Société anonyme à Directoire et Conseil de Surveillance
au capital de 544.749.360 F.
Siège social : 35, Boulevard des Invalides 75007 PARIS
R.C.S. Paris B 542 008 021

Extrait du Projet de Procès-Verbal
de la séance du Conseil de Surveillance du 4 Mai 1994
à 17 h 30

Présents :

Membres du Conseil de Surveillance :

Dr. R. SAKIZ, Président,
Dr. M. FRUEHAUF, Vice-Président,
MM. P. BOISSON, C. de CROISSET, le Pr. J. DAUSSET, B. ESAMBERT,
le Pr. G. MILHAUD, H. MONOD, E. de ROYERE, le Dr. K.G. SEIFERT.

Sans voix délibérative :

Pr. R.G. APTING, Président du Directoire,
M. G. JACQUINSON, Directeur Général, Membre du Directoire,
M. D. CAMUS, Membre du Directoire,
M. B. WINCKI, Membre du Directoire.

M. J.F. CHAVANCE et Mme D. PIERRON, Délégués du Comité Central d'Entreprise.

M. F. DESCOURS, Secrétaire du Conseil.

Absents excusés :

M. le Dr. G. METZ, Membre du Conseil de Surveillance,
M. J. MISCHE, Membre du Conseil de Surveillance.
MM. F. BRECHARD et D. GAILLET, Délégués du Comité Central d'Entreprise.

.....

.../...

PROJET 09.05.94

MIFEPRISTONE - ÉTATS-UNIS

Le Docteur E. SAKIZ informe le Conseil de Surveillance que son assentiment est demandé sur les décisions que le Directoire va être amené à prendre à propos de la mifépristone aux États-Unis d'Amérique, compte tenu des exigences pressantes formulées au plus haut niveau par les autorités gouvernementales fédérales de ce pays.

Étant donné les caractères très particuliers du système médical des États-Unis par comparaison à celui des pays d'Europe où la mifépristone est actuellement utilisée, et considérant également le climat hautement conflictuel créé autour de ce produit aux États-Unis, le Directoire estime que ROUSSEL UCLAF ne saurait en aucune façon s'impliquer elle-même dans la production ou la diffusion de la mifépristone aux États-Unis.

Toutefois, prenant acte de la volonté du gouvernement américain de procurer aux citoyennes des États-Unis cette alternative médicale à l'interruption chirurgicale de la grossesse, le Directoire s'est résolu à offrir au gouvernement des États-Unis de lui céder, sans rémunération, les deux brevets référencés "U.S. Patents Nos. 4,386,085 and 4,447,424".

Au cas où ce gouvernement déclinerait cette offre pour lui-même tout en la jugeant recevable par une institution qu'il désignerait à cet effet, ROUSSEL UCLAF accepterait de poursuivre dans cette voie et de passer les accords nécessaires, à condition d'en être formellement requise par une lettre officielle, portant la signature du Président des États-Unis, et d'obtenir un certain nombre de garanties contractuelles.

Le Conseil de Surveillance prend acte de cette position qui n'appelle de sa part aucune objection, et manifeste ainsi au Directoire l'assentiment de principe sollicité.

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[Translation of Fax from Dr. Sakiz to Mary Pendergast of draft minutes of the Supervisory Board Meeting of May 4, 1994]

MIFEPRISTONE - UNITED STATES

Dr. E. SAKIZ informed the Supervisory Board ("Conseil de Surveillance") that its assent is requested concerning decisions that the Director ["le Directoire"] is being led to take a propos mifepristone in the United States of America, taking account of pressing exigencies formulated at the highest level by authorities of the federal government of that nation.

Given the very particular characteristics of the U.S. medical system, in comparison to that of the European countries where mifepristone is currently used, and considering equally the highly conflicted climate created around this product in the U.S., the Director deems that ROUSSEL UCLAF would be in no way implicated itself in the production or distribution of mifepristone in the United States.

Nevertheless, considering the wish of the American government to procure for U.S. citizens this medical alternative to the surgical termination of pregnancy, the Director has resolved to offer to cede to the government of the United States, without remuneration, the two patents referred to as "U.S. Patents Nos. 4,386,085 and 4,447,424."

In the event that the government should decline this offer for itself and at the same time judging it receivable by an institution that it would designate to this end, ROUSSEL UCLAF would accept this path and would adopt the necessary agreements, on the condition of being formally required by an official letter, bearing the signature of the President of the United States, and of obtaining a certain number of contractual guarantees.

The Supervisory Council acknowledged this position, which generated no objections, and manifested to the Director its assent to the principle being offered.

[translated by L. Bachorik, 5/10/94]

Tab E

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THE WHITE HOUSE

WASHINGTON

May 16, 1994

Dr. Edouard Sakiz
Chairman, Supervisory Board
Roussel Uclaf
35, boulevard des Invalides
75323 Paris Cedex 07
FRANCE

file

Dear Dr. Sakiz:

It is important for the health of women in the United States that they have access to the widest possible range of safe and effective medical treatments. In support of that goal, in January 1993, I asked the Secretary of Health and Human Services to promote the testing and licensing of mifepristone (RU 486) and other antiprogestins in the United States.

I understand that since at least that time, your company has been in negotiations with The Population Council, Inc., a nonprofit organization with whom you have had dealings on mifepristone since early in the last decade. Those discussions, I understand, have been directed toward the purpose on which I charged the Secretary. I am grateful for the effort those negotiations represent.

In order to permit the appropriate testing, development, and distribution of your product, I urge, at the conclusion of your negotiations, that you bring your plans to fruition. I understand that your company will assign without remuneration your United States patent rights on mifepristone to The Population Council, Inc. which has been studying this product since 1982 and which would take all necessary steps to file a new drug application with the Food and Drug Administration, so that the agency can determine whether the drug is safe and effective for use in the United States.

On behalf of the government of the United States and for the women in America, I thank you for your work.

Sincerely,

Bill Clinton

Tab F

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Jeffrey M. Friedman
James R. (Ron) Weddington

Shari L. Nichols
Kirk W. Tate

F&W

Friedman & Weddington, Attorneys, L.L.P.

502 W. 13th Street
Austin, Texas 78701
(512) 477-9641
Fax: (512) 320-8312

January 6, 1992

file

Betsey Wright
Director for Public Outreach
Transition Team
P. O. Box 615
Little Rock, AR 72203

Dear Betsey,

Enclosed is a "letter" to your boss, which I am going to try to get published. If I am unsuccessful, I may try to raise the money to print it as an ad in The N. Y. Times and other places.

Sarah and I have been discussing the notion of our setting up a non-profit corporation to license and distribute R U 486. Being non-profit would eliminate the need for products liability insurance, which is a major hang-up for a company thinking about marketing a new drug.

It's possible that such an endeavor could be the vehicle for a number of birth control efforts. Something's got to be done very quickly. 26 million food stamp recipients is more than the economy can stand.

Congratulations on your work for Clinton. It's good to see a UTYD doing good. I hope the new President can find the time to deal with the issues I raise in my letter. Please give it to him if you get a chance.

Sincerely,

Ron

Ron Weddington

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Jeffrey M. Friedman
James R. (Ron) Weddington

Shari L. Nichols
Kirk W. Tate

F&W

Friedman & Weddington, Attorneys, L.L.P.

502 W. 13th Street
Austin, Texas 78701
(512) 477-9641
Fax: (512) 320-8312

Dear President-To-Be Clinton,

Some years ago another Southern Governor, when asked about the possibilities for prison reform, supposedly said something to the effect of, "Well, I don't think we're going to get very far until we get a better class of prisoner."

Well, I don't think you are going to get very far in reforming the country until we have a better educated, healthier, wealthier population.

Face it, you know that anything that even resembles the programs of Democratic Presidents in the past is going to make you a one term President. Reagan spent all our money on bombs and even if there were money for programs such as pre-natal health care, job training and day care centers it would be years before we would see any dramatic results. And, as anyone who follows education can see, more money doesn't necessarily translate into better educated kids.

But you can start immediately to eliminate the barely educated, unhealthy and poor segment of our country. No, I'm not advocating some sort of mass extinction of these unfortunate people. Crime, drugs and disease are already doing that. The problem is that their numbers are not only replaced but increased by the birth of millions of babies to people who can't afford to have babies.

There, I've said it. It's what we all know is true, but we only whisper it, because as liberals who believe in individual rights, we view any program which might treat the disadvantaged differently as discriminatory, mean-spirited and...well...so Republican.

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In 1989, 27 percent of all births were to unmarried mothers, a huge percentage of whom were teenagers. If current trends continue, soon a majority of the babies born will be born into poverty and one half of the country cannot support the other half, no matter how good our intentions.

I am not proposing that you send federal agents armed with Depo-Provera dart guns to the ghetto. You should use persuasion rather than coercion. You and Hillary are a perfect example. Could either of you have gone to law school and achieved anything close to what you have if you had three or four or more children before you were 20? No! You waited until you were established and in your 30's to have one child. That is what sensible people do. For every Jesse Jackson who has fought his way out of the poverty of a large family there are millions mired in poverty, drugs and crime.

If Ronald Reagan could use the media to convince the American public that a trillion dollars of borrowed money needed to be spent to combat the "Evil Empire," then you ought to be able to persuade people to only have children when they are able to afford them. Point out that only people like George Bush who inherit money can pay for more than one or two kids in today's economy. (And even then, some of the kids grow up to do embarassing things like loot savings and loans.)

You made a good start when you appointed Dr. Elders, but she will need a lot of help. You will have to enlist the aid of sports and entertainment stars to counteract the propaganda spread by church officials seeking parishioners, generals seeking cannon fodder and businessmen seeking cheap labor that, throughout the ages, has convinced the poor that children are necessary to fulfillment as a person.

It wouldn't hurt to point out that while only 11.1 percent of three person families are below the poverty level, 20.2 percent of six person families and 28.6 percent of families of seven or more are poor. (1992 Statistical Abstract of the United States, p. 459)

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And, having convinced the poor that they can't get out of poverty when they have all those extra mouths to feed, you will have to provide the means to prevent the extra mouths, because abstinence doesn't work. The religious right has had 12 years to preach their message. It's time to officially recognize that people are going to have sex and what we need to do as a nation is prevent as much disease and as many poor babies as possible.

Condoms alone won't do it. Depo-Provera, Norplant and the new birth control injection being developed in India are not a complete answer, although the savings that could be effected by widespread government distribution and encouragement of birth control would amount to billions of dollars.

No, government is also going to have to provide vasectomies, tubal ligations and abortions...RU 486 and conventional abortions. Even if we make birth control as ubiquitous as sneakers and junk food, there will still be unplanned pregnancies. There have been about 30 million abortions in this country since Roe v. Wade. Think of all the poverty, crime and misery ...and then add 30 million unwanted babies to the scenario. We lost a lot of ground during the Reagan-Bush religious orgy. We don't have a lot of time left.

You could do it, Mr. President-To-Be. You are articulate and you've already alienated the religious right with your positions on abortion and homosexuals. The middle-class taxpayer will go along with this plan because it will mean fewer dollars for welfare. The retirees will also go along because because poor people contribute very little to Social Security.

And the poor? Well, maybe if we didn't have to spend so much on problems like low birth weight babies and trying to educate children who come to school hungry, we might have some money to help lift the ones already born, out of their plight.

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The biblical exhortation to "Be fruitful and multiply," was directed toward a small tribe, surrounded by enemies. We are long past that. Our survival depends upon our developing a population where everyone contributes. We don't need more cannon fodder. We don't need more parishioners. We don't need more cheap labor. We don't need more poor babies

Very truly yours,

Ron Weddington

P.S. I was co-counsel in Roe V. Wade, have sired zero children and one fetus, the abortion of which was recently recounted by my ex-wife in her book, A Question Of Choice. (Grosset/Putnam, 1992) I had a vasectomy in 1969 and have never had one moment of regret.

EXHIBIT 49

Maarit Niinimaki et al., *Immediate complications after medical compared with surgical termination of pregnancy*, 114 Obstetrics & Gynecology 795 (2009)

Immediate Complications After Medical Compared With Surgical Termination of Pregnancy

Maarit Niinimäki, MD, Anneli Pouta, MD, PhD, Aini Bloigu, Mika Gissler, BSc, PhD, Elina Hemminki, MD, PhD, Satu Suhonen, MD, PhD, and Oskari Heikinheimo, MD, PhD

OBJECTIVE: To estimate the immediate adverse events and safety of medical compared with surgical abortion using high-quality registry data.

METHODS: All women in Finland undergoing induced abortion from 2000–2006 with a gestational duration of 63 days or less (n=42,619) were followed up until 42 days postabortion using national health registries. The incidence and risk factors of adverse events after medical (n=22,368) and surgical (n=20,251) abortion were compared. Univariable and multivariable association models were used to analyze the risk of the three main complications (hemorrhage, infection, and incomplete abortion) and surgical (re)evacuation.

RESULTS: The overall incidence of adverse events was fourfold higher in the medical compared with surgical abortion cohort (20.0% compared with 5.6%, *P*<.001). Hemorrhage (15.6% compared with 2.1%, *P*<.001) and incomplete abortion (6.7% compared with 1.6%, *P*<.001) were more common after medical abortion. The rate of surgical (re)evacuation was 5.9% after medical abortion and 1.8% after surgical abortion (*P*<.001). Although rare, injuries requiring operative treatment or operative complications occurred more often with surgical termination of pregnancy (0.6% compared with 0.03%, *P*<.001). No differences were noted in the incidence of infections (1.7% compared with 1.7%, *P*=.85), thromboembolic disease, psychiatric morbidity, or death.

CONCLUSION: Both methods of abortion are generally safe, but medical termination is associated with a higher incidence of adverse events. These observations are relevant when counseling women seeking early abortion.
(Obstet Gynecol 2009;114:795–804)

LEVEL OF EVIDENCE: II

Termination of pregnancy is one of the most common gynecologic procedures. For instance, in the United States, nearly half of pregnancies are unintended,[1] and 22% of all pregnancies (excluding miscarriages) end in termination.[2] Abortion practices have changed dramatically in recent years since the medical method with antiprogestin mifepristone and prostaglandins was introduced. For example, in 2007 in Finland 64%,[3] in Sweden 61%,[4] and in the United Kingdom 35%[5] of all abortions were performed using the medical method. Thus, the safety of induced abortion in general, especially that of the medical method, is of great public health interest.

Most previous studies focused on the short-term complications of induced abortion have been small or have not involved comparison of the two dominant methods of abortion (medical and surgical). In a large, register-based study, 5% of the patients had a complication (bleeding, infection, or (re)evacuation) after surgical abortion during a short-term follow-up period of 2 weeks.[6] In a previous meta-analysis in which medical and surgical termination of pregnancy in the

From the Department of Obstetrics and Gynecology, Oulu University Hospital, the Graduate School of Circumpolar Wellbeing, Health and Adaptation, and the National Institute for Health and Welfare, Oulu, Finland; and the National Institute for Health and Welfare and the Nordic School of Public Health, the Department of Obstetrics and Gynecology, Helsinki University Central Hospital, Helsinki, Finland.

Funded by Helsinki University Central Hospital (Drs. Suhonen and Heikinheimo), University Hospital of Oulu (Dr. Niinimäki), and The Finnish Cultural Foundation (Dr. Niinimäki).

The authors thank Matti Kesti for his help with computation.

Corresponding author: Dr. Oskari Heikinheimo, Dept Ob&Gyn, Helsinki University Central Hospital, P.O. Box 140, 00029-HUS, Helsinki, Finland; e-mail: oskari.heikinheimo@helsinki.fi.

Financial Disclosure

Dr. Suhonen has lectured at meetings organized by Schering Plough (Helsinki, Finland). Dr. Heikinheimo has been a paid consultant and lecturer for Bayer Schering Pharma AG (Berlin, Germany) and for Schering-Plough (Helsinki, Finland). He also belongs to both the international and Finnish advisory boards for Bayer Schering Pharma. The other authors did not disclose any potential conflicts of interest.

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first trimester were compared, no differences in pelvic infection or ongoing pregnancies were noted between the methods. Evidence of different rates of other potential side effects or complications between the two abortion techniques could not be confirmed because the trials included were small.[7]

Only a few randomized controlled trials have been performed to compare success rates and complications between medical and surgical abortion.[8–10] In a previous, partly randomized study, no difference in the number of complications was noted. Although the rate of complete abortion was significantly higher in the surgical group (98% compared with 94%), the surgically treated women had a higher incidence of antibiotic treatment than did those undergoing medical abortion.[8] In another randomized controlled trial, complete abortion without a second procedure occurred in 98% of cases after surgical abortion and in 95% after medical abortion. Moreover, no differences in the rates of major complications were observed.[11]

The purpose of the present study was to compare medical and surgical abortion in regard to the incidence and risk factors of immediate (ie, within 42 days after termination of pregnancy) adverse events and complications in a large nationwide cohort. A nationwide cohort with high-quality data derived from national health registries offers the possibility to estimate extensively the risk of adverse events associated with the two methods of early termination of pregnancy. Using this same cohort, we recently reported that the risk of repeat abortion after medical compared with surgical termination of pregnancy depends on various sociodemographic factors but not on the method of abortion.[12]

MATERIALS AND METHODS

This was a cohort study including all women undergoing termination of pregnancy in Finland between January 1, 2000, and December 31, 2006. According to the current law on induced abortions, women need permission with legal indication for termination of pregnancy, but the legislation is interpreted liberally. The Finnish legislation on induced abortion[13] was summarized in our recent study.[12]

The present study was conducted after receiving approval from the ethics committee of the Northern Ostrobothnia Hospital District. The Ministry of Social Affairs and Health and Statistics Finland gave their permission to use the confidential personal-level data from the registries. The Data Protection Ombudsman was notified regarding the data linkage before the analyses as required by the national data-protection legislation.

All women who underwent induced abortion by either medical or surgical methods at a gestational age of 63 days or less were included. The duration of gestation was limited to 63 days because, during the study period of 2000–2006, medical abortions, for the most part, were performed only up to that time.[14] The time of follow-up after abortion was 42 days (6 weeks). Medical abortion was defined as the use of mifepristone alone or in combination with misoprostol or other prostaglandins. Surgical abortion included induced abortions with dilation and curettage or vacuum aspiration. The participants were divided into two arms of the study according to the primary abortion method. For women having more than one abortion, only the first termination of pregnancy during the study period was included.

The study was based on three national registries: the Abortion Registry,[3] the Care Registry for Health Institutions (later renamed the Hospital Registry)[15] complied by the National Institute for Health and Welfare, and the Cause-of-Death Registry of Statistics Finland.[16] The study participants were selected from the Abortion Registry as described in our previous study,[12] after which the other registries were linked with the cohort.

We linked information on the study participants in the Hospital Registry concerning all hospital-inpatient episodes (all hospitals) and outpatient visits (public hospitals) within 42 days after termination of pregnancy to analyze complications related to induced abortion. All of the diagnoses (based on the International Classification of Diseases [ICD]-10, International Statistical Classification of Diseases and Related Health Problems[17]) and codes for surgical procedures (based on the Nordic Classification of Surgical Procedures[18]) found in the cohort were evaluated to select those considered to be of clinical importance.

Complications were divided into seven categories: 1) hemorrhage (all reported hemorrhages), 2) postabortal infections (pelvic inflammatory disease, endometritis, cervicitis, wound infections, pyrexia of unknown origin, urinary tract infections, and septicemia), 3) incomplete abortion (surgical [re]evacuation, any reported incomplete abortion), 4) injuries or other reasons for surgical operation (all injuries, cervical laceration, uterine perforation, all surgical interventions during the time of follow-up), 5) thromboembolic disease (pulmonary embolism, deep vein thrombosis), 6) psychiatric morbidity (depression, intoxication, psychoses) and 7) death (death from any cause, pregnancy-related death according to the World Health Organization definition). The classification was based on that reported in the Joint Study of

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the Royal College of General Practitioners and the Royal College of Obstetricians and Gynaecologists[19] and modified for the present study.

The Cause-of-Death Register kept by Statistics Finland contains data from death certificates and includes all deaths of Finnish citizens and permanent residents in Finland classified according to ICD-10 codes.[20] All of the early deaths (within 42 days of termination of pregnancy) were classified as direct, indirect, or unrelated. This classification was based on that in an earlier study by Deneux-Tharaux et al.[21]

Differences between the groups were assessed using Student's *t*-test for continuous variables and the χ^2 test for categorical variables. Logistic regression analyses were performed to adjust for the differences in background characteristics in the comparisons of medical and surgical abortions. Furthermore, logistic regression was used to identify risk factors for complications. Variables that showed statistically significant associations with complications in univariable analysis were further entered in multivariable analysis. The estimated risks are presented as odds ratios with 95% confidence intervals. The statistical analyses were performed by using SPSS 16.0 for Windows (SPSS Inc., Chicago, IL).

RESULTS

The total number of women in the cohort was 42,619. Of these, 22,368 had primary medical and 20,251 primary surgical termination of pregnancy. The characteristics of the women in the cohort are presented in Table 1. The women in the medical-abortion cohort were somewhat younger and more often primigravid, nulliparous, and single. The most notable difference between the groups was the shorter duration of gestation in the cohort undergoing medical abortion; surgical abortions in Finland usually are performed after the 6th week of gestation.

The incidence of various adverse events and complications is shown in Table 2. The most common adverse events were hemorrhage and incomplete abortion, both of which were more common in the medical group. The incidence of infection did not differ between the groups. Injuries requiring operation were rare but were more common in the surgical group. No differences between the two groups were noted in the incidence of thromboembolic disease, psychiatric morbidity, or death, partly because the overall incidence of these events was low. All of the deaths were unrelated to pregnancy: suicide (n=3), homicide (n=1), subarachnoid hemorrhage (n=1), and traffic accident (n=1).

When comparing the numbers of women with adverse events or complications, the difference between the two groups was notable: 20% of women in the medical-abortion group and 5.6% of women in the surgical-abortion group had at least one type of adverse event. When looking at the number of complications per patient, there were fewer multiple complications after surgical abortion (Table 2).

We also analyzed the three most common complications in relation to the duration of gestation (Fig. 1). In the medical-abortion cohort, the proportion of women with hemorrhage decreased with advancing duration of gestation; with surgical abortion it increased, albeit not significantly. In both groups, the incidence of infection and incomplete abortion increased with advancing duration of gestation.

Univariable and multivariable analyses were performed concerning the risk factors for three major classes of complications (hemorrhage, infection, and incomplete abortion) and for surgical (re)evacuation, separately for the medical and surgical abortion cohorts (Table 3), and for the whole cohort combined (Fig. 2). In multivariable analysis, the risk of hemorrhage after medical abortion was increased in the age group of 20–24 years, among parous women, among those of lower socioeconomic status, and among those living in densely populated or rural areas. The risk decreased with advancing duration of gestation. After surgical termination of pregnancy, an increased risk of hemorrhage was seen in the age groups of 20–24, 25–29, 30–34, and 35–39 years when compared with women younger than 20 years. A rural type of residence was associated with a decreased risk of hemorrhage.

Multivariable analysis revealed an increased risk of infection after medical abortion in the age group of 20–24 years and with advanced duration of gestation of 50–56 and 57–63 days. After surgical abortion, an increased risk of infection was found in the age group of 20–24 years, with increasing duration of gestation, and among women of lower socioeconomic class. A decreased risk of infection was associated with parity and with women living in densely populated or rural areas.

The risk factors associated with incomplete medical abortion were age of 20–24 years, parity, previous abortion, being single, living in a densely populated or rural area, and advanced duration of gestation. The risk of experiencing incomplete surgical abortion was associated with previous abortion, cohabiting or being single, and with a duration of gestation of 57–63 days.

In multivariable analysis, the risk of bleeding was almost eightfold higher, the risk of incomplete abor-

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Table 1. Characteristics of the Participants Included in the Study

	Medical Abortion (n=22,368)	Surgical Abortion (n=20,251)	*P*
Age (y)			
Median (mean)	25.0 (26.3)	26.0 (27.3)	<.001
95% confidence interval	26.2–26.4	27.2–27.4	
Age category (y)			
Younger than 20	5,058 (22.6)	4,352 (21.5)	<.001
20–24	5,665 (25.3)	4,337 (21.4)	
25–29	4,098 (18.3)	3,442 (17.0)	
30–34	3,406 (15.2)	3,393 (16.8)	
35–39	2,934 (13.1)	3,130 (15.5)	
40 or older	1,207 (5.4)	1,596 (7.9)	
Parity			
0	12,819 (57.3)	10,171 (50.2)	<.001
1	3,444 (15.4)	3,384 (16.7)	
2	3,897 (17.4)	4,125 (20.4)	
3 or more	2,207 (9.9)	2,570 (12.7)	
Previous abortions			
0	18,626 (83.3)	15,461 (76.4)	<.001
1	2,856 (12.8)	3,471 (17.1)	
2	664 (3.0)	927 (4.6)	
3 or more	221 (1.0)	390 (1.9)	
Marital status			
Married	4,350 (19.5)	4,718 (23.3)	<.001
Cohabiting	3,592 (16.1)	3,113 (15.4)	
Single	14,394 (64.4)	12,412 (61.3)	
Social status			
Upper white-collar worker	1,595 (7.1)	1,497 (7.4)	<.001
Lower white-collar worker	4,799 (21.5)	4,794 (23.7)	
Blue-collar worker	2,691 (12.0)	3,060 (15.1)	
Student	7,598 (34.0)	5,990 (29.6)	
Other	1,072 (4.8)	1,386 (6.8)	
Unknown	4,613 (20.6)	3,524 (17.4)	
Type of residence			
Urban	16,668 (74.5)	15,118 (74.7)	<.001
Densely populated area	2,788 (12.5)	2,286 (11.3)	
Rural	2,912 (13.0)	2,847 (14.1)	
Indication for abortion			
Social reasons	19,691 (88.0)	17,175 (84.8)	<.001
Age 17 y or younger	1,507 (6.7)	1,459 (7.2)	
Age 40 y or older	754 (3.4)	1,076 (5.3)	
Four children or more	366 (1.6)	457 (2.3)	
Other	50 (0.2)	84 (0.4)	
Duration of gestation (d)			<.001
42 or fewer	6,012 (26.9)	1,895 (9.4)	
43–49	7,355 (32.9)	4,724 (23.3)	
50–56	6,014 (26.9)	7,033 (34.7)	
57–63	2,987 (13.4)	6,599 (32.6)	

Data are n (%) unless otherwise specified.

tion was fivefold higher, and the risk of (re)evacuation was twofold higher after medical abortion compared with surgical abortion. The risk of infection, as derived from univariable analysis, was not associated with the method of abortion.

DISCUSSION

In the present study, we found that the two methods of pregnancy termination (medical and surgical) are generally safe. However, the incidence of the two most common adverse events (hemorrhage and incomplete abortion) were notably higher among women undergoing medical abortion, whereas complications requiring surgical treatment, although rare, were more common after surgical abortion. The rates of postabortal infection and serious morbidity (such as thromboembolic events) did not differ between the two groups. There were no pregnancy-related deaths

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Table 2. Incidence of Adverse Events in the Cohort

	Medical Abortion (n=22,368)	Surgical Abortion (n=20,251)	*P**	Adjusted OR† (95% CI)
Hemorrhage	3,487 (15.6)	433 (2.1)	<.001	7.93 (7.15–8.81)
Hemorrhage with surgical (re)evacuation	645 (2.9)	173 (0.9)	<.001	
Infection	383 (1.7)	342 (1.7)	.85	1.15 (0.98–1.34)
Infection with surgical (re)evacuation	172 (0.8)	122 (0.6)	.02	
Incomplete abortion	1,495 (6.7)	323 (1.6)	<.001	5.37 (4.49–6.28)
Incomplete abortion with surgical (re)evacuation	1,320 (5.9)	77 (0.4)	<.001	
Injury	6 (0.03)	122 (0.60)	<.001	NA‡
Thromboembolic disease	18 (0.08)	17 (0.08)	.90	NA
Psychiatric morbidity	2 (0.009)	1 (0.005)	.62	NA
Death	2 (0.009)	4 (0.020)	.35	NA
Women with adverse events	4,479 (20.0)	1,127 (5.6)	<.001	4.23 (3.94–4.54)
Surgical (re)evacuation	1,320 (5.9)	363 (1.8)	<.001	3.58 (3.18–4.03)
Number of adverse events per woman				
0	17,889 (80.0)	19,124 (94.4)	<.001	
1	3,624 (16.2)	1,021 (5.0)		
2	796 (3.6)	97 (0.5)		
3	59 (0.26)	9 (0.04)		

OR, odds ratio; CI, confidence interval; NA, not applicable.
Data are n (%) unless otherwise specified.
* Chi-square test for comparison between medical and surgical cohort.
† Surgical cohort as a reference adjusted for age, parity, previous abortion, social status, marital status, type of residence, and duration of gestation.
† Not applicable owing to small number of patients in one or both groups.

in our data. Because medical abortion is being used increasingly in several countries, it is likely to result in an elevated incidence of overall morbidity related to termination of pregnancy.

The present study covers almost all of the induced abortions performed in Finland during the years 2000–2006 and thus is a unique data source regarding even uncommon adverse events. However, the validity of the data is a potential problem in register-based studies such as the present one. In the Registry of Induced Abortions, 95% of the information has been proven to be identical to that in medical records.[22] However, the reliability of diagnoses and interventions can vary, and underreporting or overreporting by physicians cannot be ruled out. In addition, the Hospital Registry, which was used as a data source, contains data concerning hospital care only. Thus, adverse events dealt with outside the public hospital system, especially those treated in primary health care, will have been missed. Moreover, a single patient may have various diagnoses and complications, such as incomplete abortion and bleeding, and thus may have been registered more than once. The participants, however, each had a unique personal identification number, and we were able to eliminate double counting in our study.

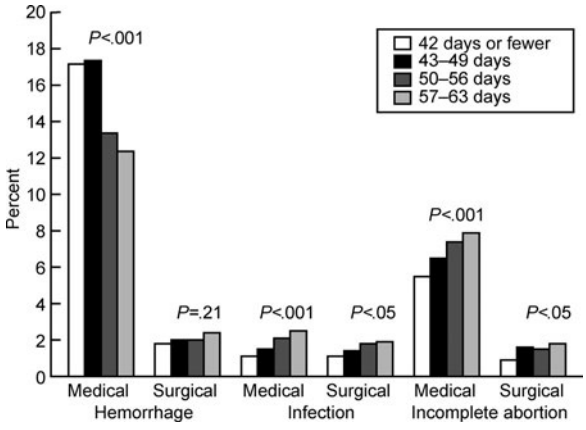


Fig. 1. Complications according to the duration of gestation in the medical and surgical cohorts (%).

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It is important to note that the severity of the diagnoses found in the Hospital Registry may vary substantially. Thus, another problem in this kind of study is the definition of criteria for complications and adverse events. We evaluated all the ICD-10 diagnoses and codes for surgical procedures included in the Hospital Registry and classified them into seven categories.[19] In addition, women choosing surgical and medical abortion differed subtly in several respects and thus may be prone to different types of adverse events.

The rate of consultation related to a diagnosis of hemorrhage was high and eight times more common after medical termination of pregnancy. Because

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Table 3. Results of the Multivariable Analysis in Three Major Complications and Surgical (Re)Evacuation

	Hemorrhage		Infection	
	Medical	Surgical	Medical	Surgical
Age (y)	1.00 (0.96–1.04)			
Age category (y)				
Younger than 20	1	1	1	1
20–24	1.26 (1.00–1.58)	1.72 (1.25–2.37)	1.37 (1.03–1.83)	1.72 (1.13–2.62)
25–29	1.29 (0.88–1.91)	1.82 (1.30–2.54)	1.31 (0.95–1.80)	1.31 (0.77–2.23)
30–34	1.47 (0.83–2.58)	2.01 (1.45–2.79)	0.82 (0.56–1.19)	1.77 (1.02–3.08)
35–39	1.17 (0.56–2.46)	1.79 (1.28–2.52)	1.10 (0.77–1.58)	1.05 (0.54–2.01)
40 or older	1.01 (0.40–2.56)	0.50 (0.26–0.95)	0.95 (0.56–1.61)	1.54 (0.74–3.20)
Parity				
None	1			1
Yes	1.25 (1.08–1.45)			0.80 (0.56–1.14)
Previous abortion				
None	1			
Yes	1.07 (0.93–1.22)			
Social status				
Upper white-collar worker	1			1
Lower white-collar worker	1.14 (0.92–1.40)			3.21 (1.38–7.46)
Blue-collar worker	1.54 (1.23–1.93)			4.40 (1.87–10.36)
Student	1.50 (1.19–1.88)			3.47 (1.44–8.36)
Other	1.58 (1.20–2.08)			4.50 (1.80–11.27)
Marital status				
Married	1			
Cohabiting	1.12 (0.94–1.34)			
Single	1.05 (0.90–1.22)			
Residence				
Urban	1	1		1
Densely populated	1.43 (1.23–1.66)	0.98 (0.72–1.33)		0.85 (0.55–1.32)
Rural	1.25 (1.07–1.45)	0.71 (0.51–0.98)		0.54 (0.33–0.87)
Duration of gestation (d)				
42 or fewer	1		1	1
43–49	0.93 (0.82–1.05)		1.33 (0.98–1.80)	1.03 (.0.59–1.80)
50–56	0.74 (0.64–0.85)		1.91 (1.42–2.56)	1.15 (0.68–1.94)
57–63	0.63 (0.51–0.76)		2.26 (1.62–3.15)	1.15 (0.68–1.96)

Data are odds ratio (95% confidence interval).
Only those variables that showed a statistically significant association with a complication in univariable analysis (data not shown) were entered in multivariable analysis.

medical abortion is associated with uterine bleeding lasting approximately 2 weeks,[23] the high rate of consultation is not surprising. Uterine bleeding requiring surgical evacuation probably better reflects the severity of bleeding after termination of pregnancy. The incidence of such bleeding was relatively low, but it was more common in the medical-abortion group. In earlier studies, an average of 10% of women who underwent medical abortion complained of excessive bleeding.[24]

In line with uterine bleeding, the rate of incomplete abortion was higher in the cohort undergoing medical abortion. Surgical evacuation performed because of incomplete abortion occurred in approximately 6% of women having medical termination of pregnancy. The highest rates of complete medical abortion, reported from centers with extensive experience of the technique, are up to 98%.[11,25] However, it is reassuring to note that a high rate of complete abortion, approaching those reported from centers with extensive experience, was reached in the present national cohort.

One of our key findings was that the rates of infectious morbidity were similar after medical and surgical abortion. In a previous survey, the need for postabortal antibiotics for suspected endometritis was higher after surgical abortion.[26] Moreover, the use of medical abortion previously has been associated with rare cases of severe infectious morbidity and mortality.[27] Reassuringly, only two cases with serious infections (septicemia caused by *Staphylococcus aureus* and *Streptococcus*) occurred in the present cohort, one in

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Incomplete Abortion		Surgical (Re)Evacuation	
Medical	Surgical	Medical	Surgical
1.04 (0.99–1.10)		1.05 (0.99–1.11)	
1		1	
1.14 (0.80–1.62)		1.15 (0.79–1.67)	
1.05 (0.60–1.86)		1.03 (0.56–1.88)	
0.89 (0.40–2.00)		0.89 (0.38–2.09)	
0.66 (0.23–1.88)		0.66 (0.22–2.00)	
0.41 (0.11–1.52)		0.39 (0.10–1.57)	
1		1	
1.65 (1.33–2.03)		1.59 (1.27–1.98)	
1	1	1	
1.34 (1.11–1.60)	1.38 (1.08–1.76)	1.30 (1.08–1.58)	
1		1	
0.97 (0.75–1.24)		0.97 (0.74–1.28)	
0.83 (0.62–1.11)		0.88 (0.65–1.20)	
1.04 (0.77–1.40)		1.02 (0.74–1.40)	
0.74 (0.50–1.08)		0.84 (0.57–1.25)	
1	1	1	
1.07 (0.84–1.35)	1.46 (1.00–2.13)	1.10 (0.86–1.41)	
0.94 (0.76–1.15)	1.46 (1.09–1.97)	0.92 (0.74–1.14)	
1		1	1
1.40 (1.13–1.74)		1.43 (1.14–1.79)	0.75 (0.52–1.08)
1.38 (1.12–1.70)		1.48 (1.19–1.84)	0.68 (0.48–0.96)
1	1	1	1
0.96 (0.78–1.16)	1.64 (0.97–2.75)	1.01 (0.81–1.24)	1.63 (0.97–2.73)
1.34 (1.12–1.66)	1.59 (0.96–2.62)	1.41 (1.14–1.75)	1.92 (1.17–3.15)
1.55 (1.22–1.98)	1.91 (1.16–3.14)	1.77 (1.38–2.28)	2.23 (1.36–3.65)

the medical and one in the surgical group. However, as previously reported, cases of *Clostridium sordellii* septicemia occurred at a rate of 1 per 100,000[27]; even the present cohort is too small to assess the incidence of such a rare infection.

Injuries and surgical interventions for other reasons were relatively rare in both groups. Not surprisingly, the incidence of postabortal surgical intervention was lower among women undergoing medical abortion. Some other serious and rare complications were identified as well. These included thromboembolic and psychiatric complications as well as some deaths. The incidence of thromboembolic complications is in line with earlier reports of an increased risk during pregnancy.[28,29] In a previous register-based study, it was concluded that deaths from external causes of injury and poisoning (including unintentional and intentional injuries, suicides, and homicides) are significantly more common in women after induced abortion compared with nonpregnant women or women after birth.[30] In the present cohort also, five out of six cases of death were the result of external causes. In addition, psychiatric diagnoses, such as depression and psychoses, were identified, but the rates of these complications did not differ between the two cohorts. Similarly, in an earlier, partly randomized study, no differences between women with medically or surgically performed abortions emerged in regard to postabortal anxiety, depression, or self-esteem.[31] Naturally, the present kind of study setting (register-based study) gives only a crude idea of short-term psychiatric morbidity associated with termination of pregnancy.

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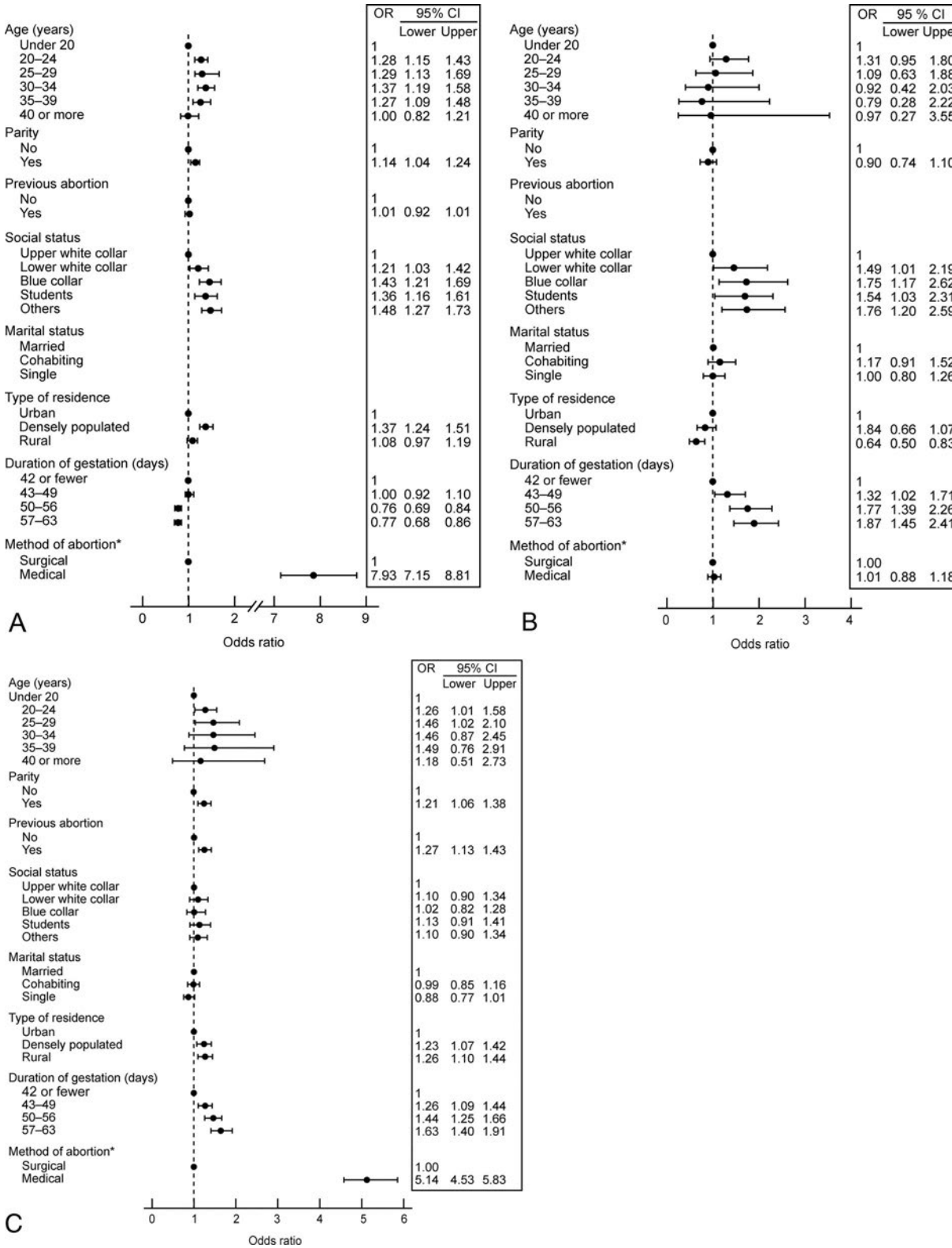


Fig. 2. Risk factors regarding three major complications (bleeding [**A**], infection [**B**], and incomplete abortion [**C**]) among the entire cohort (medical and surgical cohorts combined). OR, odds ratio; CI, confidence interval. *OR for infections is derived from univariable analysis.

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The most important risk factor with regard to the two most common adverse events (hemorrhage and incomplete abortion) was the method of abortion. Other risk factors were, for the most part, in line with those reported previously–advanced gestational age, parity, and previous induced abortions.[11,32–34] For unknown reasons, the risk of hemorrhage after medical abortion diminished with advancing duration of gestation. Tolerance of bleeding–a natural part of medical abortion–varies from one woman and physician to another and also depends on preabortion counseling. Other explanations, such as possible bias in reporting the events in the registry, are possible but cannot be verified in the present study. We included all cases requiring consultation in specialized health care because they are registered uniformly in Finland. In addition, every such visit adds to the costs of the health care system. More detailed analysis of all health care costs related to termination of pregnancy and its complications, according to the method, is needed.

In conclusion, termination of pregnancy by means of either medical or surgical methods is associated with a low level of serious complications. On the basis of the present data, however, it appears that medical abortion results in an increased incidence of adverse events.

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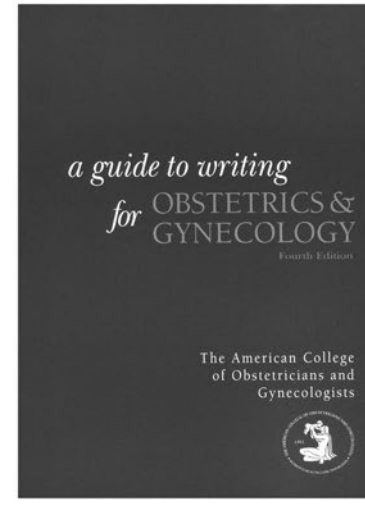
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EXHIBIT 50

Pet. and App. for Temporary and Permanent Injunctive Relief, *Texas v. Carpenter*, No. 471-08943-2024 (Tex. Collin Cnty. Dec. 12, 2024)

Filed: 12/12/2024 9:18 AM
Michael Gould
District Clerk
Collin County, Texas
By Sara Jones Deputy
Envelope ID: 95232968

CAUSE NO. 471-08943-2024

STATE OF TEXAS, ***Plaintiff*,**	§	**IN THE DISTRICT COURT OF**
v.	§	**COLLIN COUNTY, TEXAS**
MARGARET DALEY CARPENTER, M.D. a/k/a MAGGIE CARPENTER, M.D., ***Defendant.***	§	**___ JUDICIAL DISTRICT**

PETITION AND APPLICATION FOR TEMPORARY AND PERMANENT INJUNCTIVE RELIEF

Dr. Margaret Daley Carpenter (Carpenter) of New York violates Texas law by providing abortion-inducing drugs to Texans through telehealth. Carpenter is not a licensed Texas physician, nor is she authorized to practice telemedicine in the State of Texas. The Court should enjoin Carpenter from continuing to operate outside the bounds of the law and impose civil penalties for her violation of Texas law.

DISCOVERY CONTROL PLAN

1. Discovery is intended to be conducted under Level 2 of Texas Rules of Civil Procedure 190.3.

2. The State of Texas seeks injunctive relief. Therefore, this suit is not governed by the expedited actions process in Texas Rules of Civil Procedure 169.

JURISDICTION AND VENUE

3. Plaintiff seeks monetary relief of $250,000 or less and non-monetary relief. The relief sought is within the jurisdiction of this court. Tex. Const. art. V, § 8; Tex. Gov't Code §§ 24.007, 24.008; and Tex. Civ. Prac. & Rem. Code § 65.021(a). As the nonresident defendant contracted by mail or otherwise with a resident of Collin County, Texas, with performance in whole or in part in Texas, this court has personal jurisdiction over the nonresident defendant. Tex. Civ. Prac. & Rem. Code § 17.042.

4. Venue is proper in Collin County, Texas under Texas Civil Practice & Remedies Code § 15.002(a)(1) because a substantial part of the events or omissions giving rise to this claim occurred in Collin County, Texas.

PARTIES

5. Plaintiff is the State of Texas.

6. Defendant Margaret Daley Carpenter, M.D. a/k/a Maggie Carpenter, M.D. a/k/a M. Carpenter, M.D. ("Carpenter") is a physician licensed by the State of New York (license no. 236802). She is not licensed as a physician in the State of Texas. As Carpenter is a nonresident, the Texas Secretary of State is her agent for service of process. Tex. Civ. Prac. & Rem. Code § 17.044(b). Service of process or citation may be mailed by registered or certified mail in accordance with Tex. Civ. Prac. & Rem. Code § 17.045(a),(d) and Tex. R. Civ. P. 106, 108 to the Defendant at her residence 1156 Old Ford Rd., New Paltz, New York 12561-2654 or her business address 2578 Broadway, #580, New York, New York 10025-5642.

LEGAL BACKGROUND

7. The Texas Occupations Code defines "practicing medicine" as "the diagnosis, treatment, or offer to treat a mental or physical disease or disorder or a physical deformity or injury by any system or method, or the attempt to effect cures of those conditions, by a person who publicly professes to be a physician or directly or indirectly charges money or other compensation for those services." Tex. Occ. Code § 151.002(a)(13)(A). A person who is physically located in another jurisdiction but who, through the use of any medium, including an electronic medium, performs an act that is part of a patient care service initiated in this state, including the taking of an x-ray examination or the preparation of pathological material for examination, and that would affect the diagnosis or treatment of the patient, is considered to be engaged in the practice of medicine in this state. Tex. Occ. Code § 151.056(a).

8. Texas law prohibits a person from practicing medicine in this state unless the person holds a license and complies with registration requirements. Tex. Occ. Code §155.001; Tex. Occ. Code § 165.159. *See also* Tex. Admin. Code §§ 174.8, 174.12(d).

9. An "abortion" is defined as "the act of using or prescribing an instrument, drug, a medicine, or any other substance, device, or means with the intent to cause the death of an unborn child of a woman known to be pregnant." Tex. Health & Safety Code § 245.002(1).

10. An abortion in the State of Texas may only be performed by a physician licensed to practice medicine in the State of Texas. Tex. Health & Safety Code § 171.003. A physician performing or inducing an abortion, on the date the abortion is performed or induced must have active admitting privileges at a hospital that is located not further than 30 miles from the location at which the abortion is performed or induced. Tex. Health & Safety Code § 171.0031(a).

11. No physician shall treat or prescribe residents of the State of Texas with telehealth services, via communications technology, unless the individual possesses a full Texas medical license. 22 Tex. Admin. Code § 174.8. In addition, the validity of a prescription issued as a result of telemedicine medical service is determined by the same standards that would apply to the issuance of a prescription in an in-person setting. 22 Tex. Admin. Code § 174.5(a),(c). *See also* Tex. Occ. Code § 111.001(3),(4).

12. A physician or supplier may not provide to a patient any abortion-inducing drug by courier, delivery, or mail service. Tex. Health & Safety Code § 171.063(b-1).

13. Before a physician provides an abortion-inducing drug, the physician must examine the pregnant woman in person and such physician must ensure that the physician does not provide an abortion inducing drug for a pregnant woman whose pregnancy is more than 49 days of gestational age. Tex. Health & Safety Code § 171.063(c)(1),(6). A physician providing an abortion-inducing drug is required to schedule a follow-up visit to confirm that a woman's pregnancy is completely terminated and to assess any continued blood loss. Tex. Health & Safety Code § 171.063(e).

14. The Texas Health and Safety Code generally prohibits a person from knowingly performing, inducing, or attempting an abortion. Tex. Health & Safety Code § 170A.002(a).

15. The attorney general is authorized to collect a civil penalty of not less than $100,000 for each violation of Tex. Health & Safety Code § 170A.002 and may also recover costs and attorney's fees. Tex. Health & Safety Code § 170A.005. In addition, the attorney general may seek other civil remedies. Tex. Health & Safety Code § 170A.006.

FACTUAL BACKGROUND

16. Carpenter holds a medical license in the State of New York.

17. Carpenter is not licensed to practice medicine in Texas. *See* https://profile.tmb.state.tx.us/SearchResults.aspx?8c92ec07-d491-40c0-840f-d289c57fcd58. Carpenter has no hospital admitting privileges in the State of Texas.

18. Carpenter knowingly treats patients in Texas even though she is not a licensed Texas physician.

19. Carpenter is the Co-Medical Director and Founder of the Abortion Coalition for Telemedicine ("ACT"), a nationwide advocacy organization proactively working to advance telemedicine abortion. ACT references the "two-step process of mifepristone and misprostol" as a method for terminating pregnancies up to 12 weeks.

20. Carpenter's ACT biography states "[s]he has provided medical and surgical abortions since 1999. She started working with Aid Access in 2020 and helped launch Hey Jane in December 2020 and continues to work with both organizations." *See* https://www.theactgroup.org/our-team. Aid Access works to provide abortion pills to people in all 50 states. *See* https://aidaccess.org/en/page/561/who-are-we. Hey Jane advertises "no clinic visit needed" and that Hey Jane is a safe space for reproductive and sexual care like abortion pills, "from the comfort and convenience of your phone." *See* https://www.heyjane.com/. The Privacy Policy of heyjane.com states the site collects and uses personal information by or on behalf of Possible Health Medical, P.C., and Jane Medical, PLLC. *See* https://www.heyjane.com/legal/privacy-policy.

21. Carpenter is the CEO of Possible Health Medical, P.C., a New York professional service corporation with her address as 1156 Old Ford Rd., New Paltz, New York 12561 and her principal executive office address as 2578 Broadway, #580, New

York, New York 10025. Carpenter is also an officer / manager of Jane Medical, PLLC, incorporated in the State of Illinois and lists her office address as 2578 Broadway, #580, New York, New York 10025.

22. About mid-May 2024, a 20-year-old female resident of Collin County, Texas became pregnant. The mother of the unborn child did not communicate her pregnancy to the biological father of the unborn child. The mother did not have any life-threatening physical condition aggravated by, caused by, or arising from the pregnancy that placed her at risk of death or any serious risk of substantial impairment. The mother proceeded to utilize telemedicine or telehealth services and received, through Carpenter, two abortion-inducing drugs or prescriptions. The first was a box for the drug mifepristone, 200 mg, followed by the "#1" and the directions to take 1 tablet by mouth and to "take this medication first." The second was a pill bottle of misoprostol 200 mcg with directions to take 4 tablets (i.e., 800 mcg.) after the mifepristone.

23. "Mifepristone is a drug that blocks a hormone called progesterone that is needed for a pregnancy to continue. Mifepristone, when used together with another medicine called misoprostol, is used to end a pregnancy through ten weeks gestation (70 days or less since the first day of the last menstrual period). The approved mifepristone dosing regimen is: on day one, 200 mg of mifepristone taken by mouth; then 24 to 48 hours after taking mifepristone, 800 mcg of misoprostol taken buccally (in the cheek pouch), at a location appropriate for the patient; and about seven to fourteen days after taking mifepristone: follow-up with the health care provider."[1]

24. On July 16, 2024, the mother asked the biological father of her unborn child to be taken to the hospital because of hemorrhage or severe bleeding. After the mother was seen by health care professionals at a hospital in Collin County, Texas, the biological father

[1] *Questions and answers on Mifepristone for medical termination of pregnancy through ten weeks gestation,* US Food & Drug Admin., https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation#:~:text=Mifepristone%20is%20a%20drug%20that,of%20the%20last%20menstrual%20period) (last visited October 30, 2024).

of the unborn child was told that the mother of the unborn child was experiencing a hemorrhage or severe bleeding as she "had been" nine weeks pregnant before losing the child. The biological father of the unborn child, upon learning this information, concluded that the biological mother of the unborn child had intentionally withheld information from him regarding her pregnancy, and he further suspected that the biological mother had in fact done something to contribute to the miscarriage or abortion of the unborn child. The biological father, upon returning to the residence in Collin County, discovered the two above-referenced medications from Carpenter.

25. Carpenter provided abortion-inducing drugs to the pregnant Collin County woman, which caused an adverse event or abortion complication and resulted in a medical abortion. *See* Tex. Health & Safety Code § 171.061 (providing statutory definitions).

26. Carpenter's conduct violates the Texas Health and Safety Code's prohibition on prescribing abortion-inducing drugs via telemedicine.

27. Carpenter's knowing and continuing violations of Texas law places women and unborn children in Texas at risk.

28. Carpenter sees Texas patients via telehealth and prescribes them abortion-inducing medication.

REQUESTS FOR RELIEF

A. Request for Temporary and Permanent Injunctive Relief

29. Pursuant to Texas Health & Safety Code Section 170A.006, Texas Civil Practice and Remedies Code Section 65.011 and Texas Rule of Civil Procedure 680 *et seq.*, to preserve the status quo pending a full trial on the merits, *see, Butnaru v. Ford Motor Co*., 84 S.W.3d 198, 204 (Tex. 2002), the State of Texas requests a temporary injunction against Carpenter that enjoins her from illegally prescribing abortion-inducing drugs to Texas residents and illegally practicing medicine in the State of Texas.

30. To obtain a temporary injunction, the applicant must plead and prove three specific elements: (1) a cause of action against the defendant; (2) a probable right to the relief sought; and (3) a probable, imminent, and irreparable injury in the interim. *Butnaru*,

84 S.W.3d at 204.

31. The State of Texas has a valid cause of action and probable right to relief because, for the reasons stated herein, Carpenter is violating our Texas statutes. *See, e.g.,* Tex. Health & Safety Code § 170A.002(a).

32. It is well-established that the State suffers an irreparable injury when it is precluded from enforcing its own laws. *See, e.g., Abbott v. Perez*, 585 U.S. 579, 602 n. 17, 138 S.Ct. 2305, 2324 n. 17, 201 L.Ed2d 714, 734 n. 17 (2018) (*citing Maryland v. King*, 567 U.S. 1301, 133 S.Ct. 1, 3, 183 L.Ed.2d 667, 670 (2012) (Roberts, C.J., in chambers)) ("[T]he inability to enforce its duly enacted plans clearly inflicts irreparable harm on the State.").

33. Unless Carpenter is restrained by this Court, with relief that is enforceable by a contempt order, Carpenter will continue to defiantly violate Texas Law. Carpenter's continued violation of our Texas statutes as stated herein is probable and imminent. The State is not required to establish that it will prevail at trial to obtain a temporary injunction as it only needs to plead a cause of action and show a probable right to the relief sought. *Butnaru*, 84 S.W.3d at 211.

34. Furthermore, there is no adequate remedy at law. For a legal remedy to be adequate, it must give the plaintiff complete, final, and equal relief. *Huynh v. Blanchard*, 694 S.W.3d 648, 685 (Tex. 2024) (quoting *Henderson v. KRTS, Inc.*, 822 S.W.2d 769, 773 (Tex. App.—Houston [1st Dist.] 1992, no writ)). If an otherwise complete and adequate remedy at law will lead to a multiplicity of suits, that very fact prevents it from being complete and adequate. *Id.* While the Legislature has provided civil penalties in Tex. Health & Safety Code § 170A.005, Carpenter's knowing, and continued violations of Texas law demonstrate that the civil penalties do not provide complete and adequate final relief. Thus, the multiplicity of suits necessary to address each instance of Carpenter's greater scheme to flout Texas law means that the State does not have an adequate remedy at law and is thus entitled to injunctive relief.

35. The State of Texas is not required to post a bond prior to issuance of injunctive relief. Tex. Civ. Prac. & Rem. Code § 6.001(a),(b)(1).

36. In addition to the temporary relief requested, the State of Texas also requests that this Court set the matter for trial and, upon final hearing, that this Court enter a permanent injunction against Carpenter on the grounds asserted herein.

B. Request for Civil Penalties

37. Carpenter is not licensed to practice medicine in Texas. By seeing patients via telehealth appointments, she is practicing medicine in Texas in violation of state law. 22 Tex. Admin. Code § 174.8.

38. Under Texas Health & Safety Code § 170A.002 it is illegal to prescribe abortion-inducing drugs without meeting specific conditions outlined in the code. "A person who violates Section 170A.002 is subject to a civil penalty of not less than $100,000 for each violation."

C. Request for Attorney's Fees and Other Costs

39. Pursuant to Texas Health and Safety Code § 170A.005, the State of Texas, by and through the Attorney General, may recover attorney's fees and costs incurred in bringing this action.

40. Additionally, in cases where the state is entitled to recover a penalty or damages, the attorney general is entitled, in addition to any other remedy available by law and on behalf of the state, to reasonable attorney's fees, court costs and filing fees. Tex. Gov't Code § 402.006(c),(e)

41. The State of Texas requests that, upon final trial, the Court order Carpenter to reimburse the State of Texas, by and through the Attorney General for all costs of investigation and litigation including attorney's fees, reasonable investigative expenses, court costs, witness fees, deposition expenses, and civil administrative costs.

PRAYER

The State of Texas respectfully requests the following relief:

a. A temporary and permanent injunction enjoining Margaret Daley Carpenter, M.D. a/k/a Maggie Carpenter, M.D. a/k/a M. Carpenter, from

further violating Texas Health & Safety Code § 170A.002 and Texas Occupations Code § 165.159.

b. Civil penalties payable by Margaret Daley Carpenter, M.D. in the amount of not less than $100,000 for any and every violation under Section 170A.005 of the Texas Health and Safety Code.

c. Award the State of Texas all litigation and investigative costs, including, court costs, witness fees, deposition expenses, civil administrative costs, and reasonable attorney's fees in prosecuting this case through trial and, if necessary, through appeal, and that upon final trial, enter judgment against Carpenter.

d. All other relief as the Court deems equitable and just.

Date: November 19, 2024

Respectfully submitted,

KEN PAXTON
Attorney General of Texas

BRENT WEBSTER
First Assistant Attorney General

RALPH MOLINA
Deputy First Assistant Attorney General

JAMES LLOYD
Deputy Attorney General for Civil Litigation

ERNEST C. GARCIA
Chief, Administrative Law Division

/s/ *Ernest C. Garcia*
ERNEST C. GARCIA
State Bar No. 07632400
CANON PARKER HILL
State Bar No. 24140247
Assistant Attorney General
Office of the Attorney General of Texas
Administrative Law Division
P.O. Box 12548, Capitol Station
Austin, Texas 78711-2548
Telephone: (512) 936-0804
Facsimile: (512) 320-0167
ernest.garcia@oag.texas.gov
canon.hill@oag.texas.gov

Attorneys for Plaintiff

Declaration

My name is Alexandre Louis Dubeau, and I am an employee / investigator of the following governmental agency: Office of the Texas Attorney General, Administrative Law Division, located at 300 W. 15th Street, Austin, Texas 78701. I am executing this declaration as part of my assigned duties and responsibilities. I declare under penalty of perjury that the foregoing factual statements in the *Petition and Application for Temporary and Permanent Injunctive Relief*, are true and correct.

Executed in Travis County, Texas, on the 15th day of October, 2024.

Alexandre Louis Dubeau

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Case Contacts

Name	BarNumber	Email	TimestampSubmitted	Status
Ernest Garcia		ernest.garcia@oag.texas.gov	12/12/2024 9:18:20 AM	SENT
Catherine Hughes		catherine.hughes@oag.texas.gov	12/12/2024 9:18:20 AM	SENT
Canon ParkerHill		canon.hill@oag.texas.gov	12/12/2024 9:18:20 AM	SENT
Paul Pruneda		paul.pruneda@oag.texas.gov	12/12/2024 9:18:20 AM	SENT

EXHIBIT 51

Final Judgment and Order Granting Permanent Injunction, *Texas v. Carpenter*, No. 471-08943-2024 (Tex. Collin Cnty. Feb. 13, 2025)

CAUSE NO. 471-08943-2024

STATE OF TEXAS, *Plaintiff*	§	**IN THE DISTRICT COURT OF**
v.	§	**COLLIN COUNTY, TEXAS**
MARGARET DALEY CARPENTER, M.D. a/k/a MAGGIE CARPENTER, M.D., *Defendant.*	§	**471st JUDICIAL DISTRICT**

FINAL JUDGMENT AND ORDER GRANTING PERMANENT INJUNCTION

On the 12th day of February 2025, the court considered the State of Texas' ("State"), verified Second Amended Petition and Application for Permanent Injunctive Relief, Motion for Default Judgment, factual allegations, evidence, and arguments of counsel. The court finds that although the defendant was properly served; the defendant has not filed any answer or responsive pleading; has therefore defaulted and the factual allegations in the Plaintiff's Second Amended Petition are deemed admitted. The court also finds that the State continued to notify defendant by correspondence of the settings in this case and defendant still failed to appear. The court finds that the record reflects that Margaret Daley Carpenter, M.D.: (a) is not a resident of the State of Texas, but is a resident of the State of New York that has done business in Texas; (b) has not and does not maintain a regular place of business in the State of Texas; (c) has not maintained or designated an agent for service of process in the State of Texas; and (d) has been properly served with process, citation and petition, by certified mail, return receipt requested. The court finds that it has subject matter and in personam jurisdiction. The court also finds that the defendant has violated the Texas Medical Practice Act, Tex. Occ. Code, Title 3 Health Professions, Subtitle B Physicians and 22 Tex. Admin. Code § 174.8 by practicing medicine without a license and registration in the State of Texas and that the defendant has also violated Tex. Health & Safety Code § 170A.002 and that an unborn child died as a result of these violations and concludes that the State of Texas should have a judgment and a permanent injunction.

It is therefore, ordered that the State's request for civil penalties, fees, costs, attorney fees and a permanent injunction are hereby and in all things granted.

It is further ordered that plaintiff have and recover a $100,000 civil penalty in accordance with Tex. Health & Safety Code § 170A.005, an award of $12,400 in reasonable attorney fees, and $819.59 in filing fees and costs from and against defendant Margaret Daley Carpenter, M.D. a/k/a Maggie Carpenter, M.D.

It is further ordered that the total amount of the judgment here rendered will bear post judgment interest at the rate of 7.50 percent from today's date until paid, in accordance with Tex. Fin. Code Ann. § 304.003(b),(c).

It is further ordered, that, Margaret Daley Carpenter, M.D. a/k/a Maggie Carpenter, M.D., Defendant, is hereby permanently enjoined from prescribing abortion-inducing drugs to Texas residents and shall not practice medicine in the State of Texas without a license and registration in the State of Texas.

It is further ordered that, Margaret Daley Carpenter, M.D. a/k/a Maggie Carpenter, M.D. is hereby expressly also permanently enjoined from any further violation of Texas Health & Safety Code §§ 170A.002 171.003, 171.0031, 171.063, Texas Occ. Code, Title 3 Health Professions, Subtitle B Physicians, §§ 155.001, 156.001 and 22 Tex. Admin. Code § 174.8.

It is further ordered that the Clerk of the Court shall file this Order and enter it of record and issue a permanent injunction in conformity with the law and terms of this order.

SIGNED on this 13th day of February, 2025.

BRYAN GANTT
JUDGE PRESIDING

EXHIBIT 52

Bill of Indictment, *Louisiana v. Carpenter et al.*, No. 250187 (La. 18th Jud. Dist. Jan. 31, 2025)

Clerk of Court Demographic Information Report for

Judicial District:	18th
DA Name:	Tony Clayton
Judge:	
Parish:	West Baton Rouge
Defendant Name:	Dr. Margaret D Carpenter, and Nightingale Medical, PC
DOB:	12/17/1969
Race:	
Sex:	
Date of Arrest:	
Arr. Agency:	Attorney Generals Office
SID:	
US Citizen:	
Drivers License #:	
Drivers License State:	
City:	New Paltz
State:	NY
Deputy Clerk:	Sharon Saul
Minute Clerk:	Kelli Arnold
Charge:	14:87.9.B(1)
Plea:	
Date Filed:	JAN 31 2025
Date Arraigned:	

THE EIGHTEENTH JUDICIAL DISTRICT COURT
FOR THE PARISH OF WEST BATON ROUGE

STATE OF LOUISIANA

STATE OF LOUISIANA

VERSUS

DR. MARGARET D. CARPENTER AND
NIGHTINGALE MEDICAL, PC
1156 Old Ford Rd
New Paltz, NY 12561
DOB: 12/13/1969

FILED: January 31, 2025
Sharon Paul
Deputy Clerk of Court

NO. 250187

A TRUE BILL
Foreman
Date: 1-31-2025

BILL OF INDICTMENT

The GRAND JURY OF THE STATE OF LOUISIANA, *duly impaneled sworn and charge in and for the body of the Parish of West Baton Rouge, in the name and by authority of said State, upon their oath, PRESENT: that one DR. MARGARET D. CARPENTER AND NIGHTINGALE MEDICAL, PC, late of the State of New York, County of Ulster, with force and arms, in the Parish of West Baton Rouge, State of Louisiana, aforesaid, and within the jurisdiction of the Eighteenth Judicial District Court in and for the Parish of West Baton Rouge charges that* :

LA R.S. 14:87.9 (A) AND (B)(1) CRIMINAL ABORTION BY MEANS OF ABORTION-INDUCING DRUGS, Dr. Margaret D Carpenter, and Nightingale Medical, PC, on or about April 5, 2024, did knowingly cause an abortion to occur by means of delivering, dispensing, distributing, or providing a pregnant women with an abortion-inducing drug.

Contrary to the law of the State of Louisiana and against the peace and dignity of the same.

TONY CLAYTON
DISTRICT ATTORNEY

BY: Tony Clayton #21191
Assistant District Attorney
Eighteenth Judicial District
State of Louisiana

EXHIBIT 53

Letter from Governor Jeff Landry to the Governor Kathy Hochul (Feb. 11, 2025)

State of Louisiana

EXECUTIVE DEPARTMENT

JEFF LANDRY, GOVERNOR OF THE STATE OF LOUISIANA,
TO: HIS EXCELLENCY THE GOVERNOR OF THE STATE OF NEW YORK

WHEREAS, it appears by the annexed application for requisition and copies of **APPLICATION FOR REQUISITION, PROSECUTOR'S AFFIDAVIT WITH PROBABLE CAUSE ORDER, CROSS CERTIFICATION, INDICTMENT, ARREST WARRANT AND AFFIDAVIT, IDENTIFICATION MATERIALS, AND RELEVANT STATUTE,** which I certify are authentic and duly authenticated in accordance with the laws of the State of Louisiana, that under the laws of this State, **MARGARET D. CARPENTER** stands **CHARGED** with the crime(s) of **CRIMINAL ABORTION BY MEANS OF ABORTION-INDUCING DRUGS,** and it has been represented, and is satisfactorily shown to me, that the accused was present in this State at the time of the commission of said crime, and fled from the justice of this State, and has taken refuge, and can presently be found at [redacted] and

NOW, THEREFORE, pursuant to the provisions of the Constitution and the laws of the United States and the laws of the State of Louisiana and the laws of the State of New York, I do hereby respectfully demand that the above-named fugitive from justice be arrested and secured and delivered to, **WEST BATON ROUGE SHERIFF JEFF BERGERON, AND ONE/OR THEIR DULY AUTHORIZED FEMALE AGENT(S) OF THE PARISH OF WEST BATON ROUGE, STATE OF LOUISIANA,** as the proper person(s) appointed as agent(s) of the State of Louisiana, who is hereby authorized to receive, convey, and transport said fugitive to this State, here to be dealt with according to law.

IN WITNESS WHEREOF, I have set my hand officially and caused to be affixed the Great Seal of Louisiana in the City of Baton Rouge on this 11th day of February 2025.

Jeff Landry, Governor

By the Governor:

Nancy Landry, Secretary of State

State of Louisiana

EXECUTIVE DEPARTMENT

AGENT'S COMMISSION

TO ALL TO WHOM THESE PRESENTS SHALL COME:

I, **JEFF LANDRY, GOVERNOR**, hereby appoint **WEST BATON ROUGE SHERIFF JEFF BERGERON, AND ONE/OR THEIR DULY AUTHORIZED FEMALE AGENT(S) OF THE PARISH OF WEST BATON ROUGE, STATE OF LOUISIANA**, as the agent(s) of the State of Louisiana to receive **MARGARET D. CARPENTER,** fugitive from justice, from the appropriate authorities of the State of **NEW YORK** and convey said fugitive to **WEST BATON ROUGE SHERIFF JEFF BERGERON, AND ONE/OR THEIR DULY AUTHORIZED FEMALE AGENT(S) OF THE PARISH OF WEST BATON ROUGE, STATE OF LOUISIANA**, there to be dealt with according to law. The fugitive stands **CHARGED** with the crime(s) of **CRIMINAL ABORTION BY MEANS OF ABORTION-INDUCING DRUGS.**

IN WITNESS WHEREOF, I have hereunto signed my name and caused to be affixed the Great Seal of State, at Baton Rouge, Louisiana, this 11th of February 2025.

Jeff Landry, Governor

By the Governor:

Nancy Landry, Secretary of State

EXHIBIT 54

Order, *Comprehensive Health of Planned Parenthood Great Plains et al. v. Missouri*, No. 2416-CV31931 (Mo. Cir. Ct. Jackson Cnty. July 3, 2025)

FILED
DIVISION 3
03-Jul-2025 16:23
CIRCUIT COURT OF JACKSON COUNTY, MO
BY

IN THE CIRCUIT COURT OF JACKSON COUNTY, MISSOURI
AT KANSAS CITY

COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, et al.,	)	
Plaintiffs,	)	
v.	)	**Case No. 2416-CV31931**
	)	**Division 3**
STATE OF MISSOURI, et al.,	)	
Defendants.	)	

ORDER

NOW on this day, the Court takes up the injunctive relief requested in Plaintiffs' Motion for Preliminary Injunction, or, in the Alternative, Temporary Restraining Order, filed on November 6, 2024 and Plaintiffs' Motion for Reconsideration, filed on December 30, 2024. The Court held hearings on these motions and previously entered two Orders granting preliminary injunctive relief. On May 27, 2025, the Missouri Supreme Court issued a peremptory writ directing this Court to vacate its Orders granting preliminary injunctive relief with respect to the enjoinment of the state statutes and regulations identified therein and to reevaluate Plaintiffs' requests for preliminary injunctive relief. The Court, after reviewing the Court's file, in particular, Plaintiffs' Motions for Injunctive Relief and accompanying Suggestions in Support as well as Defendants' Opposition thereto, affidavits,[1] stipulated facts, and oral argument of counsel, and being apprised on the relevant law and having the full record before it, now finds as follows:

[1] Plaintiffs and State Defendants agreed to the submission of affidavits for the purposes of the pre-trial hearings only.

AMENDMENT 3

On November 5, 2024, Missouri voters approved Amendment 3 by majority vote. Election results were certified on December 5, 2024. Amendment 3 is now Article I, Section 36 of the Missouri Constitution. It states as follows:

> Section 36.1. This Section shall be known as "The Right to Reproductive Freedom Initiative."
>
> 2. The Government shall not deny or infringe upon a person's fundamental right to reproductive freedom, which is the right to make and carry out decisions about all matters relating to reproductive health care, including but not limited to prenatal care, childbirth, postpartum care, birth control, abortion care, miscarriage care, and respectful birthing conditions.
>
> 3. The right to reproductive freedom shall not be **denied, interfered with, delayed, or otherwise restricted** unless the Government demonstrates that such action is justified by a **compelling governmental interest** achieved by the **least restrictive means**. **Any denial, interference, delay, or restriction of the right to reproductive freedom shall be presumed invalid.** For purposes of this Section, a **governmental interest is compelling only if it is for the limited purpose and has the limited effect of improving or maintaining the health of a person seeking care, is consistent with widely accepted clinical standards of practice and evidence-based medicine, and does not infringe on that person's autonomous decision-making**.
>
> 4. Notwithstanding subsection 3 of this Section, the general assembly may enact laws that regulate the provision of abortion after Fetal Viability provided that under no circumstance shall the Government deny, interfere with, delay, or otherwise restrict an abortion that in the good faith judgment of a treating health care professional is needed to protect the life or physical or mental health of the pregnant person.
>
> 5. No person shall be penalized, prosecuted, or otherwise subjected to adverse action based on their actual, potential, perceived, or alleged pregnancy outcomes, including but not limited to miscarriage, stillbirth, or abortion. Nor shall any person assisting a person in exercising their right to reproductive freedom with that person's consent be penalized, prosecuted, or otherwise subjected to adverse action for doing so.

> 6. The Government shall not discriminate against persons providing or obtaining reproductive health care or assisting another person in doing so.
>
> 7. If any provision of this Section or the application thereof to anyone or to any circumstance is held invalid, the remainder of those provisions and the application of such provisions to others or other circumstances shall not be affected thereby.
>
> 8. For purposes of this Section, the following terms mean:
>
> (1) "Fetal Viability", the point in pregnancy when, in the good faith judgment of a treating health care professional and based on the particular facts of the case, there is a significant likelihood of the fetus's sustained survival outside the uterus without the application of extraordinary medical measures.
>
> (2)"Government",
>
> a. the state of Missouri; or
>
> b. any municipality, city, town, village, township, district, authority, public subdivision or public corporation having the power to tax or regulate, or any portion of two or more such entities within the state of Missouri.

(emphasis added).

STANDARD FOR PRELIMINARY INJUNCTION

Missouri Supreme Court Rule 92.02 and Chapter 526 of the Missouri Revised Statutes govern injunctive relief where "immediate and irreparable injury, loss, or damage will result in the absence of relief." Mo. Sup. Ct. R. 92.02(1). In *Dataphase*, the United States Court of Appeals for the Eighth Circuit set out to "clarify the standard to be applied . . . in considering requests for preliminary injunctive relief" and held that "whether a preliminary injunction should issue involves consideration of (1) the threat of irreparable harm to the movant; (2) the state of the balance between this harm and the injury that granting the injunction will inflict on other parties litigant; (3) the probability that movant will succeed on the merits; and (4) the public interest." *Dataphase Sys. v. C L Sys.,* 640 F.2d 109, 112-14 (8th Cir. 1981).

The Eighth Circuit provided additional clarity regarding the third prong of this test in *Rounds,* holding "a party seeking a preliminary injunction of the implementation of a state statute must demonstrate more than just a 'fair chance' that it will succeed on the merits," characterizing "this more rigorous standard . . . as requiring a showing that the movant 'is likely to prevail on the merits.'" *Planned Parenthood Minn., N.D., S.D. v. Rounds*, 530 F.3d 724, 731-32 (8th Cir. 2008). The Court further states, "[i]f the party with the burden of proof makes a threshold showing that it is likely to prevail on the merits, the [court] should then proceed to weigh the other *Dataphase* factors." *Id*. at 732.

Thus, this Court will address Plaintiffs' claims for injunctive relief by evaluating (1) the threat of irreparable harm to the moving party; (2) balancing this harm with any injury an injunction would inflict on other interested parties; (3) the moving party is likely to prevail on the merits; and (4) the effect on the public interest.

I. The Threat of Irreparable Harm

"The United States Supreme Court has held being subject to an unconstitutional statute, 'for even minimal periods of time, unquestionably constitutes irreparable injury.'" *Rebman v. Parson*, 576 S.W.3d 605, 612 (Mo. banc 2019) (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976)). An injunction may issue "to prevent the doing of any legal wrong whatever, whenever in the opinion of the court an adequate remedy cannot be afforded by an action for damages." § 526.030 RSMo.[2] Injunctive relief is unavailable unless irreparable harm is otherwise likely to result, *see City of Grandview v. Moore*, 481 S.W.2d 555, 558 (Mo. App. 1972), and plaintiff has no adequate remedy at law. *See State ex rel. Taylor v. Anderson*, 242 S.W.2d 66, 72 (Mo. 1951). Irreparable harm can also be established if monetary remedies cannot provide adequate compensation for

[2] Unless otherwise indicated, statutory citations refer to the 2016 edition of the Revised Statutes of Missouri, updated through the 2023 Cumulative Supplement.

improper conduct. *Peabody Holding Co., Inc. v. Costain Grp. PLC*, 813 F. Supp. 1402, 1421 (E.D. Mo. 1993). Movant need not show that damages have accrued, only that there is a threat of irreparable harm absent injunctive relief. *Id*.

The threat of irreparable harm is especially apparent in the context of abortion care, because it is a decision and procedure that "simply cannot be postponed, or it will be made by default with far-reaching consequences." *Bellotti v. Baird,* 443 U.S. 622, 643 (1979). Where the statutes at issue unquestionably conflict with the newly established rights afforded by Amendment 3, because they "den[y], interfer[e] with, dela[y], or otherwise restric[t]" the right to reproductive freedom, or because they discriminate against persons providing or obtaining reproductive health care or assisting another person in doing so, irreparable injury has been established. Mo. Cont. Art. I, §36.3; §36.6

II. Balance of Harm Versus Injury to Other Interested Parties

In order to obtain injunctive relief, movants need only show that the balance of equities tips in their favor. *Peabody Holding Co., Inc. v. Costain Grp. PLC*, 813 F. Supp. 1402, 1422 (E.D. Mo. 1993) (citing *Dataphase Systems Inc.,* 640 F.2d 109, 113-14 (8th Cir. 1981)). The balance-of-harms and public-interest factors "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). State Defendants argue that preliminarily enjoining the laws at issue would also impose irreparable harm on the State, whose legislature has democratically enacted these laws. "[A]ny time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers) (quoting *New Motor Vehicle Bd. of Cal. v. Orrin W. Fox Co.*, 434 U.S. 1345, 1351 (1977) (Rehnquist, J., in chambers)). It is this alleged harm the Court needs to balance against the alleged irreparable harm incurred by Plaintiffs. As Plaintiffs

argue, they and their patients are suffering serious harm, whereas Defendants only stand to lose the ability temporarily to enforce some laws that are likely to be held unconstitutional and which further no valid compelling state interest. *See Kirkeby v. Furness*, 52 F.3d 772, 775 (8th Cir. 1995) (public interest favored injunction against unconstitutional ordinance).

III. Likely to Prevail on the Merits

As discussed above, "a party seeking a preliminary injunction of the implementation of a state statute must demonstrate more than just a 'fair chance' that it will succeed on the merits." *Rounds*, 530 F.3d 724, 731-32 (8th Cir. 2008). The Court characterized "this more rigorous standard . . . as requiring a showing that the movant 'is likely to prevail on the merits.'" *Id.*

"A statute's validity is presumed, and a statute will not be declared unconstitutional unless it clearly contravenes some constitutional provision." *Planned Parenthood of Kan. & Mid-Mo., Inc. v. Nixon*, 220 S.W.3d 732, 737 (Mo. banc 2007) (citing *Doe v. Phillips*, 194 S.W.3d 833, 841 (Mo. banc 2006)). However, if a statute conflicts with a constitutional provision, the statute must be declared invalid. *Jackson County v. State*, 207 S.W.3d 608 (Mo. banc 2006). A statute cannot supersede, nor can judicial interpretation thereof, abrogate a constitutional right. *Doe v. Phillips*, 194 S.W.3d 833, 841 (Mo. banc 2006); *United C.O.D. v. State*, 150 S.W.3d 311, 313 (Mo. banc 2004) ("Courts will enforce a statute unless it plainly and palpably affronts fundamental law embodied in the constitution.") "Words used in constitutional provisions are interpreted to give effect to their plain, ordinary, and natural meaning." *Faatz v. Ashcroft*, 685 S.W.3d 388, 400 (Mo. banc 2024) (internal citation omitted).

In light of this guidance, the Court will assess whether Plaintiffs are likely to prevail on the merits by reviewing the language of the challenged statutes through the heightened scrutiny framework provided in the language of Amendment 3, namely, whether the government's

purported compelling interest (one that is "for the limited purpose and has the limited effect of improving or maintaining the health of a person seeking care, is consistent with widely accepted clinical standards of practice and evidence-based medicine, and does not infringe on that person's autonomous decision-making") is achieved by the least restrictive means.

IV. The Public Interest

Amendment 3 was passed by a majority vote on November 5, 2024, the results of which were certified on December 5, 2024. *See* Plaintiffs' Supplement Notice of Authority filed on December 5, 2024. By the language of Amendment 3, the public interest is clear that voters, i.e. the public, intended to create a new fundamental right of reproductive freedom for all Missourians, "which is the right to make and carry out decisions about all matters relating to reproductive health care, including but not limited to prenatal care, childbirth, postpartum care, birth control, abortion care, miscarriage care, and respectful birthing conditions." Mo. Const. Art. I, 36.2. It is this public interest that the Court must consider when weighing the factors for preliminary injunction, as provided above.

LEGAL ANALYSIS

For the sake of clarity, the Court will address each category of statutes at issue as they are discussed in the Motion for Preliminary Injunction, as provided below:

1. Missouri's Abortion Bans: The Total Ban, § 188.017 RSMo; Gestational Age Bans, §§ 188.056, 188.057, 188.058, 188.375, RSMo; and Reasons Ban §§ 188.038, 188.052 RSMo.,19 C.S.R. § 10-15.010(1).[3]

a. Total Ban. Section 188.017 provides, in pertinent part, that

> …no abortion shall be performed or induced upon a woman, except in cases of medical emergency…[and a]ny person who knowingly performs or induces an abortion of an unborn child in violation of this subsection shall be guilty of a class B felony, as well

[3] The State Defendants concede the Total Ban and Gestational Age Bans are no longer enforceable and argue that a preliminary injunction on this issue is not needed because there is no controversy. However, Johnson remains as a Defendant and has not conceded the same.

> as subject to suspension or revocation of his or her professional license by his or her professional licensing board…. § 188.017.2 RSMo.

The Court finds the plain language of this statute is directly at odds with Amendment 3, specifically, Art. I, § 36.2 of the Missouri Constitution. Pursuant to Art. I § 36.3, the statute is therefore presumptively invalid and, because the State Defendants have not demonstrated that the statute is justified by a compelling governmental interest achieved by the least restrictive means, this Court finds Plaintiffs are likely to prevail on the merits. Further, because "being subject to an unconstitutional statute, 'for even minimal periods of time, unquestionably constitutes irreparable injury,'" the threat of irreparable harm exists here. The parties do not articulate, and this Court does not find, that issuance of this injunction would inflict harm and injury on other interested parties. The Court also finds that the public interest, as illustrated by the majority who voted to pass Amendment 3, is on the side of granting this injunction. Therefore, the Court finds that Section 188.017 must be enjoined.

b. Gestational Age Bans. Section 188.056 provides, in pertinent part,

> …no abortion shall be performed or induced upon a woman at **eight weeks gestational age** or later, except in cases of medical emergency… [and a]ny person who knowingly performs or induces an abortion of an unborn child in violation of this subsection shall be guilty of a class B felony, as well as subject to suspension or revocation of his or her professional license by his or her professional licensing board…. § 188.056.1. RSMo. (emphasis added).

Likewise, Section 188.057 provides, in part,

> …no abortion shall be performed or induced upon a woman at **fourteen weeks gestational age** or later, except in cases of medical emergency… [and a]ny person who knowingly performs or induces an abortion of an unborn child in violation of this subsection shall be guilty of a class B felony, as well as subject to suspension or revocation of his or her professional license by his or her professional licensing board…. § 188.057.1. RSMo. (emphasis added).

Section 188.058 provides, in part,

> …no abortion shall be performed or induced upon a woman at **eighteen weeks gestational age** or later, except in cases of medical emergency… [and a]ny person who knowingly performs or induces an abortion of an unborn child in violation of this subsection shall be guilty of a class B felony, as well as subject to suspension or revocation of his or her professional license by his or her professional licensing board…. § 188.058.1 RSMo. (emphasis added).

Finally, Section 188.375 provides, in part,

> …no abortion shall be performed or induced upon a woman carrying a late-term pain-capable unborn child [defined in § 188.375.2 as "unborn child at **twenty weeks gestational age** or later"], except in cases of medical emergency… [and a]ny person who knowingly performs or induces an abortion of a late-term pain-capable unborn child in violation of this subsection shall be guilty of a class B felony, as well as subject to suspension or revocation of his or her professional license by his or her professional licensing board. § 188.375.3 RSMo. (emphasis added).

As with the Total Ban, these statutes are clearly contrary to the language of Amendment 3 in that they infringe on a person's "autonomous decision making" and violate the provision prohibiting the penalization and prosecution of a person based on pregnancy outcomes. Mo. Const. Art. I, §§ 36.3, 36.5. Consistent with this Court's analysis above, the laws are presumptively invalid under Article I, Section 36.3. Because Defendants have not demonstrated a compelling governmental interest achieved by the least restrictive means justifying these statutory provisions, the Court finds that Plaintiffs are likely to prevail on the merits. As set out above, the threat of irreparable harm is apparent here as well. Parties do not articulate, and this Court does not find, that issuance of this injunction would inflict harm and injury on other interested parties. The Court also finds that the public interest, as illustrated by the majority who voted to pass Amendment 3, is on the side of granting this injunction. Therefore, the Court finds that Sections 188.056, 188.057, 188.058, and 188.375 shall be enjoined.

c. Reasons Ban. Section 188.038.2 states,

> [n]o person shall perform or induce an abortion on a woman if the person knows that the woman is seeking the abortion solely because of a prenatal diagnosis, test, or

screening indicating Down Syndrome or the potential of Down Syndrome in an unborn child. 188.038.2 RSMo.

Section 188.038.3 states, "[n]o person shall perform or induce an abortion on a woman if the person knows that the woman is seeking the abortion solely because of the sex or race of the unborn child." 188.038.3 RSMo. Any physician or other person "who performs or induces or attempts to perform or induce an abortion prohibited by [Section 188.038] shall be subject to all applicable civil penalties under this chapter including, but not limited to, sections 188.065 [license revocation] and 188.085 [civil liability for medical malpractice]." § 188.038.4 RSMo. Section 188.052 contains a related provision which requires the physician who performed or induced the abortion to complete an individual abortion report that certifies that physician does not have knowledge that the person seeking an abortion is doing so solely because one of the reasons stated in § 188.038. § 188.052.1 RSMo.; 19 CSR 10-15.010(1).

Consistent with this Court's analysis above, the laws are presumptively invalid under Article I, Section 36.3. Because Defendants have demonstrated no compelling governmental interest achieved by the least restrictive means justifying these statutory provisions, the Court finds that Plaintiffs are likely to prevail on the merits. As above, the threat of irreparable harm is apparent here as well. Parties do not articulate and this Court does not find that issuance of this injunction would inflict harm and injury on other interested parties. The Court also finds that the public interest, as illustrated by the majority who voted to pass Amendment 3, is on the side of granting this injunction. Therefore, the Court finds that § 188.038 and reporting requirements provided in § 188.052 and 19 CSR § 10-15.010(1) shall be enjoined.

2. Missouri's Abortion Facility Licensing Requirements: §§ 197.200-.235, 334.100.2(27) RSMo. and all of its implementing regulations; 19 C.S.R. §§ 30-30.050 –.070, 20 C.S.R. § 2150-7.140(2)(V).

Sections 197.200 to 197.235 and 334.100.2(27), 19 CSR 30-30.050-.070, and 20 CSR § 2150-7.140(2)(V) contain a number of requirements specifically directed at abortion facilities and ambulatory surgical centers, as those terms are defined by § 197.200. The Missouri Constitution Article I, Section 36.6 states, "[t]he Government shall not discriminate against persons providing or obtaining reproductive health care or assisting another person in doing so." Mo. Cont. Art. I, § 36.6. This set of statutes and regulations apply only to abortion facilities and not to any other similarly situated health care facility. The regulations require physicians to perform certain exams and tests that are unnecessary when the physicians themselves are authorized and enabled to make the determination on what is and is not necessary for their individual patients. Additionally, miscarriage management can be provided on an outpatient basis without a special facility license. The stipulated affidavits show that miscarriage management and abortion medication/procedures often mirror each other. Based on the foregoing, the Court finds the facility licensing requirement is facially discriminatory because it does not treat services provided in abortion facilities the same as other types of similarly situated health care, including miscarriage care.

The Court finds Plaintiffs are likely to prevail on the merits and have met the other requirements for entry of a preliminary injunction provided in *Dataphase*. *Rounds*, 530 F.3d 724; *Dataphase,* 640 F.2d 109. Therefore, §§ 197.200 to 197.235 and 334.100.2(27), 19 CSR 30-30.050-.070, and 20 CSR § 2150-7.140(2)(V) shall be enjoined.

3. Missouri's Hospital Relationship Restrictions: §§ 188.080, 188.027.1(1)(e), 197.215.1(2) RSMo.; 19 C.S.R. § 30-30.060(1)(C)(4).

This category of laws requires physicians providing abortions to have admitting privileges at hospitals that offer obstetric or gynecological care within thirty miles or fifteen-minutes travel

time to the health center where they provide any abortion. A written transfer agreement with a nearby hospital is one option for complying with some, but not all, of these requirements. Section 188.080[4] makes it a class A misdemeanor for any physician performing or inducing an abortion to not have clinical privileges as set forth in these laws. This admitting privileges requirement and geographical limitations clearly "…den[y], interfer[e] with, dela[y], or otherwise restric[t]" reproductive freedom and since there was no evidence demonstrating that these laws are "for the limited purpose and ha[ve] the limited effect of improving or maintaining the health of a person seeking care, consistent with widely accepted clinical standards of practice and evidence-based medicine, and [do] not infringe on that person's autonomous decision-making," no compelling governmental interest exists. Mo. Const. Art. I, § 36.3. Nor was it shown that these statutes are the "least restrictive means." *Id.*

The Court finds Plaintiffs are likely to prevail on the merits, as the threat of irreparable harm has already been established as provided above, and balancing potential harm to other interested parties with the public interest also weigh in Plaintiffs' favor as this Amendment was passed by a majority vote. For all of the foregoing, §§ 188.080 (limited as provided in footnote 7), 188.027.1(1)(e), 197.215.1(2), as well as 19 C.S.R. § 30-30.060(1)(C)(4) shall be enjoined.

4. Missouri's Medication Abortion Complication Plan Requirement: § 188.021.2 RSMo.; 19 C.S.R. § 30-30.061.

Pursuant to § 188.021.2, before providing medication abortion, providers must have a DHSS-approved complication plan. This plan requires medication abortion providers to have a written contract with a board-certified or board-eligible Ob-Gyn (or Ob-Gyn group) who has agreed to be "on-call and available twenty-four hours a day, seven days a week" to "[p]ersonally

[4] The analysis in this section only pertains to the language of § 188.080 requiring a physician's clinical privileges within 30 miles from the location of the abortion facility. The analysis of the statutory requirement permitting only physicians to perform abortions is discussed in the section labeled Missouri's Advanced Practice Clinician Ban.

treat all complications" from medication abortion "except in any case where doing so would not be in accordance with the standard of care, or in any case where it would be in the patient's best interest for a different physician to treat her." 19 C.S.R. § 30-30.061. Plaintiffs argue it is difficult to find physicians willing to agree to the required responsibilities and some facilities are not able to comply.

The Court finds the language of § 188.021.2 does not necessarily deny, interfere with, delay or otherwise restrict reproductive freedom; rather it is the language in the regulations that contain this specific requirement that do deny, interfere with, delay or otherwise restrict reproductive freedom without the necessary showing that such restriction has the limited purpose and effect of improving or maintaining the health of the person seeking care. For example, a person who travels three hours to get a medication abortion and then returns home, would not benefit from this requirement. If complications arise after taking the medication, the individual would need to seek emergency care at the nearest hospital emergency room, as with any other medical emergency. Plaintiffs have demonstrated they are likely to prevail as to the regulations only, and considering all of the other factors for granting a preliminary injunction, 19 C.S.R. § 30-30.061, as it pertains to the complication plan, is enjoined.

5. Missouri's Pathology Requirements: § 188.047 RSMo.; 19 C.S.R. §§ 10-15.030, 19 C.S.R. 30-30.060(5)(B).

Missouri law requires that "[a]ll tissue . . . removed at the time of abortion shall be submitted within five days to a board-eligible or certified pathologist for gross and histopathological examination." § 188.047 RSMo. The pathologist is then required to file a "tissue report" with DHSS and provide a copy of the report to the health center that provided the abortion. *Id.*; *see also* 19 C.S.R. § 10-15.030, 19 C.S.R. § 30-30.060(5)(B). Plaintiffs stipulated, for purposes of the preliminary injunctive relief requested, that they have not attempted to contact any

pathologists in Missouri about the Pathology Requirements since at least 2022, and state that they are currently "unaware of any pathologists in Missouri who are willing to contract with them to provide such an examination and report." Plaintiffs' Suggestions in Support of Their Motion for Preliminary Injunction or, in the Alternative, Temporary Restraining Order at 37 (citing Wales Aff. ¶ 30; Muniz Aff. ¶ 31).

State Defendants argue that these laws further patient health because it helps detect incomplete abortions, however, pathology of pregnancy tissue after an abortion cannot determine whether the abortion is complete or incomplete. Plaintiffs' Reply Suggestions in Support of Their Motion for Preliminary Injunction or, In the Alternative, Temporary Restraining Order, and Suggestions in Opposition to State Defendants' Motion to Dismiss at 42 (citing Grossman Aff. ¶ 112). These pathology requirements "den[y], interfer[e] with, dela[y], or otherwise restric[t]" reproductive freedom and there was no evidence provided that these laws are "for the limited purpose and ha[ve] the limited effect of improving or maintaining the health of a person seeking care, [are] consistent with widely accepted clinical standards of practice and evidence-based medicine, and [do] not infringe on that person's autonomous decision-making" to support the government's purported compelling interest. Mo. Const. Art. I, § 36.3. Nor was it shown that this statute and regulations are the "least restrictive means." *Id.*

The Court finds Plaintiffs are likely to prevail on the merits, the threat of irreparable harm has already been established as provided in the above, and balancing potential harm to other interested parties and the public interest also weigh in Plaintiffs' favor as this Amendment was passed by a majority vote. Therefore, § 188.047 and 19 C.S.R §§ 10-15.030 and 30-30.060(5)(B) shall be enjoined.

6. Missouri's Abortion-Specific Informed Consent Laws: §§ 188.027, 188.033, 188.039, RSMo.[5]

Plaintiffs challenge §§ 188.027, 188.033, and 188.039, which the Court will refer to as Missouri's Abortion-Specific Informed Consent Laws. Pursuant to these statutes, before a patient obtains an abortion, they must receive certain state-mandated information and materials that Plaintiffs argue are biased and meant to stigmatize patients' decision to obtain an abortion. As an example, § 188.027.1(2) requires individuals be presented with "…printed materials provided by [DHHS], which describe the probable anatomical and physiological characteristics of the unborn child at two-week gestational increments from conception to full term, including color photographs or images of the developing unborn child at two-week gestational increments." 188.027.1(2) RSMo. That section further requires,

> [s]uch descriptions shall include information about brain and heart functions, the presence of external members and internal organs during the applicable stages of development and information on when the unborn child is viable. The printed material shall prominently display the following statement: "The life of each human being begins at conception. Abortion will terminate the life of a separate, unique, living human being." § 188.027.1(2) RSMo.

Section 188.027 is a long statute and encompasses many of the other legal requirements Plaintiffs seek to enjoin, such as the 72-hour waiting period that is discussed in the next section. Section 188.033 requires the same information be provided to individuals who are considering obtaining an abortion outside of the state. Plaintiffs have shown they are likely to prevail on the merits because there was no evidence that any compelling governmental interest was achieved by utilizing the "least restrictive means" as required by Mo. Const. Art. I, § 36.3. The threat of irreparable harm has already been established as provided above, and balancing potential harm to

[5] Plaintiffs collectively refer to these as the "Biased Information Law."

other interested parties with the public interest also weigh in Plaintiffs' favor as this Amendment was passed by a majority vote. Therefore, §§ 188.027 and 188.033 shall be enjoined.

Section 188.039 primarily addresses the 72-hour waiting period that the Court will address in the section below. However, the language in § 188.039.4 pertains to informed consent, specifically, that a person must sign and give their "informed consent freely and without coercion" after discussing "…the indicators and contraindicators, and risk factors, including any physical, physiological or situational factors." § 188.039.4. RSMo.

The Court finds for purposes of Plaintiffs' requests for injunctive relief, the general laws of informed consent for any medical treatment and procedures sufficiently cover any separate purposes that may be served by § 188.039.4 and that Plaintiffs are likely to prevail on the merits. There was no evidence demonstrating that any compelling governmental interest would be achieved by the "least restrictive means" as required by Mo. Const. Art. I, § 36.3. The threat of irreparable harm has already been established as provided above, and balancing potential harm to other interested parties with the public interest also weigh in Plaintiffs' favor as this Amendment was passed by a majority vote. Therefore, § 188.039.4, solely as it pertains to this special informed consent requirement, shall be enjoined.

7. Missouri's Waiting Period, In-Person, and Same Physician Requirements: §§ 188.027, 188.039, RSMo.

Sections 188.027 and 188.039 require abortion patients to make two in-person visits to see the same physician, at least 72 hours apart. If the 72-hour waiting period is enjoined, the law specifies that a 24-hour waiting period is to take its place. §§ 188.027.12, 188.039.7 RSMo. At the patient's first appointment, the physician is required to provide the patient with the information described in the preceding section. State Defendants do not contest that these requirements delay patients' access to abortion care by at least 72 hours (or, in the alternative, 24 hours). A mandatory

waiting period clearly "den[ies], interfere[s] with, delay[s], or otherwise restrict[s]" reproductive freedom and since there was no evidence presented that these laws are "for the limited purpose and ha[ve] the limited effect of improving or maintaining the health of a person seeking care, consistent with widely accepted clinical standards of practice and evidence-based medicine, and [do] not infringe on that person's autonomous decision-making," there is no compelling governmental interest. Mo. Const. Art. I, § 36.3. Nor was there any evidence to explain why a waiting period of 72 hours, or in the alternative 24 hours, is the "least restrictive means" in carrying out any purported government interest. *Id.*

The Court finds Plaintiffs are likely to prevail on the merits, the threat of irreparable harm has already been established, and balancing potential harm to other interested parties with the public interest also weigh in Plaintiffs' favor, as this Amendment was passed by a majority vote. Therefore, the provisions in Sections 188.027 and 188.039 pertaining to the waiting period shall be enjoined.

As for the In-Person requirement, State Defendants argue that an in-person appointment is necessary because only an in-person appointment can confirm gestational age for purposes of appropriate use of the abortion pill (which the FDA has approved for the first ten weeks of a pregnancy) and to rule out an ectopic pregnancy. The Court finds Plaintiffs have not demonstrated they are likely to prevail on the merits as to the In-Person requirement. The Court further finds there may be a compelling governmental interest and therefore, denies the request to enjoin this requirement.

Similarly, State Defendants argue the Same Physician requirement is necessary to establish continuity of care. Plaintiffs argue that this creates scheduling issues. The Court notes these alleged scheduling issues occur in conjunction with the 72-hour waiting period. Therefore, absent the 72-

hour waiting period, the Court finds Plaintiffs have not demonstrated they are likely to prevail on the merits as it pertains to this requirement, and denies the request to enjoin the Same Physician requirement.

8. Missouri's Telemedicine Ban: § 188.021 RSMo.

Plaintiffs challenge § 188.021,[6] which states, in part,

> [w]hen RU-486 (mifepristone) or any drug or chemical is used for the purpose of inducing an abortion, the initial dose of the drug or chemical shall be administered in the same room and in the physical presence of the physician who prescribed, dispensed, or otherwise provided the drug or chemical to the patient. § 188.021.1 RSMo.

Plaintiffs refer to this as the "Telemedicine Ban." This language prohibits telehealth appointments and requires a physician to be physically present in the room while a patient is taking the medication. This seemingly would not allow a physician to prescribe the medication after an in-person appointment and having the patient subsequently take the medication at home or even in a medical facility in the presence of a nurse or other medical professional.

The language of this portion of the statute "…den[ies], interfere[s] with, delay[s], or otherwise restrict[s]" reproductive freedom and there was no evidence that this law is "for the limited purpose and has the limited effect of improving or maintaining the health of a person seeking care, is consistent with widely accepted clinical standards of practice and evidence-based medicine, and does not infringe on that person's autonomous decision-making" to establish a compelling governmental interest. Mo. Const. Art. I, § 36.3. Nor was it shown that this statute is the "least restrictive means." *Id.*

The Court finds Plaintiffs are likely to prevail on the merits, the threat of irreparable harm has already been established as provided above, and balancing potential harm to other interested

[6] Plaintiffs cite to §188.021 in its entirety in this portion of the argument, but only 188.021.1 has language that could be interpreted as a ban on "telehealth" appointments.

parties with the public interest also weigh in Plaintiffs' favor as this Amendment was passed by a majority vote. Therefore, § 188.021.1 shall be enjoined.

9. Missouri's Advance Practice Clinician Ban: §§ 188.020, 188.080, 334.245, 334.735.3 RSMo.

Missouri law requires abortions to be performed by physicians only, rather than physician's assistants ("PAs") and Advanced Practice Registered Nurses ("APRNs"), collectively known as Advanced Practice Clinicians ("APCs"). *See* §§ 188.020, 188.080, 334.245, 334.735.3 RSMo. Plaintiffs argue that if APCs were allowed to perform abortions, it would increase their ability to provide care. Plaintiffs also argue that APCs are just as qualified as physicians to provide many forms of abortion care. There are many forms of abortion care, making this facial challenge by Plaintiffs a difficult one at this stage of litigation because there may be a compelling governmental interest to allow only physicians to perform some kinds of abortion care. Therefore, Plaintiffs have not made their threshold showing that they are likely to prevail on the merits on this point and the request for injunctive relief is denied.

10. Criminal Penalties for Abortion Providers: §§ 188.017.2, 188.030.3, 188.056.1, 188.057.01, 188.058.1, 188.075, 188.080, 188.375.3, 197.235, 334.245, 574.200.2 RSMo.

Article I, § 36.5 states:

> No person shall be **penalized, prosecuted, or otherwise subjected to adverse action** based on their actual, potential, perceived, or alleged pregnancy outcomes, including but not limited to miscarriage, stillbirth, or abortion. **Nor shall any person assisting a person in exercising their right to reproductive freedom** with that person's consent **be penalized, prosecuted, or otherwise subjected to adverse action** for doing so.

(emphasis added.)

Several of these statutes have already been discussed in the preceding sections. Specifically, the Court has already found §§ 188.017, 188.056, 188.057, 188.058, 188.375, shall be enjoined, and as such, it is appropriate that their respective criminal penalties be enjoined at this time pursuant to Mo. Const. Art. I, § 36.5.

Sections 197.235 and 334.245 were also previously discussed and were not enjoined, and their respective criminal penalties shall not be enjoined at this time.

Section 188.080 was previously discussed and enjoined only as it pertains to physicians' admitting privileges at a hospital within 30 miles of the abortion facility. The requirement to have only physicians perform abortions was not enjoined. As such, the criminal penalties will apply only to the portion of that statute that is not enjoined pursuant to Mo. Const. Art. I, § 36.5.

Plaintiffs include §§ 188.030.3 and 574.200.2 in this category of laws, but do not provide any argument regarding these specific provisions. Therefore, the Court finds the Plaintiffs have not met their burden for a preliminary injunction as to these two statutes.

BOND

Missouri Supreme Court Rule 92.02(d) requires Plaintiffs to execute a bond. Plaintiffs requests a bond of $100.00. No objection was made by Defendants. The Court finds bond set at $100.00 is appropriate.

CONCLUSION

For all of the foregoing, it is, therefore

ORDERED, ADJUDGED, AND DECREED that the requests for injunctive relief contained in Plaintiffs' Motion for Preliminary Injunction, or, in the Alternative, Temporary Restraining Order, filed on November 6, 2024 and Plaintiffs' Motion for Reconsideration, filed on December 30, 2024, are **GRANTED IN PART AND DENIED IN PART**.

IT IS FURTHER ORDERED, ADJUDGED, AND DECREED that Plaintiffs shall file a bond in the amount of $100.00.

IT IS FURTHER ORDERED, ADJUDGED, AND DECREED that any and all other relief not specifically granted herein is hereby DENIED.

IT IS SO ORDERED.

July 3, 2025
Date

HON. JERRI J. ZHANG
Judge, Division 3

CC: All counsel via e-Notification

Not an Official Court Document

EXHIBIT 55

Substitute Op., *Idahoans United for Women and Families v. Labrador et al.*, No. 52636-20255 (Idaho June 24, 2025)

IN THE SUPREME COURT OF THE STATE OF IDAHO

Docket No. 52636-2025

Re: Verified Petition for Writs of Certiorari and Mandamus.	
----------	**Boise, April 2025 Term**
IDAHOANS UNITED FOR WOMEN AND FAMILIES,	**Opinion filed: June 24, 2025**
Petitioner,	**Melanie Gagnepain, Clerk**
v.	**SUBSTITUTE OPINION, THE OPINION DATED JUNE 16, 2025, IS WITHDRAWN**
RAUL LABRADOR, in his official capacity as the Idaho Attorney General; PHIL MCGRANE, in his official capacity as the Idaho Secretary of State; LORI WOLFF, in her official capacity as the Administrator of the Idaho Division of Financial Management; and the IDAHO DIVISION OF FINANCIAL MANAGEMENT,	
Respondents.	

Original proceeding in the Idaho Supreme Court seeking writs of certiorari and mandamus.

Petitioner's Verified Petition against the Idaho Secretary of State is dismissed; its Verified Petition for a Writ of Mandamus against the Idaho Attorney General and the Idaho Division of Financial Management is partially granted; and its Verified Petition for a Writ of Certiorari against the Idaho Attorney General and the Idaho Division of Financial Management is denied.

Holland & Hart LLP, Boise, for Petitioner. Anne Henderson Haws argued.

Raúl R. Labrador, Idaho Attorney General, Boise, for Respondents. Alan M. Hurst argued.

ZAHN, Justice.

This original action concerns the fiscal impact statement and ballot titles for a citizen initiative entitled the "Reproductive Freedom and Privacy Act" ("Initiative"). Petitioner, Idahoans

United for Women and Families ("Idahoans United"), filed this original action seeking a writ of certiorari and writ of mandamus ordering the Idaho Division of Financial Management ("DFM") to revise its Fiscal Impact Statement ("FIS") and ordering the Idaho Attorney General to revise his long and short ballot titles. Idahoans United also seeks a writ against the Idaho Secretary of State but does not specify which writ is requested or what it seeks to compel.

After considering the arguments of counsel, we agree with some, but not all, of Idahoans United's arguments. For the reasons explained below, we dismiss the Petition against the Secretary of State because Idahoans United has failed to properly invoke our original jurisdiction. We partially grant the request for a writ of mandamus against DFM because the FIS fails to substantially comply with Idaho Code section 34-1812. We partially grant the request for a writ of mandamus against the Idaho Attorney General because the short ballot title fails to substantially comply with Idaho Code section 34-1809. However, we deny the request for a writ of mandamus as it pertains to the long ballot title because it substantially complies with Idaho Code section 34-1809.

I. BRIEF SUMMARY

Article III, section 1 of the Idaho Constitution reserves to the people the power to legislate directly through the initiative process, under such conditions and in such manner as provided by laws enacted by the Idaho Legislature. Idaho law requires citizens to first submit a copy of the initiative petition to the Idaho Secretary of State. Idaho law then triggers a series of events that must occur within specified timeframes. One is DFM's preparation of an FIS. Another is the Attorney General's preparation of short and long ballot titles. Idaho law identifies mandatory requirements for both the FIS and the ballot titles.

Idahoans United filed a Petition with this Court, seeking a writ of mandamus or writ of certiorari against DFM, the Attorney General, and the Secretary of State. Idahoans United argues that neither the FIS nor the ballot titles for the Initiative meet the requirements of Idaho law. It asks this Court to either certify the FIS and ballot titles it has prepared or order DFM and the Attorney General to prepare a new FIS and new ballot titles that substantially comply with Idaho law.

For reasons we discuss in more detail below, we partially grant the requested writ of mandamus against DFM. We conclude that the FIS fails to substantially comply with the requirements of Idaho Code section 34-1812 because DFM has failed to establish a factual basis

for its estimated fiscal impact. We also conclude that the FIS fails to substantially comply with the clear and concise requirement of the statute because it contains conflicting statements concerning whether there will be a fiscal impact on the budget of the Idaho Department of Correction, and its reference to the state Medicaid budget creates confusion concerning the total fiscal impact. Finally, we conclude that the FIS fails to substantially comply with the statutory requirement to avoid legal and technical terms whenever possible because it includes unnecessary references to state statutes and a vague mention of "Medicaid references." However, we deny the requested writ concerning the references to the Medicaid and prisoner populations. We conclude those references substantially comply with the statutory requirement to provide an explanation of the assumptions underlying any estimated fiscal impact.

As to the Attorney General, we partially grant and partially deny Idahoans United's Petition seeking a writ of mandamus. We conclude that the Attorney General's short ballot title fails to substantially comply with the distinctive and comprehensive requirement of Idaho Code section 34-1809 because it fails to alert a prospective signer of the Initiative to the Initiative's four distinctive characteristics. However, we deny the requested writ concerning the use of "fetus viability" in the short ballot title. We conclude that the short title substantially complies with the statutory requirement to use language by which the Initiative is commonly referred. The phrase to which Idahoans United objects, "fetus viability," has been used in Idaho before. While Idahoans United's preferred term, "fetal viability," has been used more frequently, the meaning of the two phrases does not substantially differ and they simply use different parts of speech for the same word. We therefore conclude that the short title substantially complies with section 34-1809. We deny the requested writ concerning the long ballot title and conclude that it substantially complies with the statutory requirements.

For the reasons explained below, we decline to certify Idahoans United's proffered ballot titles and FIS. This Court has previously declined to dictate the form of ballot titles because it is not our job to determine the best way to draft a ballot title. Rather, our job is to determine whether the ballot titles substantially comply with the requirements of Idaho law. The same holds true for the FIS. Therefore, we remand the short ballot title to the Attorney General and the FIS to DFM. We order them to provide us with a revised short ballot title and a revised FIS by 4 p.m. MDT on June 23, 2025. To avoid further litigation and to finalize the FIS as quickly as possible, we also

order DFM to submit a sworn declaration by the preparer of the FIS describing the process utilized, including the evidence gathered and the assumptions utilized to create the FIS.

II. FACTUAL AND PROCEDURAL BACKGROUND

Idahoans United is attempting to qualify a voter initiative entitled the "Reproductive Freedom and Privacy Act" to appear on the 2026 general election ballot. On November 20, 2024, Idahoans United submitted the Initiative to the Secretary of State. When an initiative petition is submitted to the Secretary of State, "Idaho law trigger[s] a series of events, which must occur within specific timeframes." *Idahoans for Open Primaries v. Labrador* (*In re Verified Pet. for Writs of Cert. & Mandamus*) ("*Open Primaries*"), 172 Idaho 466, 473, 533 P.3d 1262, 1269 (2023).

Upon receiving an initiative petition, the Secretary of State must immediately transmit a copy of the initiative to DFM for the issuance of an FIS under Idaho Code section 34-1812. I.C. § 34-1804(2). DFM has twenty days from its receipt of the initiative petition to write and file an FIS with the Secretary of State's office. I.C. § 34-1812(1). The Secretary of State then must immediately transmit the FIS to the party who filed the initiative. *Id.*

When soliciting signatures for an initiative, signature gatherers must offer a copy of the FIS summary to electors. I.C. § 34-1812(3). The FIS summary must also be published in the state voters' pamphlet and on the official ballot. *Id.* The FIS summary and the detailed FIS must be available to the public on the Secretary of State's website "no later than August 1." *Id.*

Upon receiving the initiative petition, the Secretary of State must also transmit a copy of the initiative to the Attorney General for the issuance of a certificate of review under Idaho Code section 34-1809. I.C. § 34-1804(1). Upon receipt of the initiative petition, the Attorney General has twenty days to review the initiative, to "recommend to the petitioner such revision or alteration of the measure as may be deemed necessary and appropriate," and to issue a certificate of review to the Secretary of State. I.C. § 34-1809(1)(a), (c).

If the party who filed the initiative chooses to proceed, the proponent has fifteen days to file the initiative with the Secretary of State for the issuance of ballot titles. I.C. § 34-1809(2). The Secretary of State must immediately submit the initiative to the Attorney General to assign ballot

titles. *Id.* The Attorney General must then prepare a short and a long ballot title[1] and submit them to the Secretary of State within ten days. I.C. § 34-1809(2)(a), (d). The Secretary of State must then provide the ballot titles to the party who filed the initiative. I.C. § 34-1809(2)(b). "The ballot titles shall be used and printed on the covers of the petition when in circulation[.]" I.C. § 34-1809(2)(c).

In this action, the Secretary of State transmitted the Initiative to DFM, which prepared an FIS that projected additional costs to the State if voters approved the Initiative:

> The laws affected by the initiative would not impact income, sales, or product taxes. There is no revenue impact to the General Fund found.
>
> The initiative could change state expenditures in minor ways. Costs associated with the Medicaid and prisoner populations may occur; see Idaho Codes 20-237B and 56-255 and the Medicaid references from Health and Welfare.
>
> Passage of this initiative is likely to cost less than $20,000 per year. The Medicaid budget for providing services was about $850 million in FY2024. If passed, nominal costs in the context of the affected total budget are insignificant to the state.
>
> Assumptions
>
> Changes in costs associated with the ballot initiative could impact state funding expenditures for Corrections [sic] and Medicaid budgets. The amount of those costs would be dependent on the frequency of need for reproductive services within the agencies. The manner of the budget impacts would be different for Corrections [sic] due to the health care provisions used by the agency; there is no expected changes to the Corrections [sic] health care budget. Billing history prior to the Dobbs decision suggests that $20,000 per year is a conservative over-estimate of the costs. Neither of these agencies reverted funding when the Dobbs decision was made in 2022 (and already established legislation in Idaho code took effect). It is assumed that any additional costs due to the passage of this ballot initiative could be absorbed in the Corrections [sic] and Health and Welfare budgets should the ballot initiative pass.

Idahoans United filed the Initiative with the Secretary of State for the assignment of ballot titles. The Attorney General sent the ballot titles to the Secretary of State, and the Secretary of State provided them to Idahoans United that same day. The short ballot title states:

> Measure establishing a right to abortion up to fetus viability and to make reproductive decisions regarding one's own body.

[1] Idaho Code section 34-1809 refers to the ballot titles as the "short title" and "general title." The parties and prior decisions of this Court often colloquially refer to the general title as the "long title." This opinion will similarly use the term "long title" to refer to the general title.

The long ballot title states:

> The measure seeks to change Idaho's laws by introducing a right to reproductive freedom and privacy including a right to abortion up to the point of the fetus's ability to survive outside the womb. After fetal viability, there would be no general right to abortion except in cases of "medical emergency." The "medical emergency" exception would expand Idaho's current life exception and allow abortions when pregnant women face complicating physical conditions that threaten their life or health, "including serious impairment to a bodily function" or "serious dysfunction of any bodily organ or part."
>
> The proposed measure codifies a right to make reproductive decisions, including contraception, fertility treatment, and prenatal and postpartum care. This includes a "right of privacy" in making these decisions. The measure seeks to prevent the state from enforcing certain abortion laws protecting the life of the unborn child. It would also impose a requirement that any restrictions on reproductive decisions, including abortion prior to fetus viability, must be "narrowly tailored to improve or maintain the health of the person seeking reproductive health care." The measure would also prevent the state from penalizing patients, healthcare providers, or anyone who assists in exercising the proposed right.

After receiving the ballot titles, Idahoans United filed a Verified Petition for Writs of Certiorari and Mandamus with this Court, arguing that the FIS and the short and long ballot titles violate Idaho law. Idahoans United asks this Court to issue a writ of certiorari or mandamus directing DFM to issue the proposed FIS prepared by Idahoans United or to issue an FIS that complies with Idaho law. It also asks this Court to issue a writ of certiorari or mandamus certifying the ballot titles prepared by Idahoans United or directing the Attorney General to provide ballot titles that comply with Idaho law.

III. ISSUES ON APPEAL

1. Whether Idahoans United has properly invoked this Court's original jurisdiction.
2. Whether the FIS substantially complies with Idaho Code section 34-1812.
3. Whether the short ballot title substantially complies with Idaho Code section 34-1809.
4. Whether the long ballot title substantially complies with Idaho Code section 34-1809.
5. Whether Idahoans United is entitled to attorney fees on appeal.

IV. ANALYSIS

A. Idahoans United has properly invoked this Court's original jurisdiction to issue a writ of mandamus.

Idahoans United seeks writs of mandamus and of certiorari from this Court. Our jurisdiction to issue the writs stems from Article V, section 9 of the Idaho Constitution, which

states that "[t]he Supreme Court shall . . . have original jurisdiction to issue writs of mandamus, certiorari, prohibition, and habeas corpus, and all writs necessary or proper to the complete exercise of its appellate jurisdiction." Before this Court will exercise its original jurisdiction to issue a writ, the petitioning party must demonstrate that the elements of the writ are met. *Labrador v. Idahoans for Open Primaries*, ___ Idaho ___, ___, 554 P.3d 85, 90 (2024).

A writ of mandamus "may be issued by the [S]upreme [C]ourt . . . to compel the performance of an act which the law especially enjoins as a duty resulting from an office, trust or station[.]" I.C. § 7-302. The writ of certiorari may be granted when an inferior tribunal, board or officer exercising judicial functions has exceeded its jurisdiction. I.C. §§ 7-201, 7-202. "It is only appropriate for a court to issue an extraordinary writ 'where there is not a plain, speedy and adequate remedy in the ordinary course of law.' " *Idaho State Athletic Comm'n ex rel. Stoddard v. Off. of the Admin. Rules Coordinator*, 173 Idaho 384, 393, 542 P.3d 718, 727 (2024) (quoting *Westover v. Cundick*, 161 Idaho 933, 936, 393 P.3d 593, 596 (2017)); I.C. §§ 7-303, 7-402. We conclude that Idahoans United has failed to demonstrate these elements are met with regard to the Secretary of State. However, it has demonstrated that the elements are met with regard to DFM and the Attorney General.

1. *We dismiss the Petition against the Secretary of State.*

Idahoans United asks this Court to issue a writ against the Secretary of State but does not specify which writ it seeks. It has not alleged that the Secretary of State has failed to comply with a clear legal duty or that the Secretary of State acted in a quasi-judicial function in excess of his jurisdiction. Instead, Idahoans United alleges that DFM and the Attorney General failed to perform the duties imposed by Idaho Code sections 34-1809 and 34-1812. They have made no such allegation concerning the Secretary of State. At oral argument, Idahoans United admitted that the Secretary of State has performed the ministerial duties required of him up to this point and that it named the Secretary of State as a party in this action out of "an abundance of caution." Idahoans United has failed to establish the elements required for a writ of mandamus or a writ of certiorari and we therefore dismiss the Petition against the Secretary of State.

2. *Idahoans United has properly invoked this Court's original jurisdiction to issue a writ of mandamus against DFM.*

Idahoans United also seeks a writ of mandamus against DFM. "[M]andamus is not a writ of right and the allowance or refusal to issue a writ of mandate is discretionary." *Coeur d'Alene Tribe v. Denney*, 161 Idaho 508, 512, 387 P.3d 761, 765 (2015). A writ of mandamus may be

issued by the Supreme Court "to compel the performance of an act which the law especially enjoins as a duty resulting from an office, trust or station[.]" I.C. § 7-302. "A writ of mandamus will lie if the officer against whom the writ is brought has a '*clear legal duty*' to perform the desired act, and if the act sought to be compelled is *ministerial or executive in nature*." *Idaho State Athletic Comm'n*, 173 Idaho at 393, 542 P.3d at 727 (emphasis added) (citation omitted). Additionally, this Court will only issue an extraordinary writ "where there is not a plain, speedy and adequate remedy in the ordinary course of law." I.C. §§ 7-303, 7-402.

Idahoans United argues that a writ is proper here because DFM has a duty to prepare an FIS that complies with Idaho Code section 34-1809, that the FIS prepared by DFM is inaccurate and does not comply with the statute, and that Idahoans United cannot begin collecting signatures for the Initiative until it has a valid FIS. Idahoans United has submitted a declaration asserting that any delay in collecting signatures will hinder its chances of collecting enough signatures to qualify for the 2026 election. DFM argues that, while it has a clear duty to prepare an FIS, it has discretion in deciding the content of the FIS, so mandamus relief is not appropriate.

We conclude that Idahoans United has properly invoked this Court's original jurisdiction. The plain language of Idaho Code section 34-1812 imposes a clear legal duty on DFM to prepare an FIS that meets the mandatory requirements of the statute. Specifically, this statute enumerates those requirements as follows:

- It "*shall* prepare an unbiased, good faith statement of the fiscal impact of the law proposed by the initiative." I.C. § 34-1812(1) (emphasis added).
- It "*shall* describe any projected increase or decrease in revenues, costs, expenditures, or indebtedness that the state or local governments will experience if the ballot measure is approved by the voters." I.C. § 34-1812(2) (emphasis added).
- It "*shall* include both immediate expected fiscal impacts and an estimate of any state or local government long-term financial implications." *Id.* (emphasis added).
- It "*must* be written in clear and concise language and *shall* avoid legal and technical terms whenever possible." *Id.* (emphasis added).
- It "*must* include both a summary of the fiscal impact statement, not to exceed one hundred (100) words, and a more detailed statement of fiscal impact that includes the assumptions that were made to develop the fiscal impact." I.C. § 34-1812(3) (emphasis added).

DFM's statutory duty to prepare an FIS that meets these requirements is clear and non-discretionary as evidenced by the statute's repeated use of the words "shall" and "must." The preparation of the FIS is an act that is ministerial or executive in nature.

The fact that DFM exercises discretion in estimating the amount of any fiscal impact does not alter our conclusion that DFM has a clear legal duty to prepare an FIS that complies with section 34-1812. DFM is correct that, generally, a writ of mandamus is improper to review acts of discretion. *See Brady v. City of Homedale*, 130 Idaho 569, 571, 944 P.2d 704, 706 (1997). However, our caselaw is clear that in instances where there is a clear legal duty for an officer to act but the details of those actions are left to an officer's discretion, mandamus may still be proper. *See Beem v. Davis*, 31 Idaho 730, 736, 175 P. 959, 961 (1918) ("The fact that certain details are left to the discretion of the authorities does not prevent relief by mandamus."); *Moerder v. City of Moscow*, 74 Idaho 410, 415, 263 P.2d 993, 996 (1953) ("Public officials may, under some circumstances, be compelled by writ of mandate to perform their official duties, although the details of such performance are left to their discretion."); *Musser v. Higginson*, 125 Idaho 392, 394–96, 871 P.2d 809, 811–13 (1994) ("For more than three-quarters of a century, the Court has adhered to the following principle: The fact that certain details are left to the discretion of the authorities does not prevent relief by *mandamus*." (internal quotation marks and citation omitted)). That principle applies with equal force to the facts of this action. While DFM has discretion in preparing the contents of the FIS, it has no discretion concerning whether to prepare an FIS that meets the requirements of section 34-1812.

We also conclude that Idahoans United has demonstrated that "there is not a plain, speedy and adequate remedy in the ordinary course of law." I.C. §§ 7-303, 7-402. In *Open Primaries*, we held that a petitioner's inability to begin collecting signatures for its initiative until the Secretary of State certifies the ballot titles was sufficient to invoke this Court's original jurisdiction. *Idahoans for Open Primaries v. Labrador* (*In re Verified Pet. for Writs of Cert. & Mandamus*) ("*Open Primaries*"), 172 Idaho 466, 475–76, 533 P.3d 1262, 1271–72 (2023). This action presents a similar situation because Idahoans United is prevented from collecting signatures until the Secretary of State certifies an FIS. I.C. § 34-1802(1); *see also Buchin v. Lance* (*In re Writ of Prohibition Entitled "Ballot Title Challenge Oral Arg. Req."*), 128 Idaho 266, 273, 912 P.2d 634, 641 (1995) (holding that "any signature collected by the circulation of a petition with . . . invalid titles cannot be valid"). Idahoans United also submitted a declaration from its executive director,

Melanie Folwell, which asserts that any delay in collecting signatures will adversely impact its efforts to qualify the Initiative for the 2026 general election. Having demonstrated both the elements of a writ of mandamus and the lack of an adequate remedy, we hold that Idahoans United has properly invoked this Court's original jurisdiction.

We decline DFM's invitation to adopt the reasoning of a recent Washington Supreme Court decision that dismissed a petition for a writ of mandamus seeking to prevent the publication of a public investment impact disclosure for several ballot initiatives. *See Walsh v. Hobbs*, 557 P.3d 701, 703, 706 (Wash. 2024) (en banc). While the Washington Supreme Court may have reached a different result under its precedent, we apply this Court's precedent and conclude that Idahoans United has properly invoked our original jurisdiction.

Idahoans United also seeks writs of certiorari against DFM and the Attorney General. We decline to separately analyze the elements of those writs because mandamus relief fully resolves Idahoans United's claim. In this action, the resolution of both writs turns on whether the FIS substantially complies with section 34-1812. The relief that Idahoans United seeks for each writ is the same: a writ requiring DFM to prepare an FIS that substantially complies with the requirements of section 34-1812. We have already held that Idahoans United properly invoked our original jurisdiction to issue a writ of mandamus. Thus, if the FIS substantially complies, then Idahoans United is not entitled to a writ of mandamus. The result would be no different for the requested writ of certiorari. If the FIS does not substantially comply, then Idahoans United is entitled to a writ of mandamus. A writ of certiorari would not award any greater relief than the requested writ of mandamus. Given that the outcomes would be the same for either writ, and given our conclusion that Idahoans United properly invoked this Court's original jurisdiction on the writ of mandamus, we do not need to address its claim for a writ of certiorari. We therefore deny Idahoans United's request for a writ of certiorari as duplicative of the relief sought in its request for a writ of mandamus.

3. *Idahoans United has properly invoked this Court's original jurisdiction to issue a writ of mandamus against the Attorney General.*

Finally, Idahoans United seeks a writ of mandamus against the Attorney General. The Attorney General does not challenge this Court's jurisdiction to issue a writ of mandamus concerning the ballot titles. We conclude that Idahoans United has properly invoked our original jurisdiction to issue a writ of mandamus against the Attorney General.

Section 34-1809 mandates that "the attorney general *shall* provide ballot titles," I.C. § 34-1809(2)(a) (emphasis added), that "*shall* contain: . . . [a] [d]istinctive short title not exceeding twenty (20) words by which the measure is commonly referred to or spoken of" and "[a] general title expressing in not more than two hundred (200) words the purpose of the measure," I.C. § 34-1809(2)(d)(i), (ii) (emphasis added). Section 34-1809 also mandates that, "[i]n making the ballot title, the attorney general *shall*, to the best of his ability, give a true and impartial statement of the purpose of the measure and in such language that the ballot title *shall* not be intentionally an argument or likely to create prejudice either for or against the measure." I.C. § 34-1809(2)(e) (emphasis added).

Idahoans United has properly pleaded that section 34-1809 imposes a clear legal duty on the Attorney General to prepare ballot titles that meet the mandatory requirements of the statute. The preparation of the ballot titles is an act that is ministerial or executive in nature. And for the reasons discussed above regarding Idahoans United's petition against DFM, we conclude that Idahoans United has properly demonstrated that "there is not a plain, speedy and adequate remedy in the ordinary course of law" with regard to the ballot titles. Further, for the reasons discussed above, we deny its request for a writ of certiorari as duplicative of its request for a writ of mandamus.

B. The FIS does not substantially comply with Idaho Code section 34-1812.

Idahoans United argues that the FIS prepared by DFM fails to comply with Idaho Code section 34-1812. The statute requires DFM to prepare "an unbiased, good faith statement of the fiscal impact of the law proposed by the initiative." I.C. § 34-1812(1). It must include both a 100-word summary of the statement and a more detailed statement of fiscal impact that includes the assumptions that were made to develop the fiscal impact. I.C. § 34-1812(3). The FIS "must be written in clear and concise language and shall avoid legal and technical terms whenever possible. Where appropriate, [an FIS] may include both estimated dollar amounts and a description placing the estimated dollar amounts into context." I.C. § 34-1812(2). Idahoans United argues that the FIS prepared for the Initiative violates these requirements because it was not made in good faith, is unclear, and impermissibly includes legal and technical terms.

Before we address the specific challenges raised by Idahoans United, we first must determine the appropriate legal standard to apply. In *Open Primaries*, we determined that we would employ a "substantial compliance" standard when reviewing ballot titles prepared by the

Attorney General. 172 Idaho at 479, 533 P.3d at 1275. We concluded this standard was appropriate because we had applied it in other situations where the critical inquiry was whether a party had met statutory requirements. *Id.* Idahoans United's arguments here require us to engage in a similar critical inquiry: whether DFM has fulfilled its mandatory duties set forth in section 34-1812. As a result, we conclude that our reasoning expressed in *Open Primaries* applies with equal force here. Therefore, we will review the FIS to determine whether it substantially complies with the requirements of Idaho Code section 34-1812.

We now turn to the specifics of Idahoans United's challenge. It claims that the FIS fails to meet nearly every statutory requirement:

- It is not drafted in good faith because it estimates a fiscal impact on taxpayers despite language in the Initiative that it "does not create a financial obligation on the state, its agencies, or their programs." It also lacks a factual basis for its conclusions that there may be a fiscal impact on the Idaho Department of Correction ("IDOC") and Medicaid budgets.
- It is not clear and concise because it creates confusion regarding whether there will be a fiscal impact.
- It fails to avoid legal and technical terms whenever possible because it cites statutes and regulatory references.
- It is prejudicial because it unnecessarily references Medicaid and prisoner populations and the Idaho Department of Health and Welfare's ("IDHW") total Medicaid budget.

We address each argument in turn.

1. *The FIS does not substantially comply with the good faith requirement.*

Idahoans United argues that the FIS fails to substantially comply with the requirements of section 34-1812 because there is no factual basis supporting the estimated fiscal impact and the Initiative specifically states that it will not impose a financial obligation on the State. DFM responds that it acted in good faith by consulting with a Medicaid expert from IDHW.

We hold that the FIS does not substantially comply with the good faith requirement of section 34-1812 because DFM has not established a reasonable basis for its estimated fiscal impacts. Idaho Code section 34-1812 requires DFM to "prepare an *unbiased, good faith* statement of the fiscal impact of the law proposed by the initiative." I.C. § 34-1812(1) (emphasis added). Good faith includes "honesty in belief or purpose" and "faithfulness to one's duty or obligation." *Good Faith*, Black's law Dictionary (12th ed. 2024). Section 34-1812 requires DFM to project and

estimate the potential fiscal impact. As such, the statute does not require certainty or exactness. However, the statute's requirement that the FIS be a "good faith statement" requires that it be more than a guess or speculation. In other words, while section 34-1812 does not require DFM to perfectly project the future, the requirement that the FIS be "a good faith statement" requires that DFM have a reasonable basis for its estimated fiscal impact.

In this case, the FIS posits that, if the Initiative passed, there may be a potential increase in state expenditures for the Medicaid and prisoner populations. However, the evidence in the record before us does not support these conclusions. As a result, the FIS fails to substantially comply with the good faith requirement of section 34-1812.

Both parties submitted evidence to this Court related to DFM's investigation of the fiscal impact of the Initiative. The evidence submitted includes DFM emails with Juliet Charron, the deputy director for Medicaid and Behavioral Health at IDHW. Those emails show that IDHW provided DFM data concerning abortion-related Medicaid claims for the years 2018 through 2022. The emails also indicate that a DFM economist had a phone call and a meeting with Charron. However, none of the materials indicate that DFM spoke with anyone at the IDOC or that it conducted any investigation of whether IDOC paid for any abortion-related care for the prisoner population. While DFM submitted several declarations to this Court, it did not provide a declaration from the economist who prepared the FIS or from anyone else at DFM to explain the evidence gathered, process employed, or reasoning underlying its FIS. DFM did submit two declarations from IDHW employees concerning abortion data and Medicaid claims data. We will evaluate the evidence before us to determine whether the FIS is a good faith statement, or put differently, whether DFM had a reasonable basis for the estimated fiscal impacts contained in the FIS.

Initially, we note that there is no evidence supporting the FIS's statement that there may be a fiscal impact to the IDOC budget due to increased costs for medical care for the prisoner population. There is no evidence that DFM communicated with IDOC or conducted any research relating to the IDOC budget and spending for abortion-related care provided to the prisoner population. As a result, it appears that the FIS's statement that the Initiative could increase the budget for prisoner medical care lacked a reasonable basis and, therefore, was entirely speculative. We hold that the FIS fails to substantially comply with the statutory requirement for a good faith statement as it relates to the estimated impact on the IDOC budget.

Next, we conclude that the FIS lacks a reasonable basis for the estimated impact on the Medicaid budget. While there is evidence that DFM investigated certain Medicaid costs, the evidence is insufficient to support the FIS's estimate that passage of the Initiative may result in additional state expenditures.

The emails between DFM and Charron include data concerning abortion-related Medicaid claims for the years 2018 through 2022:

2018: 2 claims billed, totaling $2,576; $0 paid

2019: 5 claims billed, totaling $9,795; $500 paid

2020: 4 claims billed, totaling $24,323; $9,591 paid

2021: 2 claims billed, totaling $13,806; $0 paid

2022: No claims billed

The emails do not describe what the claims were for or the reasons why the claim amounts were not fully covered by Medicaid.

DFM submitted to this Court a declaration from Miren M. Unsworth, IDHW's deputy director of the Health and Human Services Division. Unsworth's declaration provided data on the "Total Reported Idaho Abortions and Chemical Abortions by Year" between 2015 and 2023. That data indicated that beginning in 2022, the year the United States Supreme Court issued its decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), the number of Idaho resident abortions and chemical abortions decreased dramatically.

DFM also submitted to this Court a declaration from Charron. Charron testified that between July 2020 and June 2021, the average monthly enrollment for Idaho Medicaid of women between the ages of 14 and 45 was 97,055. She also testified that Idaho Medicaid provides coverage for treatment and follow-up care at hospitals following abortion complications, including complications from chemically-induced abortions. She stated that it is often difficult to quantify Idaho's costs for providing this coverage due to a variety of factors. She testified that Idaho Medicaid expended $3,025.94 in state funds to cover treatment and follow-up care for abortion-related medical complications in calendar year 2019, and $3,797.42 in state funds in calendar year 2022.

Idahoans United claims that the Initiative would not increase the State dollars expended by Idaho Medicaid on abortion-related claims for two reasons. First, the Initiative specifically states that it "does not create a financial obligation on the state, its agencies, or their programs to pay for,

fund, or subsidize the reproductive health care protected by this act." Second, federal and Idaho law significantly restrict the use of public funds for abortion and the Initiative does not change those laws.

The federal Hyde Amendment prohibits the Secretaries of Labor, Health and Human Services, and Education from utilizing federal funds for any abortion or health benefits coverage that covers abortions except in the case of rape or incest, or where the pregnancy places the mother in danger of death. *See* Further Consolidated Appropriations Act of 2024, Pub. L. No. 118-47, § 506(a), 138 Stat. 460, 703 (2024). The Hyde Amendment is significant in this context because the bulk of Idaho's Medicaid spending is accomplished with federal funds. The Charron Declaration establishes that between July 2020 and July 2021, Idaho Medicaid expended $3.24 billion on all services for Medicaid participants. Of that total, $2.27 billion was federal funds. With regard to state funds, Idaho's "No Public Funds for Abortion Act" provides that no public funds made available by the State can be used to provide for abortions. I.C. § 18-8705(1), (2). Likewise, Idaho Code section 56-209c provides that "[n]o funds available to the department of health and welfare . . . shall be used to pay for abortions" except when necessary to save the life of the mother or in the case of rape or incest. I.C. § 56-209c. The Initiative does not purport to change these laws.

Idahoans United argues that there is no evidence that DFM analyzed whether Idaho Medicaid would be required to cover any additional abortion-related claims if the Initiative passed, given state and federal law restricting the use of public funds and the Initiative's language. DFM notes that Medicaid costs related to abortion complications "are nearly certain to materialize."

We conclude that, while DFM has some evidence indicating that the number of abortions would likely increase if the Initiative passed, it has not established a reasonable basis to support its estimated fiscal impact to the Idaho Medicaid program. DFM argues that there will be a fiscal impact because Medicaid expenses will increase due to complications related to an increased number of chemically induced abortions. However, DFM did not submit a declaration from the DFM economist that prepared the FIS explaining the basis for the estimated fiscal impact. As a result, we are left to review the evidence in the record to determine whether it provides a reasonable basis for the estimated fiscal impact to the Medicaid program. We conclude that it does not.

The only evidence in the record that it appears DFM had when it prepared the FIS are the emails between DFM and IDHW. Neither the Unsworth nor the Charron declarations indicate that the data contained in those declarations was provided to DFM prior to its preparation of the FIS.

The emails only contain data on abortion-related claims made to Idaho Medicaid and the amounts paid on those claims. As noted above, both federal and Idaho law permit Medicaid funds to be used for abortions necessary to save the life of the mother. Charron has also testified that Idaho Medicaid covers claims to treat abortion-related complications resulting from chemically induced abortions. But the emailed claims data does not indicate whether the Medicaid claims paid between 2018 and 2022 were for abortions to save the life of the mother, to treat abortion-related complications resulting from chemically induced abortions, or both. Without knowing how many of the previously paid claims were for abortion-related complications, it is unclear whether the claims data provides a reasonable basis for DFM's estimated fiscal impact on the Medicaid budget.

DFM also points to the Unsworth Declaration as support for its contention that the number of chemically induced abortions will increase. While the Unsworth Declaration indicates that Idaho residents had significantly more abortions before the *Dobbs* decision than after, those numbers fail to differentiate how many of the abortions involved Medicaid recipients. The numbers also fail to differentiate between abortions that Medicaid funds would cover and those that it would not. Finally, the numbers give no indication concerning how many of the women who received chemically induced abortions could be expected to experience abortion-related complications.

The evidence contained in the record does not provide a reasonable basis supporting the estimated fiscal impact to the Medicaid program if the Initiative passed. As previously discussed, Idaho Code section 34-1812 does not require certainty or exactness, but it requires more than speculation or a guess. While DFM consulted IDHW concerning Idaho Medicaid claims, the data received from IDHW is unclear whether there could be an increase in Idaho Medicaid claims for abortion-related complications if the Initiative passes. Given the lack of a reasonable basis in the record to support the estimated fiscal impact in the FIS, we hold that the estimated impact on the Medicaid program failed to substantially comply with the good faith statement requirement of section 34-1812.

Finally, we are not persuaded by Idahoans United's argument that the only good faith estimate is zero fiscal impact because the Initiative stated that it would not impose a financial obligation on the State. Idaho Code section 34-1812 does not require DFM to adopt the Initiative's stated fiscal impact. *See* I.C. § 34-1812. Rather, it authorizes DFM to prepare a good faith statement of the fiscal impact proposed by the law and in doing so, authorizes DFM to work "in

consultation with any other appropriate state or local agency." I.C. § 34-1812(1). DFM would fail to act in good faith if it simply adopted an initiative's assertion that it would have no financial impact. Rather, DFM must conduct its own investigation to prepare the FIS.

2. The FIS does not substantially comply with the clear and concise requirement.

Idahoans United also asserts that the FIS fails to substantially comply with the requirement that it "must be written in clear and concise language." I.C. § 34-1812(2). Idahoans United contends that the FIS contains conflicting statements concerning whether passage of the Initiative will result in increased expenditures. On one hand, the FIS states that:

- "Costs associated with the Medicaid and prisoner populations may occur,"
- "Passage of this initiative is likely to cost less than $20,000 per year," and
- "Changes in costs associated with the ballot initiative could impact state funding expenditures for Corrections [sic] and Medicaid budgets."

However, on the other hand, the FIS states:

- "[T]here is no expected changes to the Corrections [sic] health care budget," and
- "[A]ny additional costs due to the passage of this ballot initiative could be absorbed in the Corrections [sic] and Health and Welfare budgets should the ballot initiative pass."

Idahoans United argues that these conflicting statements are neither concise nor clear, and they create confusion concerning whether the Initiative will have a fiscal impact.

We agree with Idahoans United that these conflicting statements in the FIS fail to substantially comply with the clear and concise requirement contained in section 34-1812(2). As quoted above, the FIS both asserts that passage of the Initiative may have a fiscal impact on the IDOC and Medicaid budgets and that there is no expected change to budgets, or changes could be absorbed in existing budgets. The inclusion of the conflicting statements not only causes confusion but also makes it longer than it would be without the conflicting statements. As a result, the FIS is neither clear nor concise.

Additionally, Idahoans United argues that the FIS is unclear due to its reference to the $850 million Medicaid budget:

> Passage of the initiative is likely to cost less than $20,000 per year. The Medicaid budget for providing services was about $850 million in FY2024. If passed, nominal costs in the context of the affected total budget are insignificant to the state.

Idahoans United argues that inclusion of the Medicaid budget also creates prejudice against the Initiative. DFM argues that it included the Medicaid budget to put the Initiative's expected fiscal impact into context.

We conclude that the reference to the Medicaid budget also fails to substantially comply with the clear and concise requirement. While it is true that Idaho Code section 34-1812(2) allows the FIS to "include a description placing the estimated dollar amounts in context[,]" in the context of this FIS, the reference creates confusion. If we read the FIS to conclude that there are potential increases in IDOC expenditures, the FIS estimates a fiscal impact of $20,000 per year but it does not specify how much of the $20,000 is due to potential increases in IDOC expenditures versus potential increases in Medicaid expenditures. As a result, the total Medicaid budget cannot provide context for the $20,000 estimated impact because we do not know how much of that impact is due to Medicaid expenditures.

If we read the FIS to attribute the entire $20,000 impact to a potential increase in Medicaid expenditures, the total Medicaid budget does little to put that amount into context and undermines the clarity of other statements in the FIS. The FIS already indicates that the changes would be "minor" and "nominal." Listing the total Medicaid budget adds no clarity to this statement and tends to play to the passions of voters who may take issue with the size of the State's Medicaid budget. Instead, it requires citizens to recognize that the total impact is not $850 million and then do the math in their heads to determine how much the total impact is. If they did that math, the estimated increased expenditures are 0.000023% of the Medicaid budget. If the desire is to represent the scope of the impact through a percentage, then DFM should either stick with "nominal," or simply include the percentage and save voters from having to do a math problem in their heads while standing in a voting booth.

3. *The FIS does not substantially comply with the requirement to avoid legal and technical terms whenever possible.*

Idahoans United argues that DFM included unnecessary legal and technical terms by citing statutes:

> The initiative could change state expenditures in minor ways. Costs associated with the Medicaid and prisoner populations may occur; see Idaho Codes 20-237B and 56-255 and the Medicaid references from Health and Welfare.

It contends that the legal citations are unnecessary because the FIS does not explain why they apply to the Initiative. Their inclusion thus creates confusion. DFM responds that it is within its

discretion to decide whether legal terms are unavoidable. Here, it claims that providing the legal citations was necessary to convey what laws would contribute to costs in conjunction with the Initiative.

We hold that DFM's inclusion of legal citations in the FIS fails to substantially comply with the statutory requirement to "avoid legal and technical terms whenever possible." I.C. § 34-1812(2). The references do not assist the FIS in "describ[ing] any projected increase or decrease in revenues, costs, expenditures, or indebtedness" as required by the statute. I.C. § 34-1812(2). The cited statutes do not mention abortions. Rather, they provide that the State will pay for certain medical services. *See* I.C. §§ 20-237B, 56-255. The mention of "Medicaid references" is vague and unclear. The legal terms referencing statutes and vague Medicaid references do nothing to help explain the potential fiscal impact of the Initiative. Indeed, a citation to "see" a specified statute is of little use to a voter standing in a voting booth deciding how to vote.

For the forgoing reasons, we conclude that it was entirely possible for DFM to explain the estimated fiscal impact without including the legal citations.

4. *DFM's references to "Medicaid and prisoner populations" substantially comply with the statutory requirements.*

Finally, Idahoans United argues that DFM's references in the FIS to the "Medicaid and prisoner populations" will prejudice the Initiative because the public generally has a negative impression of those populations, and the references will therefore cause prejudice against the Initiative. DFM responds that "Medicaid and prisoner populations" are not legal or technical terms, and the references are included to provide an explanation of the source for the increased expenditures.

We hold that DFM's use of the terms "Medicaid and prisoner populations" substantially complies with the requirements of Idaho Code section 34-1812. DFM's estimated fiscal impact for the Initiative was based on assumptions related to Idaho's prisoner population and Medicaid recipients. DFM's inclusion of this information substantially complies with the statute because it explains the basis for the estimated fiscal impact.

To summarize, we agree with some, but not all, of Idahoans United's arguments concerning the FIS. We hold that the FIS does not substantially comply with the requirements of Idaho Code section 34-1812 because its estimate lacks a good faith basis, it is not clear, and it unnecessarily includes legal terms. However, we conclude that references to the Medicaid and prisoner

populations do not prejudice the Initiative and therefore substantially comply with the statutory requirements applicable to the FIS.

C. The short ballot title does not substantially comply with Idaho Code section 34-1809.

Idahoans United next argues that the short ballot title drafted by the Attorney General fails to comply with Idaho Code section 34-1809 because it uses uncommon terms and it is not distinctive or comprehensive. We agree with Idahoans United on the latter argument and hold that the short title does not substantially comply with Idaho Code section 34-1809 because it fails to capture all of the distinctive features of the Initiative.

As noted, Idaho Code section 34-1809 requires the Attorney General to draft ballot titles for voter initiatives. I.C. § 34-1809(2)(a). The ballot title must contain "a short title of no more than twenty (20) words . . . . The short title must provide a distinctive statement by which the measure would be commonly referred. *Buchin v. Lance* (*In re Writ of Prohibition Entitled "Ballot Title Challenge Oral Arg. Req."*), 128 Idaho 266, 269, 912 P.2d 634, 637 (1995) (citing I.C. § 34-1809). When reviewing ballot titles, this Court considers whether the Attorney General substantially complied with the requirements of section 34-1809. *Open Primaries*, 172 Idaho at 479, 533 P.3d at 1275. This Court has "long recognized that 'it is not the Court's role to find another way or the best way to draft a [ballot] title, but rather to examine the Attorney General's language and ask whether it expresses the purpose of the measure without being argumentative or prejudicial.' " *Id.* (quoting *Buchin*, 128 Idaho at 270, 912 P.2d at 638).

1. *The short title substantially complies with the statutory requirement to use language by which the Initiative is commonly referred.*

The Attorney General prepared the following short title for the Initiative:

> Measure establishing a right to abortion up to fetus viability and to make reproductive decisions regarding one's own body.

Idahoans United argues that the short title fails to substantially comply with Idaho Code section 34-1809 because the phrase "fetus viability" is not language by which the measure is commonly referred or spoken of and it will therefore prejudice the Initiative. The Attorney General counters that the phrase "fetus viability" is a common phrase that substantially complies with the statute and is not argumentative or prejudicial.

We conclude that the phrase "fetus viability" has been used before in Idaho and is a variation of Idahoans United's suggested phrase "fetal viability." The two phrases employ different parts of speech for the same word and as such, the meaning of the two phrases does not

substantially differ. As a result, we hold that the short title substantially complies with the requirement that it use language by which the measure is commonly referred.

"The plain and unambiguous language of section 34-1809(2)(d)(i) requires the Attorney General to ascertain how an initiative is commonly referred to or spoken of and incorporate that language into the short title." *Open Primaries*, 172 Idaho at 481, 533 P.3d at 1277. "This task necessarily requires the Attorney General to determine how Idahoans commonly refer to and speak of the measure." *Id.* "When ascertaining the language used to commonly refer to the measure, the Attorney General must remain mindful that the statute requires him to use language that is not 'intentionally an argument or likely to create prejudice either for or against the measure.' " *Id.* (citing I.C. § 34-1809(2)(e)). The Attorney General can achieve this by, "to the best of his ability, giv[ing] a true and impartial statement of the purpose of the measure." I.C. § 34-1809(2)(e).

Idahoans United argues that the situation here is nearly identical to the one we addressed in our decision in *Open Primaries*. We disagree. In *Open Primaries*, this Court determined that the phrase "nonparty blanket primary" had not been used by any court in the United States, including the United States Supreme Court and that "it appear[ed] that the term [was] one of the Attorney General's own creation." *Id.* at 481, 533 P.3d at 1277. We also determined that the term would likely prejudice the initiative because it was confusingly similar to a different term used by the United States Supreme Court:

> The Supreme Court held that a "partisan blanket primary" is unconstitutional, but a "nonpartisan blanket primary" is constitutional. It has never discussed a "nonparty blanket primary." Using an undefined term that is very similar to, but slightly different from those discussed by the Supreme Court could cause a voter to conclude that the system proposed in the [i]nitiative has been or would be held unconstitutional, when in fact it has not.

Id. at 484, 533 P.3d at 1280.

The situation in *Open Primaries* is distinguishable from that in this action. First, the phrase "fetus viability" is not a new, undefined term of the Attorney General's own creation. In *Buchin*, the Attorney General advanced a ballot title that referred to a "viable fetus." *Buchin*, 128 Idaho at 269, 912 P.2d at 637. The parties did not challenge the use of that phrase, and this Court determined the ballot title was insufficient on other grounds. *Id.* at 272–73, 912 P.2d at 640–41. However, this Court wrote a ballot title that it "would deem acceptable[,]" which included the phrase "fetus viability." *Id*. at 273, 912 P.2d at 641. Thus, the phrase has been used in Idaho. Further, the Idaho Code discusses when a "fetus becomes viable" and a "viable fetus." I.C. § 18-604(13) to (15). As

a result, this action is distinguishable from *Open Primaries* because the challenged phrase is not one of the Attorney General's own creation and is one that has been used in Idaho.

This action is also distinguishable from *Open Primaries* because the phrase "fetus viability" is not likely to create confusion. In *Open Primaries*, we concluded that the Attorney General's terminology was likely to prejudice the initiative because it could confuse voters concerning the constitutionality of the initiative given its similarity to the name of two other voting systems discussed by the United States Supreme Court. *Id.* The short ballot title in this action is different. The words "fetus" and "fetal" are different parts of speech used for the same concept; one is a noun and the other is an adjective. *Fetus*, Merrium-Webster's Online Dictionary (assigning "fetus" as a noun); *Fetal*, Merrium-Webster's Online Dictionary (assigning "fetal" as an adjective, defined as "of, relating to, or being a *fetus*"). Regardless of which form of speech is used, the meaning is substantially the same and therefore not confusing. Applying the relevant legal standard, we hold that in this instance, the use of the term "fetus viability" substantially complies with the statutory requirement that the short title not create prejudice against the Initiative.

Next, Idahoans United argues that the phrase "*fetal* viability" is significantly more common in Idaho than the phrase "*fetus* viability." Idahoans United's argument may be persuasive if we employed a de novo standard to review the short ballot title. The applicable legal standard, however, is one of substantial compliance. *Open Primaries*, 172 Idaho at 479, 533 P.3d at 1275. Applying this standard does not involve reviewing the short title to determine if the Attorney General used the most common term, but instead whether the Attorney General accomplished the general purpose of the statute. We reiterate that "it is not the Court's role to find another way or the best way to draft a [ballot] title, but rather to examine the Attorney General's language and ask whether it expresses the purpose of the measure without being argumentative or prejudicial." *Id.* (quoting *Buchin*, 128 Idaho at 270, 912 P.2d at 638). Given that the phrase "fetus viability" has substantially the same meaning as Idahoans United's suggested phrase "fetal viability," and given that Idaho has some history of using the term "fetus viability," we hold that the short title substantially complies with the statute's common language requirement.

Idahoans United also argues that using the phrase "fetus viability" rather than "fetal viability" would prejudice the Initiative. It presented a declaration from Dr. Hillary Shulman, Ph.D., an associate professor at Ohio State University, who studies how word choice influences information processing and public engagement in politics. She opines that the individual term

"fetus" will lead people to have a more emotional response to the Initiative and thereby cause prejudice against it, while use of the term "fetal" would lead the public to have a more cognitive response.

The Attorney General first argues this Court may not consider Dr. Shulman's testimony because the expedited briefing schedule requested by Idahoans United causes difficulty in obtaining discovery concerning Idahoans United's expert and in obtaining a rebuttal expert. The Attorney General argues that the evidentiary record in this case should be limited to information the Attorney General could have considered when writing the ballot titles.

The Attorney General's arguments are unpersuasive. To the extent the Attorney General argues he is prejudiced by our consideration of the expert's testimony, he did not oppose Idahoans United's motion to expedite, move for expedited discovery concerning Dr. Shulman's report, or move for additional time to submit an opposing expert declaration. We observe that the Attorney General had more time to obtain an expert declaration than Idahoans United. Idahoans United only had twenty days to file its petition after receiving the ballot titles. I.C. § 34-1809(3)(a). After this Court granted the motion to expedite and set a briefing schedule, the Attorney General received an extension for the due date to file a response brief. The Attorney General thus had over a month to obtain a declaration from an opposing expert, which exceeded the twenty days Idahoans United had to prepare its expert's declaration. We find no prejudice to the Attorney General in this circumstance.

Nor has the Attorney General cited any rule of evidence precluding admission of the declaration or constraining our ability to consider it. In fact, when exercising our original jurisdiction, this Court often reviews evidence submitted in declarations so long as the testimony complies with the Idaho Rules of Evidence. *See, e.g.*, *Planned Parenthood Great Nw. v. State*, 171 Idaho 374, 398–99, 522 P.3d 1132, 1156–57 (2022); *Reclaim Idaho v. Denney*, 169 Idaho 406, 416–17, 497 P.3d 160, 170–71 (2021); *Ybarra v. Legislature by Bedke*, 166 Idaho 902, 907–08, 466 P.3d 421, 426–27 (2020). We therefore will consider the declaration of Idahoans United's expert.

However, nothing in the testimony of Idahoans United's expert alters our conclusion that the short title's use of "fetus viability" substantially complies with section 34-1809. Idahoans United's expert opines that the term "fetal" would be less likely to prejudice the Initiative. As previously discussed, the terms "fetus" and "fetal" are different parts of speech concerning the

same concept, so the meanings of the two phrases are substantially the same. As a result, we cannot conclude that fetus viability does not substantially comply, but fetal viability would. It bears repeating that we are not employing a de novo standard of review, and that it is not our role to determine whether the Attorney General used the best language for the short title. *See Open Primaries*, 172 Idaho at 486, 533 P.3d at 1262 ("While we understand that Petitioners would prefer different language, 'it is not the Court's role to find another way or the best way to draft a long title[.]' " (quoting *Buchin*, 128 Idaho at 270, 912 P.2d at 638)).

2. *The short title fails to substantially comply with the distinctive and comprehensive requirement.*

Idahoans United also argues that the short title is not distinctive and comprehensive because it omits two important characteristics of the Initiative: the right to abortion in medical emergencies and the right to privacy. The Attorney General contends that the short title is distinctive because it highlights the "[I]nitiative's most distinctive change to Idaho law." He claims that the Initiative includes too many distinctive features to fit in a twenty-word short title, but that the short title properly sets forth the general topic of the Initiative and informs potential signers of what they would be sponsoring.

"In drafting the short title, the Attorney General must, by force of circumstances, analyze and appraise the initiative in order to determine what the initiative means and its *distinctive* characteristics. *The short title is to be comprehensive in nature*." *Buchin*, 128 Idaho at 270, 912 P.2d at 638 (emphasis added) (citing *In re The Pet. of Idaho State Fed'n of Labor (AFL)*, 75 Idaho 367, 373, 272 P.2d 707, 710 (1954)). "The Court has defined 'distinctive' as a statement that would refer to that which would distinguish one thing as it related to other things." *Id.* at 272, 912 P.2d at 640 (citing *AFL*, 75 Idaho at 373, 272 P.2d at 710). "[I]n order to be distinctive, a short title must communicate the chief characteristics of the initiative—including, when necessary how the initiative proposes to alter current law." *Open Primaries*, 172 Idaho at 482, 533 P.3d at 1278 (first citing *Buchin*, 128 Idaho at 272, 912 P.2d at 640; and then citing *Am. Civ. Liberties Union, Idaho Chapter v. Echohawk*, 124 Idaho 147, 151, 857 P.2d 626, 630 (1993)). "When assessing the sufficiency of a short title, the fundamental inquiry is whether the short title sets forth the characteristics which distinguish this proposed measure and expeditiously and accurately acquaint the prospective signer with what he or she is sponsoring." *Open Primaries*, 172 Idaho at 482, 533 P.3d at 1278 (cleaned up) (quoting *Echohawk*, 124 Idaho at 151, 857 P.2d at 630).

The Attorney General claims that there are at least ten key characteristics in the Initiative and they cannot all be included in the short title. In contrast, Idahoans United argues that there are three key characteristics in the Initiative and that the short title fails to acknowledge two of them. We conclude that the Initiative contains four distinctive characteristics because it proposes four changes to existing Idaho law:

- It establishes a statutory right to abortion before the viability of the fetus.

  Idaho law currently criminalizes the termination or attempted termination of a clinically diagnosable pregnancy except when "necessary to prevent the death of the pregnant woman" or during the first trimester in certain cases of rape or incest. I.C. § 18-622(2)(a)(i). The Initiative would create an unfettered right to abortion prior to fetal viability, which the Initiative defines as the point when "the fetus has a significant likelihood of sustained survival outside of the uterus without extraordinary medical measures."

- It establishes a statutory right to abortion after fetal viability to protect the health of the mother.

  As discussed above, existing Idaho law only permits the termination of a clinically diagnosable pregnancy in limited circumstances. I.C. § 18-622(2)(a)(i). The Initiative proposes to change Idaho law by allowing abortions after fetal viability if continued pregnancy may "place the health of the pregnant patient in serious jeopardy," "cause serious impairment to a bodily function," or "cause serious dysfunction of any bodily organ."

- It establishes statutory protections for healthcare providers.

  Idaho law currently states it is a crime to perform or attempt to perform an abortion. I.C. § 18-622(1). Further, healthcare professionals who perform, attempt to perform or assist in performing an abortion may have their professional licenses suspended. *Id.* The Initiative would limit the criminal and licensure liability of healthcare providers: "[i]n no case may reproductive health care provided consistent with this act by a health care provider be a basis for professional discipline, civil liability, or criminal liability."

- It establishes a statutory right to freedom in making reproductive healthcare decisions.

> The Initiative creates a "right to reproductive freedom and privacy," which includes "the right of privacy in making personal decisions about reproductive health care in consultation with a health care provider."

We conclude that the Attorney General's short title fails to capture two key characteristics of the Initiative: the expanded right to an abortion post-viability and the limitations on healthcare provider liability. In doing so, the short title indicates that the Initiative only concerns two changes to Idaho law: a right to abortion up to fetal viability and a right to make reproductive healthcare decisions. As a result, the short title is misleading and fails to "accurately acquaint the prospective signer with what he or she is sponsoring." *See Open Primaries*, 172 Idaho at 482, 533 P.3d at 1278 (cleaned up) (quoting *Echohawk*, 124 Idaho at 151, 857 P.2d at 630).

However, we do not agree with Idahoans United that the short title fails to accurately capture the right to privacy aspect of the Initiative. The short title provides that the Initiative establishes "a right . . . to make reproductive decisions regarding one's own body." In comparison, the Initiative defines the right to reproductive freedom and privacy as "the right to make personal decisions about reproductive health care that directly impact the person's own body." The short title language is very similar to the Initiative's definition of the right to privacy. We conclude that the short title therefore accurately captures the right to privacy aspect of the Initiative.

We are not persuaded by the Attorney General's argument that the short title is substantially compliant with the distinctiveness requirement because it includes the "general topic" of the Initiative. Citing our decision in *Echohawk*, the Attorney General claims that the short title does not need to be "all-encompassing" to be distinctive. Our decision in *Echohawk* is distinguishable.

In *Echohawk*, the petitioners filed an initiative that proposed several changes to then-existing Idaho law. 124 Idaho at 151, 857 P.2d at 630. The Court identified four distinctive elements of the initiative:

> the prohibition of granting homosexuals "minority status," the prohibition of "same-sex marriages" and "domestic partnerships," restrictions against discussing homosexuality in the public schools, and restrictions against the expenditure of public funds for certain purposes relating to homosexuals.

Id. The Attorney General's short title stated: "An act establishing state policies regarding homosexuality." *Id.* at 149, 857 P.2d at 628. The Court found that the short title included the

distinctive characteristic of the initiative that "it would establish various state policies towards homosexuality." *Id.* at 151, 857 P.2d at 630.

In *Echohawk*, the Court specifically noted that the short title captured the *distinctive* characteristic of the initiative, which was to establish state policies relating to homosexuality. *Id.* This action presents a different situation. Here, because the short title only identifies two distinctive characteristics, it suggests that those are the only two changes to Idaho law proposed by the Initiative. While the Attorney General's short title in this case may identify what he believes to be the Initiative's most distinctive changes, the Initiative proposes to change Idaho law in other significant ways. Different people may find different aspects of the Initiative to be the most distinctive. For instance, the most important characteristic of the Initiative to healthcare providers may be that it limits their liability in certain circumstances. Another group may find the most distinctive feature to be the expanded right to an abortion after fetal viability to protect the health of the mother. However, the short title fails to alert a prospective signer to either of these proposed changes to Idaho law.

We acknowledge that fitting the distinctive characteristics of an initiative into twenty words is a challenging task. Idaho law, however, has long required that the short title be distinctive and comprehensive. *AFL*, 75 Idaho at 373, 271 P.2d at 710 ("[T]his short title . . . must also be distinctive."); *Echohawk*, 124 Idaho at 151, 857 P.2d at 631 ("[T[he fundamental inquiry is whether the short title is 'distinctive.' "); *Buchin*, 128 Idaho at 270, 912 P.2d at 638 ("The short title is to be comprehensive in nature."). While *Echohawk* provides one example of how this may be done for a short title with multiple distinctive elements, the Attorney General is not constrained to the method used in *Echohawk.* It may be possible to include all four characteristics into a twenty-word short ballot title. The Attorney General is free to exercise his discretion in writing the short ballot title so long as he substantially complies with the statutory requirements in a manner consistent with this opinion.

D. The long title substantially complies with Idaho Code section 34-1809.

The Attorney General's long ballot title states:

> The measure seeks to change Idaho's laws by introducing a right to reproductive freedom and privacy including a right to abortion up to the point of the fetus's ability to survive outside the womb. After fetal viability, there would be no general right to abortion except in cases of "medical emergency." The "medical emergency" exception would expand Idaho's current life exception and allow abortions when pregnant women face complicating physical conditions that

> threaten their life or health, "including serious impairment to a bodily function" or "serious dysfunction of any bodily organ or part."
>
> The proposed measure codifies a right to make reproductive decisions, including contraception, fertility treatment, and prenatal and postpartum care. This includes a "right of privacy" in making these decisions. The measure seeks to prevent the state from enforcing certain abortion laws protecting the life of the unborn child. It would also impose a requirement that any restrictions on reproductive decisions, including abortion prior to fetus viability, must be "narrowly tailored to improve or maintain the health of the person seeking reproductive health care." The measure would also prevent the state from penalizing patients, healthcare providers, or anyone who assists in exercising the proposed right.

Idahoans United argues that the long title is prejudicial because "fetus viability" is "uncommon and potentially politically charged terminology." It further argues that the long title is confusing because it uses the phrases "fetus viability" and "fetal viability" interchangeably.

Idaho Code section 34-1809 tasks the Attorney General with writing a long title "expressing in not more than two hundred (200) words the purpose of the measure." I.C. § 34-1809(2)(d)(ii). "[U]nlike the short title, the long title is not required to be distinctive or to use language by which the measure is commonly referred to or spoken of." *Open Primaries*, 172 Idaho at 487, 533 P.3d at 1283. It bears repeating that "[i]t is not the Court's role to find another way or the best way to draft a long title, but rather to examine the Attorney General's language and ask whether it expresses the 'purpose of the measure' without being argumentative or prejudicial." *Id.*

For the reasons previously discussed, we hold that the phrase "fetus viability" substantially complies with the statutory requirement that the language of the long title not prejudice the Initiative. We further hold that the use of both "fetal viability" and "fetus viability" in the long title does not create confusion. As previously noted, the terms "fetus" and "fetal" are different parts of speech describing the same concept and as a result the use of both phrases is not confusing. We hold that the long title substantially complies with Idaho Code section 34-1809.

E. We retain jurisdiction of this matter and issue writs of mandamus ordering DFM to provide a new FIS and ordering the Attorney General to provide a new short ballot title to this Court for review.

Having determined that the FIS and the short ballot title fail to substantially comply with Idaho law, we now turn to the appropriate remedy. Idahoans United asks this Court to certify the FIS and short ballot title drafted by Idahoans United. In the alternative, it asks us to issue writs of mandamus to DFM and the Attorney General directing them to issue an FIS and a short ballot title

in accordance with Idaho law. We decline to certify the FIS or the ballot titles provided by Idahoans United and instead issue writs of mandamus to DFM and the Attorney General.

As in *Open Primaries*, the most appropriate remedy in this action is to retain jurisdiction of this matter and order DFM to provide a statutorily compliant FIS and order the Attorney General to provide a statutorily compliant short ballot title. *See Open Primaries*, 172 Idaho at 490, 533 P.3d at 1286. It is not appropriate at this stage for the Court to dictate the details of either document or draft a short ballot title itself. However, given that the people's constitutional right to direct legislation reserved in Article III, section 1 of the Idaho Constitution is at issue, and the time concerns expressed by Idahoans United, we will retain jurisdiction to ensure a timely resolution of this action. *Id.*

We understand that DFM may require some time to gather the necessary information and input to calculate the fiscal impact of the Initiative's proposed changes to Idaho law. Accordingly, we will give DFM seven calendar days to prepare a new FIS. We order DFM to provide a new FIS that complies with Idaho Code section 34-1812 to this Court by 4 p.m. MDT on June 23, 2025. To avoid further litigation concerning the reasonable basis for any estimated impact that may be described in the FIS, we also order DFM to submit a sworn declaration by the preparer of the FIS describing the process utilized, including the evidence gathered and the assumptions utilized to create the FIS. We will review the FIS and supporting declaration to determine whether it substantially complies with section 34-1812. No further briefing or oral argument will be granted concerning the new FIS.

We order the Attorney General to provide a new short title to this Court. In the interest of consistency, we will also grant the Attorney General seven calendar days to prepare a new short ballot title. We order the Attorney General to provide a new short ballot title that complies with Idaho Code section 34-1809 to this Court by 4 p.m. MDT on June 23, 2025. We will review the short ballot title to determine whether it substantially complies with the statute. No further briefing or oral argument will be granted concerning the short ballot title.

F. We decline to grant attorney fees to Idahoans United.

Idahoans United seeks attorney fees under Idaho Code section 12-117(1). Idaho Code section 12-117(1) allows the prevailing party in a proceeding between a person and a governmental entity to be awarded attorney fees if the "nonprevailing party acted without a reasonable basis in fact or law." I.C. § 12-117(1); *Open Primaries*, 172 Idaho at 491, 533 P.3d at 1287. This Court

"examines the prevailing party question from an overall view, not a claim-by-claim analysis." *Open Primaries*, 172 Idaho at 491, 533 P.3d at 1287 (quoting *Dep't of Transp. v. Grathol*, 158 Idaho 38, 53, 343 P.3d 480, 495 (2015)).

Considering the mixed results in this action, and taking an overall view of the proceedings, we decline to grant attorney fees to Idahoans United against DFM. The claims against DFM presented an issue of first impression and DFM's arguments were reasonable. We also decline to grant attorney fees to Idahoans United against the Attorney General. Both parties prevailed in part and therefore we hold there is no prevailing party for purposes of attorney fees.

V. CONCLUSION

For the reasons discussed herein, we dismiss the Petition against the Secretary of State, partially grant the Petition for writs of mandamus against DFM and the Attorney General, and deny the Petition for writs of certiorari.

We retain jurisdiction of this matter and order DFM to provide a new FIS that complies with Idaho Code section 34-1812 to this Court by 4 p.m. MDT on June 23, 2025. At that time, DFM shall also file with this Court a sworn declaration by the preparer of the submitted FIS that explains the process utilized, evidence gathered, and assumptions used to create the new FIS. We order the Attorney General to submit a new short ballot title that complies with Idaho Code section 34-1809 to this Court by 4 p.m. MDT on June 23, 2025. No party is awarded costs or attorney fees.

Chief Justice BEVAN, and Justices BRODY, MOELLER, and MEYER CONCUR.

ON THE SUBMISSION OF A NEW FISCAL IMPACT STATEMENT AND A NEW SHORT BALLOT TITLE

ZAHN, Justice.

DFM timely submitted a new FIS along with a sworn declaration by the preparer of the submitted FIS in accordance with this Court's June 16, 2025, opinion and order. The new FIS states:

> ***Summary of Fiscal Impact Statement***
> The State estimates the initiative would increase state expenditures between $3,100 and $7,800 annually, less than 0.001% of the state share of Idaho's Medicaid budget. This impact is derived from the costs of treating chemical abortion complications for women enrolled in Idaho's Medicaid program. Medicaid covers medically necessary services to treat complications from all abortions. It is

anticipated that as legal abortions increase, the complications will also increase. This will likely result in an increase in Medicaid covered services and expenditures to treat complications from chemical abortions, which the State has reliable and readily available data to support.

Detailed Statement of Fiscal Impact Including Assumptions

Based on the amount of reliable data gathered by the Division [sic] Financial Management (DFM) and the outcome of the initiative (if passed), DFM limited its assumptions about any increase in costs to the state to those costs arising from the treatment of Medicaid recipients for chemical abortion complications. DFM does not have reliable and readily accessible data to reasonably calculate the fiscal impact attributable to the complications for surgical abortions.

Based on data provided by Department of Health and Welfare (DHW), DFM considered the number of childbearing women on Medicaid in 2021 which was 97,055. This represents about 25% of the total Idaho population for women in this same age group. DFM assumed that, as a result of this initiative, the number of chemical abortions conducted annually would increase to the levels prior to 2022, the year of the U.S. Supreme Court's decision returning the regulation of abortion to the States. Based on the number of chemical abortions performed in Idaho using the 2021 data from the vital records report (approximately 1,180), DFM assumed 25% (approximately 300) of those individuals were Medicaid recipients.

Taking the number of Medicaid recipients who would receive a chemical abortion, DFM assumed that 2% - 5% of those chemical abortions would result in complications. DFM assumed this based on information provided in (1) the United State's [sic] Food and Drug Administration's warning label for the Mifeprex and (2) studies related to abortion complications that were published on the National Library of Medicine website, which DHW provided to DFM.

Based on the claims for complications from chemical abortions provided by DHW for 2019 and 2022 claims data, DFM applied an average per person claim cost and added a 4% medical inflation year over year to account for current medical costs in FY2026. Based on that calculation, DFM assumes that about 300 individuals on Medicaid in Idaho could receive a chemical abortion and of those, 6 to 15 individuals could have complications from that chemical abortion with an average claim cost of about $531 (state portion of the cost). Based on the process utilized, evidence readily available and gathered, and assumptions used to create the fiscal impact statement, total expenditures for the state would range from $3,100 to $7,800 per year.

While the specific fiscal impact to the state's expenditures is difficult to quantify, DFM cannot in good faith conclude that the proposed initiative will have no fiscal impact on state expenditures.

Having reviewed the new FIS and accompanying declaration, we conclude that the new FIS is consistent with the views expressed in our prior opinion dated June 16, 2025. We also conclude that the FIS substantially complies with the requirements of Idaho Code section 34-1812.

The Attorney General timely submitted a new short ballot title in accordance with this Court's June 16, 2025, opinion and order. The revised short ballot title states:

> Measure creating right to abortion before fetus viability, and post-viability to protect health; right to privacy; healthcare provider liability protections.

Having reviewed the new short ballot title, we conclude that it is consistent with the views expressed in our prior opinion dated June 16, 2025, and that it also substantially complies with the requirements of Idaho Code section 34-1809. Therefore, we certify the new short ballot title to the Idaho Secretary of State as required by Idaho Code section 34-1809(3)(c).

Chief Justice BEVAN, and Justices BRODY, MOELLER, and MEYER CONCUR.

EXHIBIT 56

HHS, Identification of Drug and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies for Purposes of the Food and Drug Administration Amendments Act of 2007, 73 Fed. Reg. 16,313, 16,314 (Mar. 27, 2008)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0174]

Identification of Drug and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies for Purposes of the Food and Drug Administration Amendments Act of 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing this notice to notify holders of certain prescription new drug and biological license applications that they will be deemed to have in effect an approved risk evaluation and mitigation strategy (REMS) under the Food and Drug Administration Amendments Act of 2007 (FDAAA). Holders of applications deemed to have in effect an approved REMS are required to submit a proposed REMS to FDA.

DATES: Submit proposed REMSs to FDA by September 21, 2008.

ADDRESSES: Written communications regarding the applicability of this notice to a specific product should be identified with Docket Number FDA–2008–N–0174 and submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic communications to *http://www.regulations.gov*. Information about FDA implementation of FDAAA is available on the Internet at *http://www.fda.gov/oc/initiatives/advance/fdaaa.html*.

FOR FURTHER INFORMATION CONTACT: Mary Dempsey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4326, Silver Spring, MD 20993–0002, 301–796–0147.

SUPPLEMENTARY INFORMATION:

I. Introduction

On September 27, 2007, the President signed into law FDAAA (Public Law 110–85). Title IX, subtitle A, section 901 of FDAAA created new section 505–1 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355–1). Section 505–1(a) of the act authorizes FDA to require persons submitting certain applications[1] to submit and implement a REMS if FDA determines that a REMS is necessary to ensure that the benefits of a drug outweigh the risks of the drug and informs the holder of the application for the drug of the determination. Section 909 of FDAAA provides that Title IX, subtitle A takes effect 180 days after its enactment, which is March 25, 2008.

FDAAA also contains REMS requirements for drug and biological products approved before the effective date of Title IX, subtitle A. Section 909(b)(1) of FDAAA specifies that a ''drug that was approved before the effective date of this Act is * * * deemed to have in effect an approved risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act * * * if there are in effect on the effective date of this Act elements to assure safe use—(A) required under section 314.520 or section 601.42 of title 21, Code of Federal Regulations; or (B) otherwise agreed to by the applicant and the Secretary [of Health and Human Services] for such drug.''

Section 909(b)(3) of FDAAA states: ''Not later than 180 days after the effective date of this Act, the holder of an approved application for which a risk evaluation and mitigation strategy is deemed to be in effect * * * shall submit to the Secretary a proposed risk evaluation and mitigation strategy. Such proposed strategy is subject to section 505–1 of the Act as if included in such application at the time of submission of the application to the Secretary.''[2]

Section 909(b)(2) of FDAAA states that a REMS for a drug deemed to have a REMS consists of the timetable required under section 505–1(d) of the act and any additional elements under section 505–1(e) and (f) of the act in effect for the drug on the effective date of FDAAA.

The purpose of this notice is to identify those drugs that FDA has determined will be deemed to have in effect an approved REMS and to notify holders of applications for such drugs that they are required to submit a proposed REMS by September 21, 2008. FDA is developing guidance on the preferred content and format of a proposed REMS required to be submitted under section 909(b) of FDAAA and will issue it as soon as possible.

II. List of Drug and Biological Products Deemed to Have a REMS

Drug and biological products deemed to have in effect an approved REMS are those that on March 25, 2008 (the effective date of Title IX, subtitle A of FDAAA), had in effect ''elements to assure safe use.'' ''Elements to assure safe use'' include the following: (1) Health care providers who prescribe the drug have particular training or experience, or are specially certified; (2) pharmacies, practitioners, or health care settings that dispense the drug are specially certified; (3) the drug is dispensed to patients only in certain health care settings, such as hospitals; (4) the drug is dispensed to patients with evidence or other documentation of safe use conditions, such as laboratory test results; (5) each patient using the drug is subject to certain monitoring; or (6) each patient using the drug is enrolled in a registry (see section 505–1(f)(3) of the act).

Some applications approved before the effective date of FDAAA Title IX, subtitle A contain these elements to assure safe use.[3] Some of these applications were approved under § 314.520 (21 CFR 314.520) or § 601.42 (21 CFR 601.42). Others were not approved under part 314, subpart H or part 601, subpart E, but still contain elements to assure safe use that were agreed to by the applicant and the Secretary for such drug. Since 2005, these elements typically appeared in approved risk minimization action plans (RiskMAPs) (see the guidance for industry entitled ''Development and Use of Risk Minimization Action Plans'' (70 FR 15866, March 29, 2005)).

FDA has reviewed its records to identify applications that were approved before the effective date of Title IX of FDAAA with elements to assure safe use and has identified the drug and biological products listed in table 1 of this document as those that will be deemed to have in effect an approved REMS.

[1] Section 505(p)(1) of the act (21 U.S.C. 355(p)(1)) states that section 505–1 of the act applies to applications for prescription drugs approved under section 505(b) or (j) of the act and applications approved under section 351 of the Public Health Service Act (42 U.S.C. 262).

[2] Title IX, subtitle A of FDAAA, which includes section 909, takes effect March 25, 2008; 180 days after that date is September 21, 2008.

[3] These plans sometimes contain other elements to minimize risk such as a Medication Guide (21 CFR part 208) or a communication/educational plan for health care providers or patients. A drug will not be deemed to have a REMS if it has only a Medication Guide, patient package insert, and/or communication plan (see section 505–1(e)(2) and (e)(3) of the act).

TABLE 1.—PRODUCTS DEEMED TO HAVE IN EFFECT AN APPROVED REMS

Generic or Proper Name	Brand Name	Application Number[1]	Date of Approval[2]
Abarelix	Plenaxis[3]	NDA 21–320	11/25/2003
Alosetron	Lotronex	NDA 21–107	02/09/2000
Ambrisentan	Letairis	NDA 22–081	06/15/2007
Bosentan	Tracleer	NDA 21–290	11/20/2001
Clozapine	Clozaril	NDA 19–758 ANDA 74–949 ANDA 75–417 ANDA 75–713 ANDA 75–162 ANDA 76–809	09/26/1989 11/26/97 5/27/99 11/15/02 4/26/05 12/16/05
	Fazaclo ODT	NDA 21–590	02/09/2004
Dofetilide	Tikosyn	NDA 20–931	10/01/1999
Eculizumab	Soliris	BLA 125166	03/16/2007
Fentanyl PCA	Ionsys[3]	NDA 21–338	05/22/2006
Fentanyl citrate	Actiq	NDA 20–747	11/04/1998
Isotretinoin	Accutane Amnesteem Claravis	NDA 18–662 ANDA 75–945 ANDA 76–135 ANDA 76–356	05/07/1982 11/2002 04/2003 04/2003
	Sotret	ANDA 76–041 ANDA 76–503	12/2002 06/2003
Lenalidomide	Revlimid	NDA 21–880	12/27/2005
Mifepristone	Mifeprex	NDA 20–687	09/28/2000
Natalizumab	Tysabri	BLA 125104	11/23/2004
Small pox (Vaccinia) Vaccine, Live	ACAM2000	BLA 125158	08/31/2007
Sodium oxybate	Xyrem	NDA 21–196	07/17/2002
Thalidomide	Thalomid	NDA 20–785 NDA 21–430	07/16/1998

[1] New drug application (NDA), abbreviated new drug application (ANDA), biologics license application (BLA).
[2] The original date of approval of the drug. FDA may have required elements to assure safe use at a later date.
[3] Product is not currently marketed in the United States.

FDA is further asking members of the public to please notify the agency if they are aware of applications that have not been identified in this document and that they believe should be deemed to have in effect an approved REMS. Please provide the information to Mary Dempsey, Risk Management Coordinator (see the **FOR FURTHER INFORMATION CONTACT** section of this document).

Any application holder that believes its product identified in this notice should not be on the list of drug or biological products that will be deemed to have in effect an approved REMS should submit a letter identified with Docket Number FDA–2008–N–0174 to the Division of Dockets Management (see **ADDRESSES**) stating why the application holder believes its product was improperly identified in this notice. FDA will notify the application holder within 30 days of receipt of the letter of its determination.

Dated: March 19, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–6201 Filed 3–26–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

EXHIBIT 57

FDA, Questions and Answers on FDA's Adverse Event Reporting System (FAERS)

U.S. Department of Health and Human Services
Food and Drug Administration

FDA Adverse Events Reporting System (FAERS) Public Dashboard

The FAERS public dashboard is a new, user-friendly and interactive web-based tool that was created to give the public the ability to query the FDA FAERS database and improve transparency. The data presented in the FAERS public dashboard has several key limitations. The existence of adverse event reports for a drug or biologic in FAERS does not mean that the drug or biologic caused the adverse event. Importantly, the FAERS data is not an indicator of the safety profile of the drug or biologic. For more information, please refer to the question What points should I consider while viewing the dashboard content?

Frequently Asked Questions (FAQs)

Expand all | Collapse all

General Questions

[+] What is FAERS?

[+] How does FDA use the information in FAERS?

[+] Who sends reports to FAERS?

[+] How can I report an adverse event or medication error to FDA?

[+] Can mandatory reporters submit adverse events electronically?

[–] Does FAERS data have limitations?

Yes, FAERS data does have limitations. First, there is no certainty that the reported event (adverse event or medication error) was due to the product. FDA does not require that a causal relationship between a product and event be proven, and reports do not always contain enough detail to properly evaluate an event. Furthermore, FDA does not receive reports for every adverse event or medication error that occurs with a product. Many factors can influence whether an event will be reported, such as the time a product has been marketed and publicity about an event. There are also duplicate reports where the same report was submitted by a consumer and by the sponsor. Therefore, FAERS data cannot be used to calculate the incidence of an adverse event or medication error in the U.S. population. For more information, please refer to the question What points should I consider while viewing the dashboard content?

[+] Is FAERS data available to the public?

[+] How do I find or confirm my report is in FAERS?

[+] What are the benefits of the FAERS public dashboard?

[+] Will there be a tutorial so I can learn how to use this database?

[+] Is the FAERS public dashboard accessible on an Android™ or iPhone®?

[+] Can I download my search results from the dashboard?

[+] Where else can I find safety information?

[+] How are versions of a case in FAERS handled?

[+] How frequently is the data in the FAERS public dashboard updated?

[+] What points should I consider while viewing the dashboard content?

Data Questions

[+] How do I know if a side effect I saw on the dashboard is related to the drug I was taking?

[+] If an adverse event wasn't caused by a drug, what could have caused it?

[+] Is every adverse event reported with a drug on the dashboard caused by the drug?

[+] Are drugs with fewer side effects reported to the dashboard safer than those that have a higher number of side effects reported?

[+] How should reports of death be interpreted?

[+] Does the FAERS Dashboard have all the side effects that have occurred with a drug?

[+] What is the difference between an adverse event, a side effect, and an adverse drug reaction?

[+] Should I discontinue a prescription drug I'm taking if I think that it's causing an adverse event?

[+] I looked up a drug that I am taking on the FAERS dashboard and the list of adverse events includes deaths. What should I do?

[+] Where can I find the safety profile of the drug?

[+] After the data refresh for Q4 2021, why do I now see reduced counts in the Home page for previous time periods (Q3 2021 and older)?

Technical Questions

[+] Which internet browsers can I use to access the dashboard?

- What's the recommended screen resolution for viewing the dashboard?
- How do I navigate through different sheets of the dashboard?
- How can I view report statistics for quarters and months of a specific year?
- How do I search for cases for a product or products?
- Can I search for generic products as well as specific trade names?
- How can I change my product search?
- Does FAERS include over-the-counter (OTC) or just prescription drugs?
- How can I search for cases for specific side effects/reactions?
- How can I change my reaction search?
- What can I search for using the search box in the navigation bar?
- How many products or reactions can I search for at a time?
- Does the “Search” sheet allow selecting products and reactions for the same search?
- How can I view the distribution of report or case counts for different parameters?
- Can I view charts and tables in full screen mode? How do I exit from full screen mode?
- Can I filter data in charts and tables?
- How do I reset selected search criteria and remove all filters?
- Can I extract or download dashboard data?
- When using filter panes (or drop-downs) for filtering, I have noticed that different colors are used to highlight different values. What do these colors indicate?
- Can I use the dashboard without accepting the disclaimer?
- Why does the sum of case counts for individual reactions not add up to the overall case count for the product?
- Why does the sum of individual outcome counts not add up to the overall count for the product?
- How do I scroll in the “Listing of Cases” table?
- Can I rearrange columns in the “Listing of Cases” table?
- Some of the cells seem to be showing only partial data. How can I see the entire content of such cells?
- How do I filter and sort data in the “Listing of Cases” table?
- How do I download data from the “Listing of Cases” table?

EXHIBIT 58

Supplemental Approval Letter from FDA to Danco Laboratories, LLC (Apr. 11, 2019)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020687/S-022

SUPPLEMENT APPROVAL

Danco Laboratories, LLC
(b) (4), (b) (6)
P.O. Box 4816
New York, NY 10185

Dear (b) (4), (b) (6):

Please refer to your Supplemental New Drug Application (sNDA) dated November 4, 2015, received November 5, 2015, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mifeprex (mifepristone) Tablets.

This Prior Approval supplemental new drug application proposes modifications to the approved risk evaluation and mitigation strategy (REMS) for Mifeprex to establish a single, shared system (SSS) REMS for mifepristone products for the medical termination of intrauterine pregnancy and updates to the approved Prescribing Information, Medication Guide, and REMS materials including the Prescriber Agreement and Patient Agreement Forms to incorporate language reflecting the proposed SSS REMS.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at:

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Mifeprex (mifepristone) Tablets was originally approved on June 8, 2011. The most recent modification was approved on March 29, 2016. The REMS consists of elements to assure safe use, an implementation system, and a timetable for submission of assessments of the REMS. Your proposed modifications to the REMS establish a SSS REMS for the elements to assure safe use and the implementation system required for the reference listed drug (RLD) Mifeprex and ANDAs referencing Mifeprex, called the Mifepristone REMS Program.

Your proposed modified REMS, submitted on January 25, 2018, and appended to this letter, is approved.

The timetable for submission of assessments of the REMS must be revised to one year from the date of the initial approval of the SSS REMS (04/11/19) and every three years thereafter.

The revised REMS assessment plan must include, but is not limited to, the following:

Both cumulative data from the date of the initial approval of the SSS REMS (04/11/19) and data from the reporting period (i.e., from the preceding Mifeprex REMS assessment cut-off date to the cut-off date for the Mifepristone REMS Program.)

REMS Assessment Plan

Provide each metric for the current reporting period and cumulative for the RLD and ANDA(s):

1. Number of prescribers enrolled
2. Number of prescribers ordering mifepristone
3. Number of healthcare providers who attempted to order mifepristone who were not enrolled; describe actions taken
4. Number of women exposed to mifepristone
5. Summary and analysis of any program deviations and corrective action taken
6. Based on the information reported, an assessment and analysis of whether the REMS is meeting its goals and whether modifications to the REMS are needed

Reference ID: 4418041

The requirements for assessments of an approved REMS under section 505-1(g)(3) include with respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal or whether 1 or more such goals or such elements should be modified.

We remind you that in addition to the REMS assessments submitted according to the timetable in the approved REMS, you must include an adequate rationale to support any proposed REMS modification for the addition, modification, or removal of any of goal or element of the REMS, as described in section 505-1(g)(4) of the FDCA.

We also remind you that you must submit a REMS assessment when you submit any future supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of the FDCA. This assessment should include:

a) An evaluation of how the benefit-risk profile will or will not change with the new indication;
b) A determination of the implications of a change in the benefit-risk profile for the current REMS;
c) If the new indication for use introduces unexpected risks: A description of those risks and an evaluation of whether those risks can be appropriately managed with the currently approved REMS.
d) *If a REMS assessment was submitted in the 18 months prior to submission of the supplemental application for a new indication for use*: A statement about whether the REMS was meeting its goals at the time of that the last assessment and if any modifications of the REMS have been proposed since that assessment.
e) If a REMS assessment has not been submitted in the 18 months prior to submission of the supplemental application for a new indication for use: Provision of as many of the currently listed assessment plan items as is feasible.
f) *If you propose a REMS modification based on a change in the benefit-risk profile or because of the new indication of use, submit an adequate rationale to support the modification, including*: Provision of the reason(s) why the proposed REMS modification is necessary, the potential effect on the serious risk(s) for which the REMS was required, on patient access to the drug, and/or on the burden on the health care delivery system; and other appropriate evidence or data to support the proposed change. Additionally, include any changes to the assessment plan necessary to assess the proposed modified REMS. *If you are not proposing REMS modifications*, provide a rationale for why the REMS does not need to be modified.

If the assessment instruments and methodology for your REMS assessments are not included in the REMS supporting document, or if you propose changes to the submitted assessment instruments or methodology, you should update the REMS supporting document to include specific assessment instrument and methodology information at least 90 days before the assessments will be conducted. Updates to the REMS supporting document may be included in a new document that references previous REMS supporting document submission(s) for unchanged portions. Alternatively, updates may be made by modifying the complete previous

REMS supporting document, with all changes marked and highlighted. Prominently identify the submission containing the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

NDA 020687 REMS CORRESPONDENCE
(insert concise description of content in bold capital letters, e.g.,
UPDATE TO REMS SUPPORTING DOCUMENT - ASSESSMENT METHODOLOGY

An authorized generic drug under this NDA must have an approved REMS prior to marketing. Should you decide to market, sell, or distribute an authorized generic drug under this NDA, contact us to discuss what will be required in the authorized generic drug REMS submission.

We remind you that section 505-1(f)(8) of FDCA prohibits holders of an approved covered application with elements to assure safe use from using any element to block or delay approval of an application under section 505(b)(2) or (j). A violation of this provision in 505-1(f) could result in enforcement action.

Prominently identify any submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

NDA 020687 REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 020687/S-000/ SECONDARY TRACKING NUMBER
CHANGES BEING EFFECTED IN 30 DAYS
PROPOSED MINOR REMS MODIFICATION

Or

NEW SUPPLEMENT FOR NDA 020687/S-000/ SECONDARY TRACKING NUMBER
PRIOR APPROVAL SUPPLEMENT
PROPOSED REMS MODIFICATIONS DUE TO SAFETY LABEL CHANGES SUBMITTED IN SUPPLEMENT XXX

Or

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 020687/S-000
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

Should you choose to submit a REMS revision, prominently identify the submission containing the REMS revisions with the following wording in bold capital letters at the top of the first page

Reference ID: 4418041

of the submission:

REMS REVISIONS FOR NDA 020687

To facilitate review of your submission, we request that you submit your proposed modified REMS and other REMS-related materials in Microsoft Word format. If certain documents, such as enrollment forms, are only in PDF format, they may be submitted as such, but the preference is to include as many as possible in Word format.

SUBMISSION OF REMS DOCUMENT IN SPL FORMAT

FDA can accept the REMS document in Structured Product Labeling (SPL) format. If you intend to submit the REMS document in SPL format, as soon as possible, but no later than 14 days from the date of this letter, submit the REMS document in SPL format using the FDA automated drug registration and listing system (eLIST).

For more information on submitting REMS in SPL format, please email REMS_Website@fda.hhs.gov.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call (b) (6)

Sincerely,

{See appended electronic signature page}

(b) (6)

Center for Drug Evaluation and Research

ENCLOSURES:

Content of Labeling
Prescribing Information
Medication Guide
REMS

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

(b) (6)

04/11/2019 02:13:59 PM

EXHIBIT 59

FDA Supplemental Approval Letter to Danco Laboratories, LLC (May 14, 2021)

NDA 020687/S-024

SUPPLEMENT APPROVAL

Danco Laboratories, LLC
(b) (4), (b) (6)

P.O. Box 4816
New York, NY 10185

Dear (b) (4), (b) (6):

Please refer to your supplemental new drug application (sNDA) dated and received March 15, 2021, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mifeprex (mifepristone) Tablets.

This Changes Being Effected sNDA provides for changes to the single, shared system risk evaluation and mitigation strategy (REMS) for mifepristone products for the medical termination of intrauterine pregnancy, known as the Mifepristone REMS Program, to include gender neutral language in the Patient Agreement Form. This sNDA also provides for minor changes to the REMS document to be consistent with the changes made to the Patient Agreement Form.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

The REMS for Mifeprex was originally approved on August 7, 2012, and the most recent REMS modification, establishing the Mifepristone REMS Program, was approved on April 11, 2019. The Mifepristone REMS Program consists of elements to assure safe use, an implementation system, and a timetable for submission of assessments of the REMS. Your proposed modification to the Mifepristone REMS Program consists of a

revised Patient Agreement Form to include gender neutral language and minor revisions to the REMS document to be consistent with the revisions to the Patient Agreement Form.

The timetable for submission of assessments of the REMS remains the same as that approved on April 11, 2019.

There are no changes to the REMS assessment plan described in our April 11, 2019 letter.

We remind you that in addition to the REMS assessments submitted according to the timetable in the approved Mifepristone REMS Program, you must include an adequate rationale to support a proposed REMS modification for the addition, modification, or removal of any goal or element of the Mifepristone REMS Program, as described in section 505-1(g)(4) of the FDCA.

We also remind you that you must submit a REMS assessment when you submit a supplemental application for a new indication for use, as described in section 505-1(g)(2)(A) of the FDCA. This assessment should include:

a) An evaluation of how the benefit-risk profile will or will not change with the new indication;

b) A determination of the implications of a change in the benefit-risk profile for the current REMS;

c) *If the new indication for use introduces unexpected risks*: A description of those risks and an evaluation of whether those risks can be appropriately managed with the currently approved REMS.

d) *If a REMS assessment was submitted in the 18 months prior to submission of the supplemental application for a new indication for use*: A statement about whether the REMS was meeting its goals at the time of that last assessment and if any modifications of the REMS have been proposed since that assessment.

e) *If a REMS assessment has not been submitted in the 18 months prior to submission of the supplemental application for a new indication for use:* Provision of as many of the currently listed assessment plan items as is feasible.

f) *If you propose a REMS modification based on a change in the benefit-risk profile or because of the new indication of use, submit an adequate rationale to support the modification, including*: Provision of the reason(s) why the proposed REMS modification is necessary, the potential effect on the serious risk(s) for which the REMS was required, on patient access to the drug, and/or on the burden on the

health care delivery system; and other appropriate evidence or data to support the proposed change. Additionally, include any changes to the assessment plan necessary to assess the proposed modified REMS. *If you are not proposing REMS modifications*, provide a rationale for why the REMS does not need to be modified.

If the assessment instruments and methodology for your REMS assessments are not included in the REMS supporting document, or if you propose changes to the submitted assessment instruments or methodology, you should update the REMS supporting document to include specific assessment instrument and methodology information at least 90 days before the assessments will be conducted. Updates to the REMS supporting document may be included in a new document that references previous REMS supporting document submission(s) for unchanged portions. Alternatively, updates may be made by modifying the complete previous REMS supporting document, with all changes marked and highlighted. Prominently identify the submission containing the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

NDA 020687 REMS ASSESSMENT METHODOLOGY
(insert concise description of content in bold capital letters, e.g., ASSESSMENT METHODOLOGY, PROTOCOL, SURVEY METHODOLOGIES, AUDIT PLAN, DRUG USE STUDY)

An authorized generic drug under this NDA must have an approved REMS prior to marketing. Should you decide to market, sell, or distribute an authorized generic drug under this NDA, contact us to discuss what will be required in the authorized generic drug REMS submission.

We remind you that section 505-1(f)(8) of FDCA prohibits holders of an approved covered application with elements to assure safe use from using any element to block or delay approval of an application under section 505(b)(2) or (j). A violation of this provision in 505-1(f) could result in enforcement action.

Prominently identify any submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

NDA 020687 REMS ASSESSMENT

or

NEW SUPPLEMENT FOR NDA 020687/S-000
CHANGES BEING EFFECTED IN 30 DAYS
PROPOSED MINOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR NDA 020687/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED MAJOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR NDA 020687/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED REMS MODIFICATIONS DUE TO SAFETY LABELING CHANGES SUBMITTED IN SUPPLEMENT XXX

or

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 020687/S-000/
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

Should you choose to submit a REMS revision, prominently identify the submission containing the REMS revisions with the following wording in bold capital letters at the top of the first page of the submission:

REMS REVISIONS FOR NDA 020687

To facilitate review of your submission, we request that you submit your proposed modified REMS and other REMS-related materials in Microsoft Word format. If certain documents, such as enrollment forms, or website screenshots are only in PDF format, they may be submitted as such, but Word format is preferred.

SUBMISSION OF REMS DOCUMENT IN SPL FORMAT

FDA can accept the REMS document in Structured Product Labeling (SPL) format. If you intend to submit the REMS document in SPL format, as soon as possible, but no later than 14 days from the date of this letter, submit the REMS document in SPL format using the FDA automated drug registration and listing system (eLIST).

For more information on submitting REMS in SPL format, please email FDAREMSwebsite@fda.hhs.gov.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

If you have any questions, call (b) (6).

Sincerely,

{See appended electronic signature page}

(b) (6)

Center for Drug Evaluation and Research

ENCLOSURE:

- REMS

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

(b) (6)

05/14/2021 02:14:29 PM

EXHIBIT 60

Rachel Roubein, *'Shield' Laws Make it Easier to Send Abortion Pills to Banned States*, Washington Post (July 20, 2023)

This article was published more than **1 year ago**

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Health Brief

The Washington Post's essential guide to health policy news

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'Shield' laws make it easier to send abortion pills to banned states



Analysis by Rachel Roubein
with research by McKenzie Beard

July 20, 2023 at 7:14 a.m. EDT

Happy Thursday! A big shout out to **Caroline Kitchener** for her excellent reporting in the top of today's newsletter.

And one note: I'll be heading out on summer vacay for a few days, and you'll have a great rotating cast of Post reporters bringing you this newsletter. See you next week! In the meantime, send all your news and tips to mckenzie.beard@washpost.com.

Today's edition: A hearing continues today on a lawsuit seeking clarity over exceptions to Texas's strict abortion ban. Sen. **Bernie Sanders** (I-Vt.) introduces a competing bill to fund community health centers as a critical deadline nears. **But first ...**

Aid Access launches new way to send abortion pills into states with bans

There's a new, more efficient pipeline sending abortion pills into states with bans.

Europe-based **Aid Access,** one of the largest abortion pill suppliers, revamped its protocols in mid-June. **The result?** Doctors in certain Democratic-led states with "shield" laws can now mail and prescribe pills directly to patients in antiabortion states.

The new process could ignite a complex interstate battle over abortion, where U.S. doctors in blue states are empowered to legally circumvent abortion laws in red states. The move could also undermine abortion bans at a time when antiabortion groups and doctors are seeking to revoke the approval of key medication used in over half of all abortions in the country.

Our colleague **Caroline Kitchener** dove deep into the new effort — and here's what she found.

The details

Previously, Aid Access only allowed Europe-based doctors to prescribe abortion pills to women in states where abortion is restricted. Those pills were shipped from India, and often took weeks to get to patients, which could push abortions well into the second trimester. (The **Food and Drug Administration** has approved mifepristone through 10 weeks gestation, though some studies have shown it can be used safely and effectively later in pregnancy.)

But new laws enacted over the past year are helping to streamline the process. Democratic-led states have moved to protect medical professionals and others who practice in states where abortion is legal from potential punishment in states with bans. **New York, Massachusetts, Washington, Vermont** and **Colorado** explicitly protect abortion providers who mail pills to restricted states from inside their borders, Caroline writes.

The new landscape: In less than a month, seven U.S.-based providers affiliated with Aid Access have mailed **3,500 doses** of abortion pills to people residing in states with bans. All together, the small group could help facilitate at least **42,000 abortions** in antiabortion states in a year. (Those numbers could grow, of course, if more providers join in.)

- As one expert told Caroline, the shield laws are "a huge breakthrough for people who need abortions in banned states," said **David Cohen,** a **Drexel University** law professor who focuses on abortion legislation. "Providers are protected in many ways as long as they remain in the state with the shield law."

Could doctors face legal risks?

That's a key question. And it could ultimately be resolved by the courts.

Some lawyers say the doctors — who are preparing and packaging the pills sent to restricted states themselves — could face repercussions, even if they don't travel to states that prosecute abortion providers. Some wonder whether states with abortion bans would try to extradite medical providers from states with shield laws, though that could prove difficult.

Jonathan Mitchell, the former solicitor general of Texas and architect of the state's roughly six-week ban, said it seems too early to predict what will happen, but that "there absolutely is a world in which they could get in trouble for it." (In many states with bans, those found guilty of distributing abortion pills could be sentenced up to at least several years in prison.)

But some involved in the effort say they're not worried.

"Everything I'm doing is completely legal," a doctor in New York's Hudson Valley, who spoke on the condition of anonymity to protect her safety, told Caroline. "Texas might say I'm breaking their laws, but I don't live in Texas."

Read the full story here.

Reproductive wars

Testimony begins in hearing seeking clarity on Texas's abortion exceptions

Three women gave accounts yesterday of being denied abortions or given delayed medical care due to confusion over the exceptions in Texas's strict abortion laws.

The testimony in a Texas courtroom was often emotional. At one point, one woman was reading a letter from her doctor describing how her baby had been diagnosed with a condition incompatible with life. She became sick on the stand, and the judge quickly recessed.

The case, which was filed by the Center for Reproductive Rights, is believed to be the first lawsuit from women denied abortions since the nation's highest court overturned *Roe v. Wade* last summer. The hearing began yesterday, as three women and a doctor took the witness stand for the plaintiffs, and will continue today.

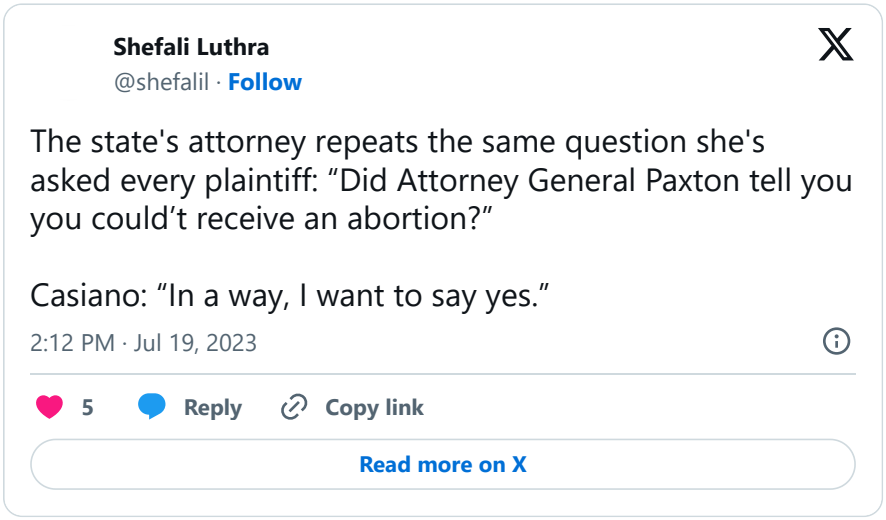
The legal challenge isn't seeking to overturn the state's abortion ban, but rather to clarify when an abortion is allowed in the case of a medical emergency. The plaintiffs are also seeking a temporary injunction blocking the state's ban in instances where a patient experiences a pregnancy complication.

During the hearing, **Molly Duane** — an attorney with the **Center for Reproductive Rights** — argued that the exceptions in the state's abortion ban are either "conflicting or lack definitions," and that doctors fear the high penalties they'd face if they're found to violate the law.

On the other side, **Amy Pletscher,** who represented the Republican attorney general's office, called the legal challenge an "ideological crusade."

"Plaintiffs simply do not like Texas's restrictions on abortion," she said.

Shefali Luthra, reporter at the 19th:



On the Hill

Sanders introduces bill to fund community health centers

Senate HELP Committee Chair Bernie Sanders (I-Vt.) unveiled a bill yesterday that aims to overhaul the country's primary health-care system — a move that indicates there isn't a bipartisan compromise in the Senate over funding for health centers that provide care to the country's most vulnerable.

The details: The legislation would invest **$20 billion** per year over a five-year period to expand community health centers and expand the health workforce. **The panel is slated to mark up the legislation next Wednesday.**

Sanders's proposal comes days after the panel's top Republican, Sen. **Bill Cassidy** (La.), introduced a bill to reauthorize the fund comprising roughly **70 percent** of federal dollars for health centers, which is set to expire Sept. 30. That legislation mirrors the funding plan the **House Energy and Commerce Committee** advanced with unanimous support in late May.

The view from Cassidy: "This is partisan legislation that cannot pass the Senate," he said in a statement. "There is already reauthorization legislation that unanimously passed out of the House E&C committee, has been introduced in the Senate and is endorsed by community health centers. **That is the bill we should mark up next week**."

EXHIBIT 61

Rachel Roubein, *How Blue States are Responding to the Post*-Roe *World*, Washington Post (June 21, 2023)

This article was published more than **1 year ago**

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How blue states are responding to the post-Roe world



Analysis by Rachel Roubein
with research by McKenzie Beard

June 21, 2023 at 8:11 a.m. EDT

Happy official first day of summer (the absolute best season) Send news and tips for the longest day of the year to rachel.roubein@washpost.com. Not a subscriber? Sign up here.

Today's edition: Half of OBGYNS in states with bans say they've had patients who were unable to obtain an abortion despite seeking one, a new survey finds. A federal judge strikes down Arkansas's first-in-the-nation ban on gender transition care for minors. **But first ...**

Democratic-led states are passing shield laws, solidifying abortion rights post-Roe

Democratic-led states rushed to shore up abortion protections in the first legislative season of the post-*Roe* era.

Lawmakers in blue states passed an array of bills, from solidifying abortion rights to expanding access to medication abortion to shielding providers who practice in states where abortion is legal.

The goal? Democrats are seeking to ensure abortion remains legal in their states, while continuing to serve as a destination for women who live in conservative areas with strict abortion bans. Their efforts this year built on legislation passed in 2022 in anticipation of the Supreme Court overturning *Roe v. Wade* — and some abortion rights advocates say it's just the beginning.

- "This is truly the next iteration of innovation and creativity at the state level, as well as at the local level," said **Andrea Miller,** the president of the **National Institute for Reproductive Health.**

We've written a lot about how abortion bans fared during state legislative sessions this year. This morning, we're turning to trends in states seeking to counteract such restrictions.

Trend #1: Some states sought to shore up abortion rights.

There were several prominent examples of this effort popular among liberal states and abortion rights groups.

In Minnesota: In a surprising upset during November's midterm elections, Democrats took full control of the state government for the first time since 2014. They rushed to enact a law codifying the right to an abortion into state law. (The procedure was already protected under a 1995 state Supreme Court decision, but supporters said they wanted to take the decision out of the hands of "individual judges.")

In Michigan: Democrats also won control of both the state House and Senate for the first time in nearly four decades. In April, Gov. **Gretchen Whitmer** (D) signed legislation to repeal a 1931 near-total abortion ban, which came after voters in the state approved a constitutional amendment to enshrine the right to an abortion into the state constitution.

In Maryland: The General Assembly gave the greenlight to let voters decide whether to enshrine abortion rights into the state constitution next year.

In New York: For the second time, state lawmakers passed an amendment to enshrine abortion rights into the state constitution. That means the measure will also now head to voters next year.

More from Whitmer:

Today, we are repealing Michigan's extreme 1931 law that bans abortion and criminalized nurses and doctors for doing their jobs.

This is long overdue. pic.twitter.com/PCOqJhTtb4
— Governor Gretchen Whitmer (@GovWhitmer) April 5, 2023

Trend #2: Democrats look to shield providers.

While the specifics in states may differ, this policy is generally aimed at protecting medical professionals and others who practice in states where abortion is legal from punishment in states with bans.

Advocates for such laws acknowledge there don't appear to be cases of charges filed against providers in such instances. But they say the new measures send a message and act as a guard against lawsuits.

In New York: The legislature gave approval yesterday to legislation granting legal protection for doctors in the state to prescribe and send abortion pills to patients in states with bans. Gov. **Kathy Hochul** (D) has indicated her support for the idea of a new shield law, per **the New York Times.**

The state certainly isn't the only one to enact new shield laws. In Vermont, Republican Gov. **Phil Scott** signed a shield law that explicitly protects access to mifepristone, even if the federal government withdraws approval of the commonly used abortion pill.

Other states passing various forms of shield laws include **Hawaii, Illinois, Minnesota, Colorado** and **several more.**

David S. Cohen, a professor at Drexel University's law school:

BIG NEWS out of New York. It becomes the fifth state to pass this type of shield law, but the first with providers who are openly talkingTh about how they are going to mail pills to ban states. 1/2 https://t.co/g75rKXqbJS
— David S. Cohen (@dsc250) June 20, 2023

Trend #3: States are testing out a smattering of new bills.

States tend to follow each other's lead, so it's worth watching closely what could emerge as a trend during the next legislative cycle.

Some bills that caught our eye:

- In **New York,** Hochul signed a bill aimed at ensuring all public colleges and universities offer medication abortion.
- In **Washington state,** a new law will ensure the Department of Corrections can sell, deliver, distribute and dispense abortion pills.
- And **Rhode Island** has become the latest state with a measure letting state funds cover abortion in the Medicaid program and for those on state employee insurance plans.

Meanwhile ... State and local governments are putting more money toward expanding access to abortion. Since the Supreme Court's decision, at least 15 municipal governments and six states have put **nearly $208 million** toward funding abortion, reproductive health services, patient navigation programs and other services, according to the **National Institute for Reproductive Health.**

Rhode Island Gov. Dan McKee (D):

Here in Rhode Island, we will always protect a woman's right to choose and ensure equal access to these crucial health care services.

I'm proud to sign the Equality in Abortion Coverage Act into law and include related funding in my budget proposal. pic.twitter.com/wJvHG6p5Q0
— Governor Dan McKee (@GovDanMcKee) May 18, 2023

Chart check

New this a.m.: How OBGYNs say new abortion restrictions are affecting maternal care

In the year since the Supreme Court overturned *Roe v. Wade*, half of OBGYNs working in states with abortion bans say they have had patients who were unable to terminate their pregnancies despite seeking to do so, according to a new survey out this morning from **KFF**.

By the numbers: Across the country, **68 percent** of OBGYNs said the effects of the *Dobbs* ruling have made managing pregnancy-related medical emergencies worse, while **64 percent** said they believe the ruling has exacerbated pregnancy-related mortality, according to the poll.

Zooming out: The findings represent the first nationally representative survey of OBGYNs since the ruling and provide one of the clearest views yet of how the decision has affected reproductive and sexual health care in the United States, The Post's **Kim Bellware** writes.

Transition care

Federal judge in Ark. blocks first ban on gender transition care

A federal judge struck down a law in Arkansas banning gender-affirming care for youth as unconstitutional yesterday, ruling that the first-in-the-nation ban violated the rights of doctors and discriminated against transgender people, our colleague **Anne Branigin** reports.

U.S. District Judge **James Moody** of the Eastern District of Arkansas issued a permanent injunction forbidding the enforcement of the ban, which he had previously temporarily blocked from taking effect. The state plans to appeal the decision, Arkansas Attorney General **Tim Griffin** (R) said in a statement yesterday.

The bigger picture: Moody's closely watched ruling marks the first time a federal court has decided the legality of such restrictions, which have been adopted by at least 20 additional states in recent years, according to data compiled by the **ACLU**.

Arkansas Gov. Sarah Huckabee Sanders (R):

This is not "care" — it's activists pushing a political agenda at the expense of our kids and subjecting them to permanent and harmful procedures.

Only in the far-Left's woke vision of America is it not appropriate to protect children.

We will fight this and the Attorney… https://t.co/7wCeR4I1Vo
— Sarah Huckabee Sanders (@SarahHuckabee) June 20, 2023

The ACLU of Arkansas:

VICTORY! A federal district court judge has ruled against the Arkansas law banning gender-affirming care for trans youth, marking a groundbreaking victory to #ProtectTransYouth. We stand with all brave Arkansans fighting for their right to thrive & be healthy. 🏳️‍⚧️ #arpx #arleg pic.twitter.com/TQrDoq3DED
— ACLU of Arkansas (@ArkansasACLU) June 20, 2023

Meanwhile …

The U.K.'s publicly funded **National Health Service for England** announced this month that it would limit the use of most puberty blockers for youth to clinical trials, saying more evidence is needed about their potential benefits and harms, the Wall Street Journal's **Jathon Sapsford** and **Stephanie Armour** reported over the weekend.

It's an argument that has cropped up among Republicans in Congress, with GOP lawmakers seizing on European doubts last week to support their push for increased caution and restrictions.

On the other side, Democrats contend Republicans are attempting to score political points. The U.S. medical community largely hasn't wavered in its support for clinical interventions. Last week, delegates from the **American Medical Association** endorsed a resolution reiterating support for access to gender-affirming care, saying that GOP claims "do not reflect the research landscape."

State scan

Inside how Gov. DeSantis used secretive panel to flip Florida Supreme Court

Our colleagues **Beth Reinhard** and **Josh Dawsey** published a deep dive yesterday on how Florida Gov. **Ron DeSantis** (R) seized on the unusual retirement of three liberal justices on the state Supreme Court at once to quickly reshape the panel into a conservative stronghold.

The details: After DeSantis narrowly won election in 2018, he enlisted the help of a secretive panel led by **Leonard Leo** — the key architect of the U.S. Supreme Court's conservative majority — to quietly vet judicial nominees to fill the vacancies.

The group grilled finalists on whether their principals matched those of the Federalist Society, an organization for conservative and libertarian attorneys that's led by Leo, people familiar with the process told The Post. DeSantis would go on to appoint three new justices in his first two weeks in office, flipping the court from what he described as a **4-3** liberal majority to a **6-1** conservative advantage.

Why it matters: The governor's efforts have yielded one of the most conservative state Supreme Courts in the country, and it is set to weigh the constitutionality of Florida's 15-week abortion ban in the coming months. A six-week ban that DeSantis approved this year also hangs in the balance, Beth and Josh write.

Our colleague Caroline Kitchener, who covers abortion for The Post:

> Soon, the FL supreme court is expected to issue a decision that will end most abortions in the third most populous state.
>
> DeSantis reshaped the court for this exact moment.
>
> Crucial reporting on how he did it, from @bethreinhard + @jdawsey1 https://t.co/C29lx3oDvd
> — Caroline Kitchener (@CAKitchener) June 20, 2023

In other news from the states ...

In Kansas: State officials have agreed to not yet enforce a new law requiring clinics to inform patients of the disputed notion that a medication abortion can be interrupted using an unproven drug regimen until a judge weighs in on a formal request to block it, the **Topeka Capital-Journal**'s **Andrew Bahl** reports.

In Missouri: A judge rejected Republican Attorney General **Andrew Bailey**'s bid to stop a constitutional amendment to restore abortion rights, ordering him to approve Republican Auditor **Scott Fitzpatrick**'s cost estimate of the proposal within 24 hours of the ruling, **Kurt Erickson** reports for the **St. Louis Post-Dispatch**.

In other health news

- **The Senate voted 51-43 yesterday to confirm Julie Rikelman** to the U.S. Court of Appeals for the 1st Circuit, overcoming opposition from some Republicans and antiabortion advocates over her work as an abortion rights attorney.
- **The Supreme Court threw out a lower-court ruling yesterday** stopping South Carolina from cutting off public funding to Planned Parenthood, remanding the case to the U.S. Court of Appeals for the 4th Circuit for further consideration.
- **On the move: Anne Esposito**, **PhRMA**'s senior vice president for federal advocacy, will leave the lobbying group later this summer after over three years at the organization, **Stat**'s **Rachel Cohrs** reports.
- **The U.S. Preventive Services Task Force finalized its recommendation yesterday** urging primary care providers for the first time to screen all adults younger than 65 for anxiety disorders, The Post's **Lindsey Bever** reports.

Health reads

EXHIBIT 62

Rebecca Grant, *Group Using 'Shield Laws' to Provide Abortion Care in States That Ban It*, The Guardian (July 23, 2023)

Abortion

This article is more than **1 year old**

Group using 'shield laws' to provide abortion care in states that ban it

Aid Access ships medication abortion to all 50 states under the protection provided to clinicians serving patients in banned states



Boxes of mifepristone. Each of the Aid Access providers is sending approximately 50 packages a day. Photograph: Evelyn Hockstein/Reuters

Rebecca Grant

Sun 23 Jul 2023 07.00 EDT

Dr Linda Prine is providing abortion access to people in all 50 states, even those that have banned it. That might seem like an admission to be discreet about in post-Roe America, but Prine and her colleagues at Aid Access, a telemedicine abortion service, are doing it openly and in a way they believe is on firm legal ground.

On 14 July, Aid Access announced that over the past month, a team of seven doctors, midwives and nurse practitioners have mailed medication abortion to 3,500 people under the protection of "shield laws", which protect clinicians who serve patients in states where providing abortion is illegal. As soon as she learned about shield laws, Prine knew it represented an opportunity to go on the offensive, for those bold enough to try it.

"It made me think, OK, we need to fight back," Prine said. "We can't just take this lying down. We've got to do something. And this was what we can do."

From its origins, Aid Access has always been willing to test legal boundaries. It was started in 2018 by the Dutch physician Dr Rebecca Gomperts. At the time, FDA regulations prevented licensed US providers from mailing mifepristone, one of the two drugs in the medication abortion regimen, so Aid Access was structured like Gomperts' other telemedicine service, Women on Web. That process involved abortion seekers filling out an online consultation, and if eligible, Gomperts wrote a prescription from Europe and the pills were dispatched by a pharmaceutical partner in India.

Then, in 2020, Covid hit. And a federal judge suspended the FDA's in-person dispensing requirement for mifepristone. For the first time, legally prescribed medication abortion could be put in the mail. Aid Access used this opportunity to implement a hybrid model: in states where telemedicine abortion was legal, US clinicians handled the prescriptions, while in states where it wasn't, the pills continued to be mailed from India.

One drawback of shipping from India was the packages could take weeks to arrive. In addition to the stress and uncertainty involved in waiting, the time lag could push people past the 12-week limit recommended by the World Health Organization (although there is some emerging research that abortion pills can safely be taken later.) Covid also created concerns about shipping delays, and there was always the chance that customs could seize the packages.

> *then needing to wait three or four weeks to get it to happen ... that's just so hard*
> **Dr Linda Prine**

"The whole experience of wanting an abortion and then needing to wait three or four weeks to get it to happen, and not even be sure if those pills are ever going to come, that's just so hard," said Prine, who started working with Aid Access in 2021. "Who wants to do that? Nobody."

In March 2022, Prine read an op-ed by three legal scholars - David S Cohen of Drexel University, Rachel Rebouché of Temple University, and Greer Donley of the University of Pittsburgh - that introduced her to the idea of shield laws. The trio had published a paper titled The New Abortion Battleground in the Columbia Law Review, which outlined the ways that shield laws could protect abortion providers who treated patients in banned states if Roe fell.

"Certainly, it's not a surprise that post-Dobbs, there are going to be medical care providers who want to push the limits and care for as many people as they can, including people in other states," Cohen said in an interview. "People are going to do this, so we were thinking about what can the states where they live do to help them the most?"

Inspired by their work, a wave of states started passing shield laws. The first, in Connecticut, passed in May 2022. Massachusetts, the fifth state to pass a shield law in July 2022, was the first to include a telemedicine provision, meaning the state pledged to protect a provider licensed there who prescribed and mailed medication abortion pills, via telemedicine, to a patient in a state where abortion was banned - like Texas or Alabama. Currently, 15 states have shield laws in place, and five - Massachusetts, Washington, Vermont, Colorado and New York - have specific telemedicine protections.

> *Post-Dobbs, there are going to be medical providers who want to push the limits and care for as many people as they can*
> **David S Cohen**

Before Aid Access, no US providers had publicly tested them. Then, on 18 June, the organization started serving patients nationwide with providers licensed in those five states. Up to 13 weeks, they offer prescriptions for $150 with a sliding scale that asks people to pay whatever they can afford, with a shipping time of two-five days. (In a physical clinic, the median cost of medication abortion is over $500.)

"Now Aid Access is completely US provider-led," Lauren Jacobson, a nurse practitioner licensed in Massachusetts who joined Aid Access in February 2023, told the Guardian this month. "I think this is important because it sends the broader message that this is an American issue, a US problem, and taking advantage of the shield laws means we are returning this to an at-home solution."

In addition to enabling faster shipping times, Jacobson said some people also feel more secure knowing that the pills are coming from licensed clinicians through an FDA-approved pipeline. This is part of what distinguishes Aid Access from abortion pill suppliers that operate through unofficial channels, such as unregulated online pharmacies and clandestine community networks. While the non-profit Plan C has found those medications to be as advertised, and reliably safe and effective (and also, in the case of community networks, free), they don't offer interaction with a licensed clinician, and some people want that support as part of the process.

Right now, each of the Aid Access providers is sending approximately 50 packages a day. Prine said all the packing and postage and shipping tasks are a "big pain in the rear", but it's manageable. They are prepared to scale, both in terms of infrastructure and in terms of the legal challenges their actions could invite.

Cohen suggests there will be a "coming battle" as shield laws get tested, and emphasized that providers have the greatest amount of protection while they are in shield law states. Jacobson and Prine are not overly concerned about legal repercussions, but that doesn't mean they're not taking precautions.

If it happens, it happens, and we are prepared," Prine said. "But I'm definitely not taking any vacations in Texas."

Because shield laws are designed to protect providers, patient risk is a separate factor - one that's particularly acute for people from communities that face heightened surveillance from law enforcement. A state doesn't need to have an explicit law criminalizing people who have abortions to prosecute them, often under unrelated statutes, like the illegal concealment of human remains. Even before Dobbs, people were arrested for self-managing abortions. The risk is real, but in a moment where people have too few options and time is of the essence, Prine said, every option counts.

"I do consults all the time, and people are not saying, 'What about the legality of this?'" Prine said. "That is not their concern. Their question is, 'How soon will the pills arrive?' That is the number one question."

More on this story

US appeals court upholds restrictions on abortion pill access

16 Aug 2023



Girl, 13, gives birth after she was raped and denied abortion in Mississippi

14 Aug 2023



Texas questions rights of fetus in prison guard lawsuit despite arguing opposite on abortion

12 Aug 2023



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EXHIBIT 63

Abigail Brooks and Dasha Burns, *How A Network of Abortion Pill Providers Works Together in the Wake of New Threats*, NBC News (April 7, 2024)

ABORTION RIGHTS

How a network of abortion pill providers works together in the wake of new threats

Groups such as Aid Access, Hey Jane and Just the Pill stay in close contact to help women seeking abortions in states with bans.



A shield law provider packs abortion pills into envelopes to be sent from New York to states with bans.

Callan Griffiths / NBC News

April 7, 2024, 6:00 AM CDT

By Abigail Brooks and Dasha Burns

When the U.S. Supreme Court heard oral arguments in March about restricting access to the abortion drug mifepristone, Elisa Wells, co-founder and co-director of Plan C, was ready.

Plan C, an information resource that connects women to abortion pill providers, almost immediately saw a spike in searches for the medication.

W

more search activity and more creative thinking from providers.

“When these egregious decisions happen, first, they cause harm,” she says. “And the second thing that happens is people get organized and mad and take action.”

Since the Supreme Court overturned Roe v. Wade in its 2022 Dobbs decision, upending abortion access in the U.S., a network of abortion providers has sprung into action, weaving an abortion safety net across the country even as the procedure has been effectively banned in 15 states.

Providers such as Aid Access, Hey Jane and Just the Pill operate both within and outside the established health care system – including mailing abortion medications to women in states with bans, setting up mobile clinics and offering financial assistance – often staying in close contact with one another.



— Bottles of Misoprostol Tablets. NBC News

Many of those efforts center on access to abortion medication by mail, which the Food and Drug Administration made fully legal in 2021, creating a sort of “sisterhood of the traveling pill” that keeps groups connected as new restrictions on abortion arise.

Wells says Plan C called different providers for a meeting on how best to pivot in the changing abortion landscape.

“

would be competing with one another to come together and discuss, you know, how can we make a difference? How can we collectively address this issue?”

One such group is Aid Access, an online-only service based in the Netherlands. Originally a resource for women in the U.S. to get abortion pills from overseas, providers for the organization now ship pills from within the U.S. under telemedicine shield laws. The shield laws have been enacted in six states: California, Colorado, Massachusetts, New York, Vermont and Washington. The laws protect providers who prescribe and ship abortion pills to patients who live in states where abortion is banned or severely restricted.

“Before we had the shield law, we were mailing pills to the blue states, and only [pills from] overseas could be sent to the restricted states,” said Dr. Linda Prine, a New York City-based shield law provider.

After New York’s shield law passed, Prine said, “the first month we sent about 4,000 pills into restricted states, and now we’re up to around 10,000 pills a month.”

In a basement in upstate New York, another Aid Access provider who asked to not be identified for safety reasons underscored the importance of sending these pills from the U.S., rather than overseas.

“Sometimes they got stuck in customs,” the provider explained as more than 100 prescriptions were being packaged around them, preparing to be shipped into states with bans.

“When you’re doing a medication abortion, the faster you can get these medications, the better,” the provider said in an interview. “It’s easier, there’s less bleeding, there’s less cramping, and not to mention the anxiety that these women go through when they’re waiting for those medications to get to them in the mail.”



— Boxes of pills will be packed into envelopes to ship around the country. Callan Griffiths / NBC News

Aid Access providers say they're sending pills to some who are in the most desperate situations – people who are willing to risk going outside the established health care system to access abortion services. The organization is exploring contingency plans in the event that access to the abortion pill through the mail is disrupted.

"We have so many patients who write to us who've been raped, who can't travel," the provider explained. "So we have to come up with other ways. I would say the last resort would be that these medications come again from overseas."

And while shield laws have yet to be challenged in courts, anti-abortion groups have taken notice.

"The fact remains that just because you are sitting in California does not mean that you are not violating the laws of Florida, Texas and 30 other states," Katie Daniel, state policy director for the anti-abortion group Susan B. Anthony Pro-Life America, told NBC News. "So I think they have a false sense of security about this."

In the six months after Dobbs, researchers saw an increase in women getting abortion medication outside the traditional health care system, with more than 27,000 additional instances, according to a recent study in the journal JAMA.

"These are groups like Las Libres, WeSaveUs, Arkansas Together," said Wells, who was a co-author of the study. "They're serving a significant number of people for an all volunteer-led effort."

Even within the traditional health care system, abortions via medication are increasing, too. Medication abortions accounted for 63% of all abortions in 2023, up 10% from the year before, according to research from reproductive rights think tank the Guttmacher Institute, making it the most common method for terminating a pregnancy.



— Envelopes filled with abortion pills. Callan Griffiths / NBC News

New York-based Hey Jane has seen that demand firsthand. Founder Kiki Freedman, an early Uber employee, launched the telemedicine-only abortion provider in 2018 after seeing other startups deliver medications and savings to customers via online-only prescription services. After the FDA eased restrictions on mifepristone prescriptions during pandemic, allowing women to get the abortion pill through the mail, Hey Jane took off. The company has shipped abortion pills to at least 50,000 patients, according to a statement.

“We have the added benefit of this sort of geographic fluidity where a doctor in New York can serve a patient in Illinois, or New Mexico if the doctor in New Mexico or the provider in New Mexico is busy,” said Freedman. “The other piece is financial accessibility and being able to access scalable ways of doing that, so via insurance, in particular.”

Hey Jane only prescribes and ships abortion medication to states where it’s legal, marking a difference from shield law providers and organizations like Aid Access.

Access to medication abortion helps patients avoid traveling and wait times at in-person clinics, and allows them to take the pills in private at home. While providers who ship to states with bans have struggled with traditional payment platforms, Hey Jane’s focus is on keeping access covered by insurance.

"Still, 75% of abortions are taking place in these 20 states we're in. It's still where the vast majority of care occurs," said Freedman. "It's not like access in those states has been seamless to date, right? It's always been difficult even there, and particularly post-Dobbs, wait times and things like that have really surged within those states."



Empty pill bottles in the basement of a shield law provider in New York will be filled with abortion medication.
Abigail Brooks / NBC News

Just the Pill provides abortion access to women in states with bans using discreet mobile clinics set up just across state lines.

The group has bulletproof vans in Colorado, Minnesota and Montana, and a brick-and-mortar location in Wyoming. Appointments are conducted via telemedicine, always within a state where abortion is legal, making shield laws unnecessary, a backstop a Just the Pill provider said is intentional, so care won't be interrupted if the shield laws are challenged.

"I totally support what these other organizations are doing," she said in an interview, asking not to be identified for safety reasons. "I'm cheering them on from afar, but want to make sure our service isn't challenged."

Just the Pill works with abortion funds, which provide financial assistance to patients who are seeking the procedure, to help patients travel across state lines for their appointments. After a telemedicine visit, pills are then prescribed and patients can pick them up and take them, all within the borders of a state where the procedure is

legal. Because Just the Pill's clinics are mobile, they can travel along the borders of banned states and ensure they get as close as possible to women traveling from rural areas or long distances for care.

Meanwhile, Plan C is already working with more international pill providers to help with telehealth prescription access in the U.S. if telehealth visits for mifepristone are affected here, Wells said.

"We know we live in a time when anything can happen," Wells said. "We want to have as many alternate routes and access as possible. Many eggs and many baskets."

Abigail Brooks
Abigail Brooks is a producer for NBC News.


Dasha Burns
Dasha Burns is a correspondent for NBC News.

EXHIBIT 64

Elissa Nadworny, I*nside a Medical Practice Sending Abortion Pills to States Where They're Banned*, NPR (Aug. 7, 2024)

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NATIONAL

Inside a medical practice sending abortion pills to states where they're banned

AUGUST 7, 2024 · 9:00 AM ET

Elissa Nadworny



“Welcome to modern abortion care,” says Angel Foster, who leads operations at what’s known as the MAP, a Massachusetts telehealth provider sending pills to people who live in states that ban or restrict abortion.

Elissa Nadworny/NPR

The packages, no bigger than a hardcover book, line the walls of the nondescript office near Boston. It's not an Etsy retailer or a Poshmark seller or, as the nearby post office workers believe, a thriving jewelry business.

These boxes contain abortion pills.

"Welcome to modern abortion care," says Angel Foster, as she holds up a box for mailing. Foster, who has an M.D. degree, leads operations at what's known as the MAP, a Massachusetts telehealth provider sending pills to people who live in states that ban or restrict abortion.

The MAP is one of just four organizations in the U.S. operating under recently enacted state shield laws, which circumvent traditional telemedicine laws requiring out-of-state health providers to be licensed in the states where patients are located. Eight states have enacted these shield laws.

Sponsor Message

Pregnant patients can fill out an online form, connect with a doctor via email or text and, if approved, receive the pills within a week, no matter which state they live in.



SHOTS - HEALTH NEWS

Abortion is becoming more common in primary care clinics as doctors challenge stigma

Shield law practices account for about 10% of abortions nationwide. There were 9,200 abortions a month provided under shield laws from January to March of this year, according to fresh data from the Society of Family Planning's WeCount project. And some researchers estimate that this number has risen since then and could be as high as 12,000 per month.

The rise of telehealth is part of why the number of abortions in the U.S. has continued to go up since the Supreme Court overturned *Roe v. Wade* in 2022 — even though 14 states have near-total abortion bans. In those states, shield law providers represent the only legal way people can access abortions within the established health care system.



"If you want to have your abortion care in your state and you live in Texas or Mississippi or Missouri, right now shield law provision is by far the most dominant way that you'd be able to get that care," says Foster.

Elissa Nadworny/NPR

Back in Massachusetts, Foster glances down at the list of today's patients. The practice's four OB-GYNs have signed off on prescriptions for nearly two dozen women — in Texas, Florida, Tennessee, Georgia, Alabama, Oklahoma and South Carolina. Most of today's patients are around six weeks along in their pregnancy. Many already have children.

"I really need an abortion pill. My state has banned it. My funds are really low," one patient wrote on the online form she filled out for the doctor.

"I'm a single mom with a kid under two," another wrote. "I can't afford a baby. I can't even afford this abortion."

Foster and her team serve patients who are up to 10 weeks pregnant and who are 16 or older. It costs $250 to get the two-drug regimen — mifepristone and misoprostol — in the mail, but there's a sliding scale and patients can pay as little as $5. The MAP is funded through abortion funds, individual donations and philanthropic gifts, and Foster has plans to apply for grants and state funding to help make the organization more sustainable. The MAP currently sends out about 500 prescriptions a month.

Yet to be tested in court, shield laws have some legal vulnerability

In the eight states with shield laws, abortion providers can treat out-of-state patients just as if they were in-state patients. The laws give abortion providers some protection from criminal prosecution, civil claims and extradition, among other threats. The laws have yet to be tested in court, but they certainly haven't gone unnoticed by lawmakers and groups looking to limit abortion.

"These websites are breaking the law … aiding and abetting crimes in Texas," says John Seago, the president of Texas Right to Life. "We want to use all the instruments that we have, all the tools available, to really fight against this new trend of abortion pills by mail."

Seago says providers should still be held responsible for committing a crime that is executed across state lines. "Mailing the abortion pill is a state jail felony according to our pro-life laws," he says, "but enforcement of those policies has been a real, real challenge."



Mifepristone, a drug used in abortion care, at the MAP's office in Massachusetts.
Elissa Nadworny/NPR

His organization has been looking for the right individual or circumstance to challenge shield laws directly in court. Three Republican-led states recently tried to sue the Food and Drug Administration over regulations allowing doctors to send pills through the mail, but the Supreme Court threw out the case in June over issues of standing. Those plaintiffs say they'll fight on. And a Republican attorney general in Arkansas sent a cease-and-desist letter to a shield law provider.

SHOTS - HEALTH NEWS



Seago thinks many conservative prosecutors have been hesitant to take legal action, especially in an election year. But he says it's important to act quickly, before abortion by mail becomes pervasive.

The people who are sending these pills know that there's risk in what they're doing. Some providers say they won't travel to or through states with bans so that they can't be subpoenaed, be served legal papers or even be arrested if there's a warrant. That may mean avoiding layovers at Dallas Love Field airport or a detour around those places on a cross-country road trip. For Foster, it means she can't visit her mom and stepdad, who retired to South Carolina.

"The thing about shield laws is that they're new, so we don't have a precedent to go off of," says Lauren Jacobson, a nurse practitioner who prescribes abortion medication through Aid Access, the largest of the four shield law providers. She says she avoids large swaths of the United States. "We don't really know what will or won't happen. But I'm not going to Texas. I've been before though, so that's OK for me."



SHOTS - HEALTH NEWS

Abortion bans still leave a 'gray area' for doctors after Idaho Supreme Court case

Shield laws don't offer blanket protection. The doctors and nurse practitioners who prescribe the pills have malpractice insurance in their states, but it's unclear whether those policies would cover suits from states with abortion restrictions. Patients use third-party payment services like Cash App or PayPal, which are also

untested in how they would work under a shield law. Would they give up information on a provider or patient if requested to do so by law enforcement?

How the experience looks

Lauren, who is 33 and lives in Utah, got pregnant while on birth control and decided that she couldn't afford another child. (NPR is not using her last name because she's worried about professional repercussions.)

Abortion is legal in Utah until 18 weeks, but there are only a handful of clinics in the state. The closest one to Lauren was several hours away by car. Several years prior, she had an abortion at a clinic in Salt Lake City, and it hadn't been a pleasant experience — she had to walk through protesters. The guilt from her conservative Christian upbringing was overwhelming.



Shield law practices account for about 10% of abortions nationwide. There were 9,200 abortions a month provided under shield laws from January to March of this year, according to fresh data from the Society of Family Planning's WeCount project. Some researchers estimate that this number has risen since then and could be as high as 12,000 per month.
Elissa Nadworny/NPR

"I got in my car and I cried," she recalls. "I just never wanted to go through it again."

This time, Lauren got pills from Aid Access, a shield law provider similar to the MAP. "I was a little bit sketched out, I won't lie," she says. "Because like, well, where is this coming from? Who is this under? How are they prescribing this?"

She and her partner did research to try to figure out whether what they were doing was legal. She says ultimately she couldn't find anything that clearly stated that what she wanted to do — have pills sent from an out-of-state doctor — was illegal.

She filled out a form online with questions about how far along she was and her medical history and then connected with a doctor via email and text messages. She googled the doctor, who she found was legit and practicing out of New York.

A few days later, she received abortion medication in the mail and had her abortion at home.

"To do it in the privacy of your own home, where I felt more support as opposed to going through protesters," Lauren says. "Especially with a provider within the state of Utah. I feel like there's always a judgmental indication or undertone."

The online doctor also followed up to make sure everything had gone OK, which Lauren appreciated. "I felt it was a little bit more thorough," she says. "They're checking in on you, like, 'How did you respond? What symptoms? What's going on?'"



A staff member of the MAP brings the boxes containing abortion medication to the local post office.
Elissa Nadworny/NPR

In Massachusetts, the folks who run the MAP hear much the same from their patients. Many emails and messages are logistical, like this email: "I took the first pill on Friday and all the other pills on Saturday. For how long should I be bleeding as I'm still bleeding this morning?"

Many others offer disbelief, relief and gratitude. "I just wanted to say thank you so much," wrote one woman. "I was terrified of this process. It goes against everything I believe in. I'm just not in a place where I can have a child. Thank you for making the pills easily accessible to me."

When Foster, who runs operations for the MAP, does a final tally of the patients who are ready to have their pills sent out, she notices a new note from a woman who just paid, bringing the day's total number of patients from 20 to 21.

"I am a single mother on a fixed income, and I can not afford a kid right now."

It's from a woman in Alabama who is six weeks pregnant and filled out her form around lunchtime. Within an hour, a MAP doctor had reviewed her case and prescribed her the medication. She paid the fee as soon as she was approved. All in all, the whole process took about three hours. Foster is able to pack up those pills and add them to the batch headed to the post office.

By 3 p.m., the Alabama woman's package is scanned by the Postal Service worker.

It's expected to arrive by the week's end.

abortion drugs mifepristone abortion provider misoprostol dobbs v jackson women's health organization roe v. wade



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EXHIBIT 65

Caroline Kitchener, *Blue-State Doctors Launch Abortion Pill Pipeline Into States With Bans*, Washington Post (July 19, 2023)

Abortion providers in Democrat-led states work with Aid Access to funnel pills into antiabortion states

washingtonpost.com/politics/2023/07/19/doctors-northeast-launch-abortion-pill-pipeline-into-states-with-bans

July 20, 2023

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Blue-state doctors launch abortion pill pipeline into states with bans

At least 3,500 doses have been shipped to antiabortion states since mid-June, a process enabled by new shield laws

A doctor reviews mailing labels as she prepares to ship abortion pills from her home in New York's Hudson Valley. (Nadia Sablin for The Washington Post)

11 min



By Caroline Kitchener
July 19, 2023 at 8:19 p.m. EDT

The doctor starts each day with a list of addresses and a label maker.

Sitting in her basement in New York's Hudson Valley, next to her grown children's old bunk beds, she reviews the list of towns and cities she'll be mailing to that day: Baton Rouge, Tucson, Houston.

A month ago, a phone call was the only thing the doctor could offer to women in states with abortion bans who faced unexpected pregnancies. Hamstrung by the laws, she could only coach them through the process of taking abortion pills they received from overseas suppliers.

Then, all of a sudden, the whole system changed. Now she can legally mail them pills herself.

A new procedure adopted in mid-June by one of the largest abortion pill suppliers, Europe-based Aid Access, allows U.S. medical professionals in certain Democratic-led states that have passed abortion "shield" laws to prescribe and mail pills directly to patients in antiabortion states.

Previously, Aid Access allowed only Europe-based doctors to prescribe abortion pills to women in states where abortion is restricted and then shipped those pills internationally, leaving patients to wait weeks. The telemedicine shield laws, enacted over the past year in New York, Massachusetts, Washington, Vermont and Colorado, explicitly protect abortion providers who mail pills to restricted states from inside their borders.

The result is a new pipeline of legally prescribed abortion pills flowing into states with abortion bans. In less than a month, seven U.S.-based providers affiliated with Aid Access — including the Hudson Valley doctor, who spoke on the condition of anonymity because she was concerned for her safety — have mailed 3,500 doses of abortion pills to people in antiabortion states, according to Aid Access, putting just this small group aloneon track to help facilitate at least 42,000 abortions in restricted states over the next year. If more doctors and nurses sign up, as current providers hope they will, the numbers could climb far higher.

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"Everything I'm doing is completely legal," the Hudson Valley doctor said, her family's ping-pong table covered with abortion pills bound for the South and Midwest, where abortion has been largely illegal since the Supreme Court overturned *Roe v. Wade* in June 2022.

"Texas might say I'm breaking their laws, but I don't live in Texas."

The development tees up a complicated interstate battle where doctors on U.S. soil are empowered to legally circumvent abortion laws — allowing blue states to potentially undermine the red state bans that many Republicans hoped would end abortion within their borders. Meanwhile, some conservative groups are angling to outlaw the abortion pill nationwide, attempting to outlaw the medication in the courts as well as calling for a national abortion ban.

The increasing flow of prescribed pills adds to an already expanding underground network for pills being imported from overseas and illegally distributed by abortion rights advocates largely without medical oversight, underscoring the prominent role pills are playing in post-*Roe* America.

The shield laws are “a huge breakthrough for people who need abortions in banned states,” said David Cohen, a Drexel University law professor who focuses on abortion legislation. “Providers are protected in many ways as long as they remain in the state with the shield law.”

Some lawyers say these doctors could face repercussions, even if they steer clear of traveling to states in which abortion bans call for prosecuting abortion providers. At a minimum, some experts said, the question of legal peril could wind up in a gray area ultimately resolved by the courts,such as whether shield law states have the power to block other states from extraditing people charged with crimes.

Major groups that support abortion rights, including Planned Parenthood and the American College of Obstetricians and Gynecologists (ACOG), have been largely silent on the subject of mailing pills from shield law states. Several Aid Access providers say the groups have expressed concern about backing the approach, worried that providers could put themselves at risk.

Molly Meegan, the ACOG’s general counsel and chief legal officer, said the group is “not positioned to provide legal advice to individual members,” adding that “it is wrong for a state to be able to prosecute clinicians and patients in other states where abortion remains legal and unrestricted.” Planned Parenthood issued a statement saying that its advocacy arm was “doing everything possible, and looking into every opportunity, to ensure that patients can access care no matter where they live.”

Jonathan Mitchell, the former solicitor general of Texas and architect of the state’s six-week abortion ban, said it was too early to predict how these shield laws would play out, but said the providers may face consequences.

“There absolutely is a world in which they could get in trouble for it,” he said. “Someone in Texas could do a sting operation and charge them with attempted murder.”

In many states, including Texas, someone found guilty of distributing abortion pills could be sentenced to at least several years in prison. Current abortion bans explicitly exempt those seeking abortions from prosecution, though prosecutors have a history of charging people who have abortions with other crimes.

The Hudson Valley doctor said she’s not worried about her own legal risk. When she arrives at the post office with dozens of new packages every afternoon, she said, no one ever asks any questions.

“Nobody has any idea. I could be doing so many different mailer businesses from home,” she said. “It could be beaded necklaces. It could be soaps. It could be candy.”

Massachusetts passed the first telemedicine abortion shield law of its kind just days after *Roe v. Wade* was overturned. The most recent law passed in New York in mid-June.

The New York law specifies that no state or local government employee “shall cooperate with or provide information to any individual or out-of-state agency or department regarding any legally protected health activity in this state.”

With shield laws, abortion rights advocates have seized an opportunity to “define the landscape,” said Julie F. Kay, a human rights lawyer and the legal director of the Abortion Coalition for Telemedicine Access. One key question that could emerge in the coming months is whether prosecutors in any antiabortion states would attempt to extradite medical providers from shield law states, thereby challenging the power of the new laws.

Kay said that traditional extradition laws would be difficult to apply in these circumstances.

“One state can extradite if a person commits the crime in the state, then flees,” Kay said. “But no one is fleeing here. You are just sitting in your office in New York.”

Aid Access started sending abortion pills to women in the United States long before the June 2022 Supreme Court ruling. The service, which costs $150 or less, is far cheaper than having a surgical abortion or obtaining medication at a clinic — usually between $500 and $800 — making it an appealing option even to people in states where abortion is readily accessible.

Once *Roe* fell, the organization operated in a legal gray area, shipping pills to antiabortion states from India. Aid Access providers mail pills sealed in clearly marked boxes, setting the organization apart from many other overseas pills suppliers, which send pills without a prescription, sometimes unmarked and unsealed.

Demand for pills from Aid Access has soared since the June 2022 Supreme Court ruling, with the organization receiving almost 60 percent more requests for pills this spring than in the months immediately following the decision, according to Abigail Aiken, lead investigator of the Self-managed Abortion Needs Assessment Project at the University of Texas at Austin. People seeking an abortion often find the group online, then make their request through its website. The request gets forwarded to one of the providers.

U.S.-based Aid Access providers were used to the process of receiving and processing requests for abortion pills, accustomed to working with patients in states where abortion is legal — but the process of ordering the medication and mailing it out was far less familiar.

The providers order mifepristone and misoprostol — the pills in a two-step medication abortion regimen — from licensed pill distributors, and ship out the pills to patients fairly quickly along with detailed instructions.

Before the recent change in procedure, the Aid Access providers would send all of their prescriptions to an online pharmacy in California to handle shipping, one of two online pharmacies nationwide that dispenses abortion pills. But neither of those pharmacies is located in a state with a shield law. Until California passes one, a development that is expected this fall, the doctors have to prepare and package the pills bound for restricted states themselves, creating their own labels to stick on the pill boxes they receive, providers said. (Doctors are legally permitted to order and distribute pills on their own, the providers said — it’s just not typical.)

“We’re medical providers suddenly thrown into this world of shipping,” said Lauren Jacobson, a nurse practitioner who operates out of Massachusetts. “Do we write labels by hand? What if we mess up an address? How on earth do we ship 50 packages a day?”

Jacobson concedes that this system is far from perfect. While medication abortion is overwhelmingly safe and effective, she said, on rare occasions her patients in restricted states require in-person care — and they fear the legal risk that could come with a trip to the hospital. In those cases, she said, she will try to help them navigate their state’s health-care system safely, searching online for a trustworthy provider and advising them on what to say. Sometimes, she said, she’ll go on LinkedIn and scope out the local OB/GYNs, searching for someone who has posted something that supports abortion rights.

“This isn’t normal health care,” she said. “We don’t want to have to do this.”

Providers also recognize that many patients prefer or require a surgical procedure to end their pregnancy instead of pills.

One major impetus for Aid Access changing its protocol was the shipping time, said Linda Prine, an Aid Access provider and doctor based in New York. Patients would have to wait weeks for pills shipped from India, she said, often pushing their abortions well into the second trimester — a far more difficult and complicated process. (The U.S. Food and Drug Administration endorses the use of abortion pills up to 10 weeks, though some studies show it's safe and effective to use them significantly later in pregnancy.)

"They were having a really scary miserable experience," Prine said, with some far enough along that they wouldpass a recognizable fetus.

Prine founded the Miscarriage and Abortion Hotline, where people often call with questions about medication abortion. Since Aid Access's protocol change, she said, she has noticed a significant decrease in calls from women who are taking pills in their second trimester.

Eventually, the Aid Access providers fully expect Republicans to take a swing at their efforts.

"We're all like, 'Okay which one of us is going to be the case?'" said the doctor in the Hudson Valley. "It's not if there will be lawsuits, it's when."

Jacobson said she trusts the Massachusetts courts to protect her.

"We have seven American providers who are stepping in and saying, 'You know what, we're not going to be intimidated,'" Jacobson said.

The providers are eagerly waiting for the shield law to pass in California.

Once that passes, the Hudson Valley doctor may no longer have to run a complex shipping operation from her basement. She'll likely be able to send her prescriptions to the pharmacy, just like she used to, she said.

For now, she said, she doesn't mind staying up until 1 a.m. to finish the packing.

"It feels like I'm giving a big middle finger to that part of the country that has done this," she said.

U.S. abortion access, reproductive rights

Tracking abortion access in the United States: Since the Supreme Court struck down *Roe v. Wade*, the legality of abortion has been left to individual states. The Washington Post is tracking states where abortion is legal, banned or under threat.

Abortion and the election: Voters in about a dozen states could decide the fate of abortion rights with constitutional amendments on the ballot in a pivotal election year. Here's where Vice President Kamala Harris and former president Donald Trump stand on abortion.

Abortion pills: The Supreme Court refused to limit access to the abortion pill mifepristone. Here's how mifepristone is used and where you can legally access the abortion pill.

Reproductive rights: The Senate voted to block a bill to create a federal right to contraception access. Since *Roe v. Wade* was overturned, far-right conservatives have been trying to curtail birth-control accessby sowing misinformation about how various methods work to prevent pregnancy. See how every senator voted on the Right to Contraception Act.

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EXHIBIT 66

Caroline Kitchener, *Alone in a Bathroom: The Fear and Uncertainty of a Post-Roe Medication Abortion,* Washington Post (April 11, 2024)

Alone in a bathroom:

The fear and uncertainty of a post-Roe medication abortion

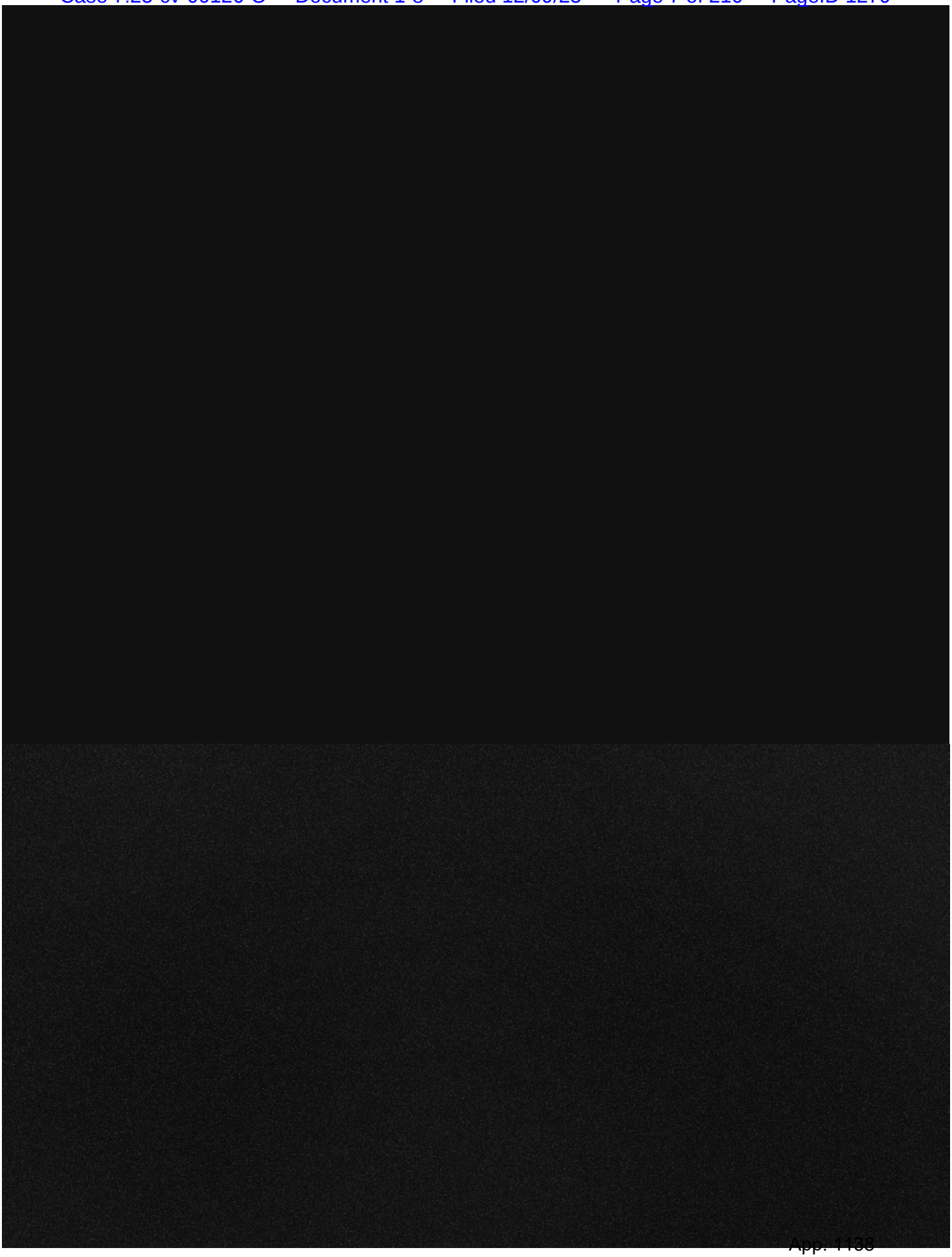
By Caroline Kitchener

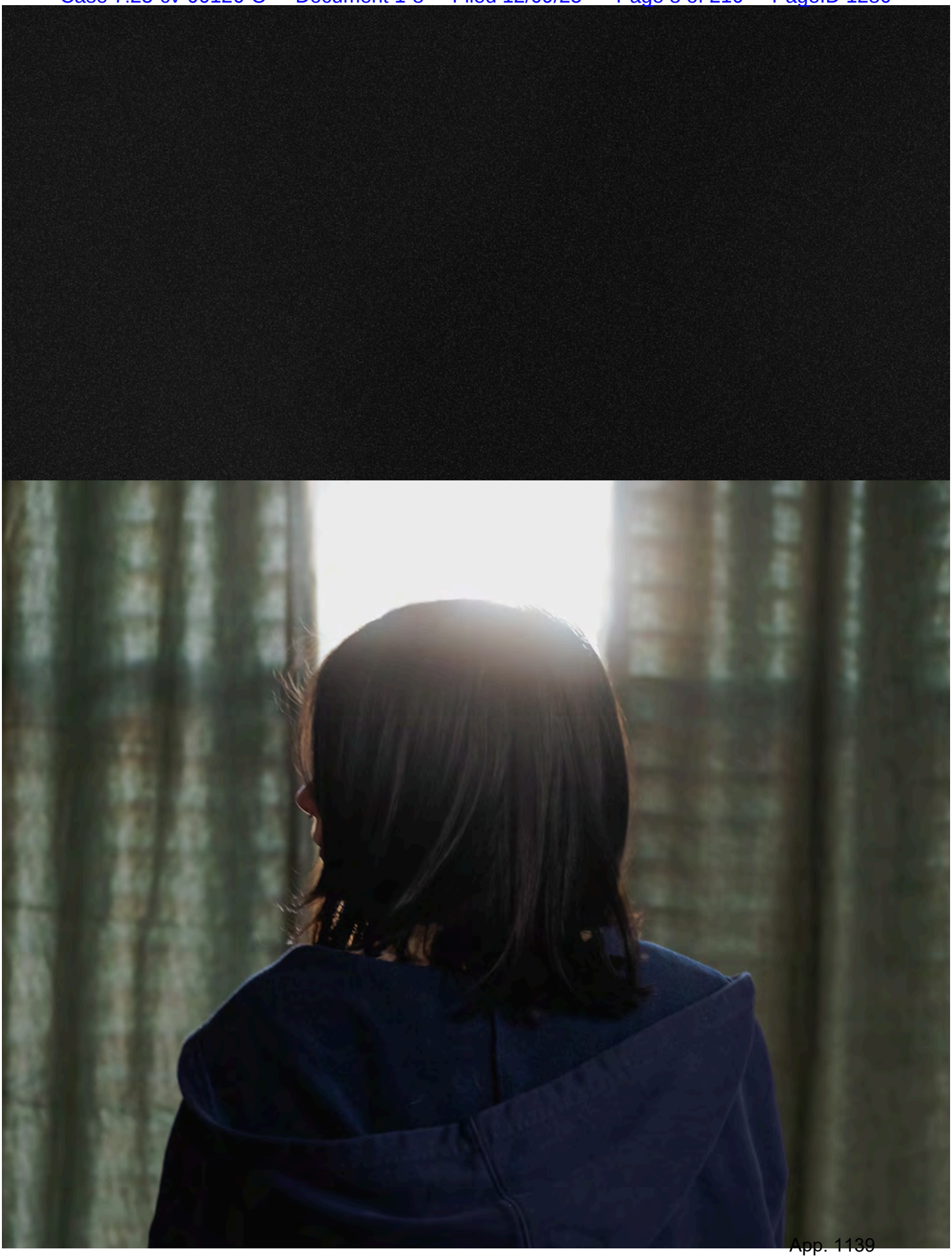
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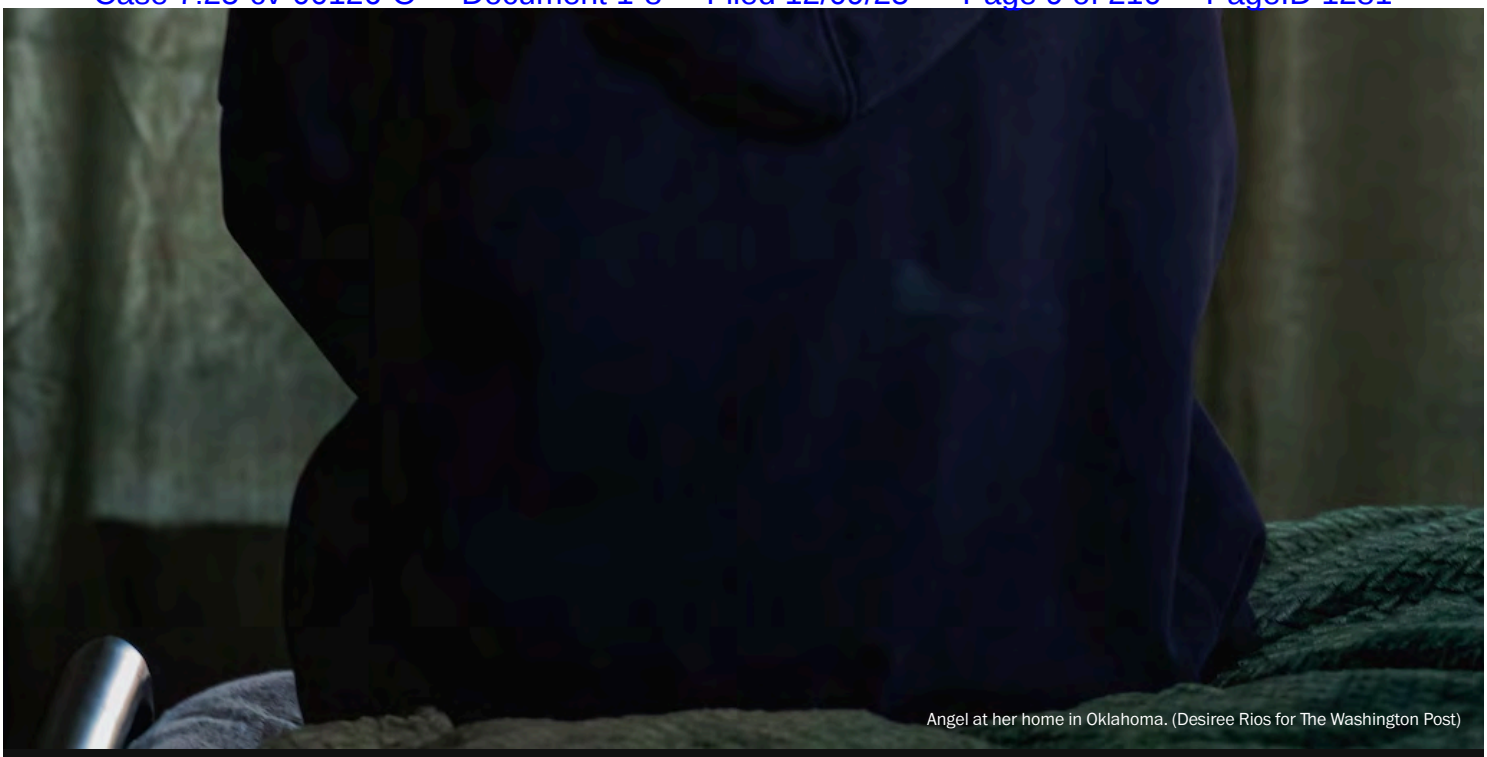
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Angel tucked two white pills into each side of her mouth, bracing herself as they began to dissolve.







Angel at her home in Oklahoma. (Desiree Rios for The Washington Post)

Angel had wanted to talk to a doctor before she took the pills to end her pregnancy, worried about how they might interact with medication she took for her heart condition.

But in her home state of Oklahoma, where almost all abortions are banned, that wasn't an option.

The pain kicked in after about an hour, around midnight on a Sunday in January, eventually becoming sharp enough that the 23-year-old said she struggled to stand. While Angel would be fine by the next morning, she worried that something might be very wrong as she lay on the cold bathroom tile, her body racked by some of the worst pain she could remember.

When Angel's fiance came in to check on her, she was having diarrhea while vomiting into their popcorn bowl.

"F---," she remembered yelling, over and over. "I feel like I need to push."

Overwhelming evidence shows that abortion pills are safe and effective, and that many patients who take them go through the process without much difficulty, experiencing little more than the sharp cramping and bleeding of an unusually heavy period. That is true even when the pills, approved by the U.S. Food and Drug Administration with a prescription for use through 10 weeks of pregnancy, are taken somewhat independently — administered by a doctor over text, email, or a call and mailed to the patient at home.

But the experience can feel very different in states where abortion is illegal. As more women in states with abortion bans choose to end their pregnancies on their own, without directly interacting with a medical professional, they are thrust into a largely ad hoc, unregulated system of online and grass-roots abortion pill distributors — an experience that, while deemed generally safe by medical experts, can be confusing, scary and, at times, deeply traumatic.

"I feel like I need to push."

"Self-managed" abortions increased dramatically after *Roe v. Wade* was overturned — with women in antiabortion states obtaining pills through several distinct channels. At least 6,000 women every month in states with bans are now receiving pills from Aid Access, a Europe-based online clinic that prescribes the medication without requiring a patient to interact with a doctor in real time, according to founder Rebecca Gomperts. Thousands of others are turning to at least 25 nonmedical websites that sell the pills, or one of several volunteer-led networks that distribute them for free.

With abortion clinics shuttered across the South and Midwest, many women said they have nowhere to go to confirm that their abortion pill supplier is "legit" or that their symptoms after taking the medication are normal. They worry that a call to a doctor or a trip to the emergency room could land them in jail. And while abortion rights advocates have tried to build new infrastructure to support women in these situations — with volunteer doctors answering phone calls or former abortion providers staffing the occasional bricks-and-mortar office in an antiabortion state — organizers say that such resources are no replacement for the array of choices women had before *Roe* fell.

The demand for self-managed abortions in states with bans, already enormous, is sure to increase dramatically in the coming weeks, as strict new abortion laws

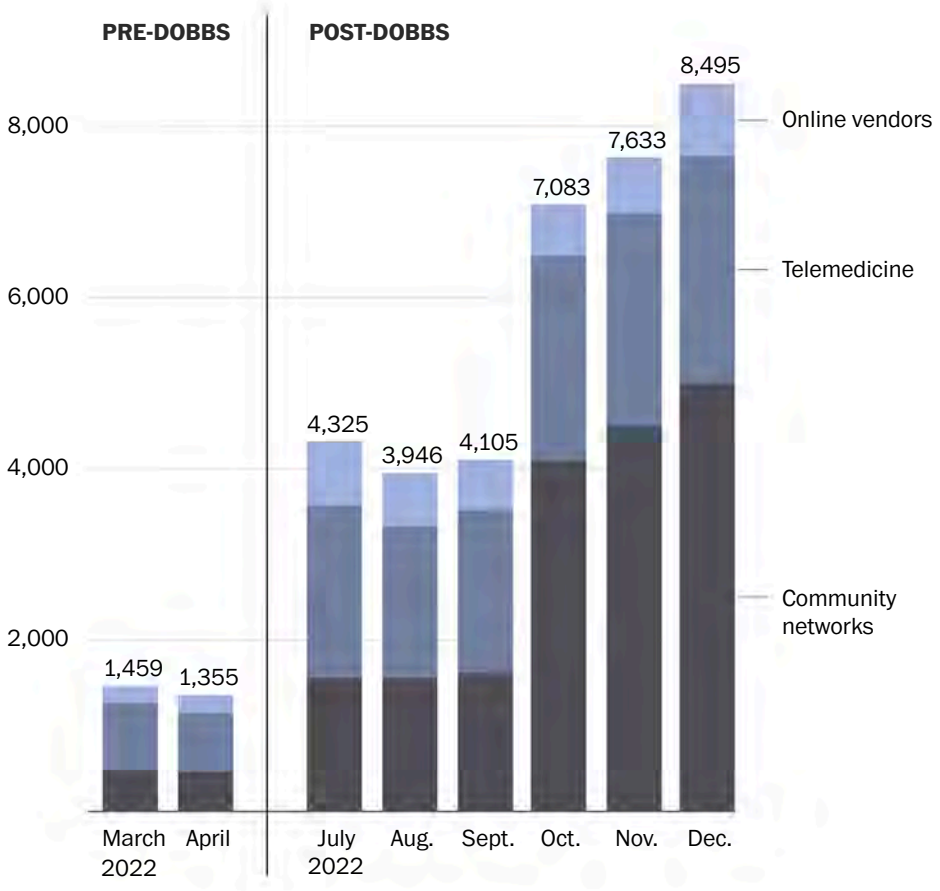
take effect in Florida and Arizona — the result of two recent court rulings.

"This is not the way health care should be," said Linda Prine, a New York-based doctor who prescribes pills through Aid Access and co-founded a hotline for people taking them. "All the options have been taken away from people by these bans and this is all that's left," she added, referring to the networks providing pills for women self-managing their abortions.

"It really is all we can do."

Supply of abortion pills for self-managed abortions

The supply of abortion pills outside of the formal health-care setting increased sharply in the six months after *Dobbs v. Jackson Women's Health Organization*, a landmark ruling that eliminated the constitutional right to abortion. A major factor in the increase was the rise of community-based, volunteer-led networks that organized to help women in states with abortion bans.



Source: JAMA (2024)

Adding to the difficulty is a polarized political debate with dueling narratives about what it's actually like to take abortion pills. Antiabortion activists say the pills are highly dangerous, or even deadly, for pregnant women — false assertions based largely on studies that have now been retracted by the journal that published them. Meanwhile, many abortion rights advocates describe the experience as straightforward and easy to handle on your own, a

characterization that some women say glosses over what can be a more complicated reality of ending a pregnancy alone in your bathroom.

The Washington Post spoke with more than three dozen doctors, advocates, leading researchers, and women who took the pills in states where abortion has been banned since *Dobbs v. Jackson Women's Health Organization,* the Supreme Court case that overturned *Roe* in June 2022. Over the phone and in person, many women described experiencing deep anxiety and uncertainty about doing something they assumed was illegal. These feelings often intensified after they took the medication, with some not expecting the level of pain or amount of bleeding they would experience, or how much of the fetus they would see. A few used the pills later in pregnancy than the FDA recommends.

"I wish I would have known that it wasn't just blood clots. … I was really confused and shocked," said Briana, a 34-year-old in Alabama who took pills she ordered online when she was at least five weeks beyond the FDA's 10-week limit. Like other women interviewed for this article, Briana spoke on the condition that her last name not be used so she could discuss sensitive medical information in a state that outlaws abortion — describing her experience in graphic detail because she said she wanted other women to know what to expect.

The complex legal landscape can be hard to understand. Abortion bans do not allow people seeking abortions to be prosecuted, targeting only doctors and others involved in facilitating the abortion. But people have been charged under other laws for self-managing their abortions, especially later in pregnancy.

A legal challenge to the abortion drug mifepristone brought by conservative advocates — which drew skeptical questions from the Supreme Court during oral arguments last month — seeks to further restrict the post-*Roe* landscape by requiring in-person medical visits for all legally administered medication abortions. Such a change could prevent U.S.-based medical providers from mailing pills into antiabortion states under "shield laws," recently enacted in a handful of blue states, that protect doctors from prosecution under red state bans.



Angel pours out her heart medication at her home. (Desiree Rios for The Washington Post)



Angel was worried about how abortion pills might interact with medication she takes for her heart condition.

In Oklahoma, Angel ordered her pills from Aid Access, according to emails reviewed by The Post, and took them five to six weeks into her pregnancy. She'd told doctors at the online clinic about her heart medication when she filled out its online form, she said, but no one ever reached out about it — a silence easily explained, Prine said, because Angel's medication is not one that would raise concerns.

Angel had no way of knowing that.

Sitting on the toilet, she could hear her heart pounding in her ears. She placed two fingers on the side of her neck to take her pulse and started a timer, she recalled — counting about 190 beats per minute.

With her heart condition, she said, she was supposed to seek medical attention if her heart rate got that high.

Angel had no idea who to call. She vaguely remembered a hotline number in the Aid Access instructions, but figured the line would be closed that time of night.

The hospital didn't feel like an option, either. She worried about the questions she might get from suspicious doctors if she showed up at the emergency room.

She closed her eyes and tried to steady her breath, determined to keep her heart rate down. Then she spoke to herself as she imagined a doctor might.

"You will be okay," said Angel, who would wake up the next morning no longer pregnant, the worst moments of her abortion behind her.

"This pain can't last forever."

"Your body will be just fine."

"Your uterus knows what to do."

A doctor answers panicked calls

"It's normal to be scared."

"Just wait it out."

"Call back any time."

Linda Prine was answering a few emails, coffee mug in hand, when her cellphone rang.

"Hi, this is the hotline doctor," the 72-year-old said from her New York City home one Sunday morning in January. "Can I help you?"

The voice Prine heard was quiet and scared — belonging to a 15-year-old with an area code in a state with an abortion ban who had taken pills and passed a fetus larger than she'd expected.

Unable to flush the fetus down the toilet, the girl asked about throwing it away.

She was young enough to be Prine's granddaughter.

Prine cradled the phone in both hands and leaned in, trying to channel every ounce of reassurance and understanding she could muster through the phone line.

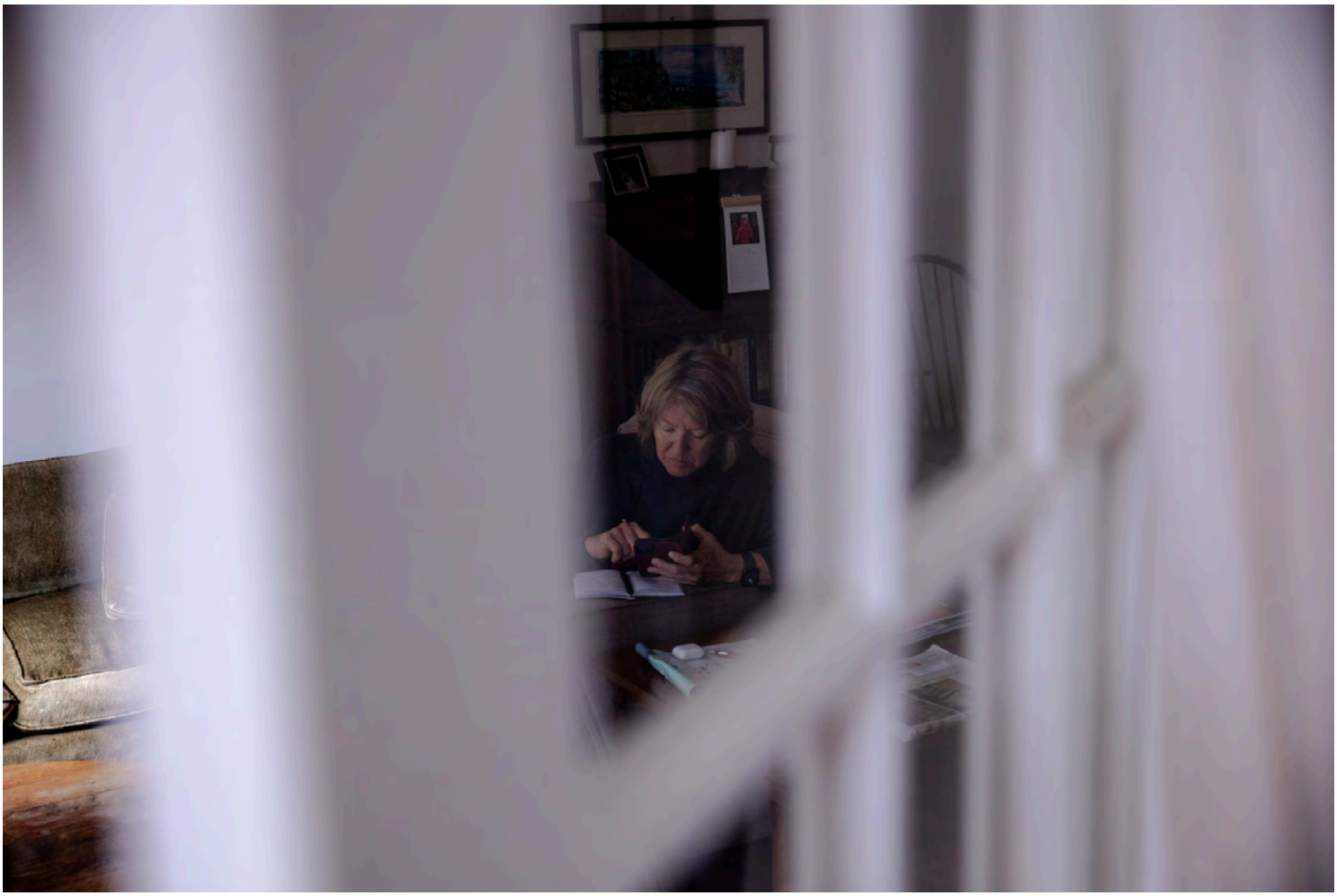
There's nothing in there that's traceable back to you," she said. "As long as you don't tell anybody."

The girl asked if the abortion made her a bad person.

"No it doesn't," Prine said. "Not a bit."

"You are doing what's right for you and your future family," she added, her voice firm.

"This way you can be a good mom when you're ready to be a good mom."



Linda Prine answers calls and texts for the Miscarriage and Abortion Hotline. (Natalie Keyssar for The Washington Post)

A semiretired family medicine physician, Prine co-founded the Miscarriage and Abortion Hotline in 2019 as a resource for people self-managing miscarriages or abortions at home. She got the idea from Gomperts, of Aid Access, who had already been mailing pills to Americans who struggled to access abortion. The American patients had a lot of questions and concerns about ordering pills outside a formal health-care setting, Gomperts told Prine — and her inbox was constantly flooded with emails.

They needed a U.S.-based doctor to call.

> "You are doing what's right for you and your future family."

Calls to the hotline surged after Texas enacted an early law banning most abortions in the fall of 2021, Prine said, and again after new abortion bans took effect across the South and Midwest when *Roe* fell. Now the line is staffed by over 50 U.S.-based medical providers who volunteer their time, a mix of doctors, midwives, nurse practitioners and physician assistants with experience in abortion care. The doctors who run the hotline recruit volunteers through word-of-mouth recommendations, then administer a few hours of virtual training before they start.

In interviews, Prine stressed that hotline doctors are not practicing medicine under their licenses or establishing a doctor-patient relationship — a posture Prine said legally protects the physicians. By design, the hotline volunteers don't ask for the names, locations or full medical histories of the people who call. On the hotline's website, a disclaimer notes that they are not offering "legal or medical advice," and that the information they provide "does not substitute for the … advice of a doctor."

The hotline typically receives roughly 30 calls and 50 texts from people every day. Many say they are in states that ban abortion.

"They'll say, 'I'm in a state where this is illegal, so I can't go get medical care. I want to check in and make sure everything is going okay,'" Prine said.

She and her colleagues hear the same questions again and again: Am I bleeding too much? Am I not bleeding enough? Is it normal to have this much pain? People call to see if they can drink alcohol or smoke marijuana after taking the pills. One woman asked whether it was safe to walk up the stairs.

[What to know after taking abortion pills]

Anxiety and uncertainty are common even among patients who receive the medication at an abortion clinic in a state where abortion is legal, said Prine — because they're at home by the time they start feeling the full effects.

"People from anywhere can be freaking out because everyone is taking these pills at home alone," Prine said.

Still, some feel better taking the pills after having a direct conversation with a medical professional. Since *Dobbs*, many women in antiabortion states who

have the resources to travel have continued to leave the state to obtain pills at a clinic instead of ordering online, preferring the experience of being face to face with a doctor, even if it means a long drive or a flight.



The Miscarriage and Abortion Hotline is staffed by over 50 U.S.-based medical providers, a mix of doctors, midwives, nurse practitioners and physician assistants with experience in abortion care. (Natalie Keyssar for The Washington Post)



A cross stitch at the home of Linda Prine.

For those who choose to self-manage their abortions, Prine said, she is there to offer reassurance that their experiences are nothing out of the ordinary, and that they almost certainly don't need to go to the emergency room. A medication abortion is just like a miscarriage, she'll tell them, with hundreds of women going through the same process every day.

Of the approximately 5.9 million patients in the United States who took mifepristone — the first drug in a two-step medication abortion regimen — between its 2000 approval and December 2022, just 32 died, according to the FDA. Those cases, the agency says, "cannot with certainty be causally attributed to mifepristone." Major adverse events — in which a blood transfusion, major surgery or overnight hospital stay is required — occur in fewer than 0.5 percent of cases, a figure that remains the same whether a patient has met with a doctor in person.

A significantly larger share of patients who take abortion pills seek emergency care, ranging from 1.3 to 8 percent in leading studies.

Adverse effects are extremely rare among those who take abortion pills

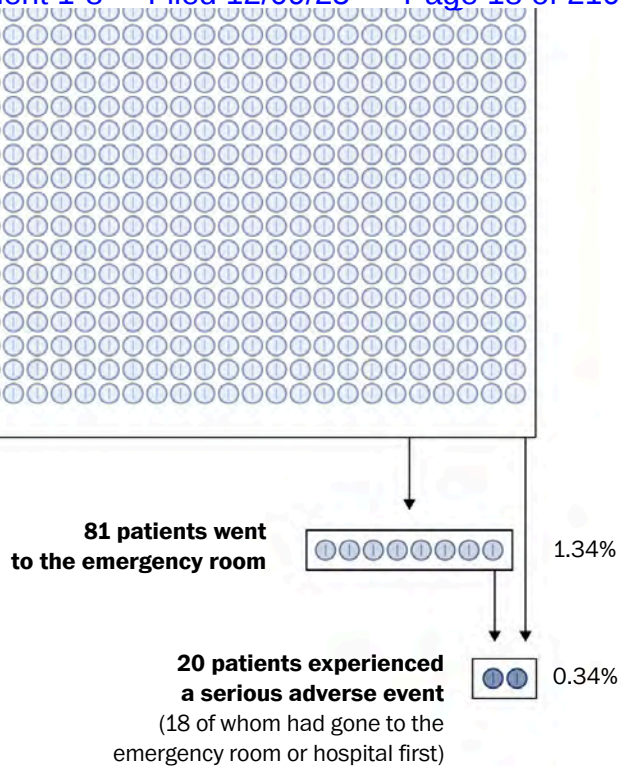
A tiny fraction of patients who take abortion pills have a serious adverse event such as a blood transfusion, major surgery or overnight hospital stay.

ⓘ = 10 estimated patients who took abortion pills

6,034 patients took abortion pills



100%



Note: Estimated patient numbers are based on percentages included in a 2024 study and are rounded to whole people.

Source: Ushma Upadhyay/Nature Medicine

Antiabortion activists portray those emergency room visits as an indication of a safety issue, but leading medical experts say they instead highlight the confusion and fear that many women experience after taking the pills. Patients often go for a gut check, doctors and medical researchers said, wanting to confirm that they're not bleeding too much, or that the pills worked and they are no longer pregnant. Studies show that 35 to 50 percent of people who go to an ER after taking abortion pills receive no treatment.

"With medication abortion, there's no one saying, 'You're doing great. This is normal,'" said Ushma Upadhyay, a professor at the University of California at San Francisco and a leading researcher on the safety of abortion pills, drawing a distinction between the pill and a surgical procedure. "Often people are going through it alone, so they want to know everything is okay."

On the hotline, Prine said she's felt the need to send someone to the emergency room only once in nearly five years.

"Your uterus knows what to do," Prine told a woman who called that January morning with reports of unexpectedly heavy bleeding. "It's going to take care of itself."

Others in the medical community are quicker to suggest that someone be seen in

person.

On the infrequent occasions when a patient calls with concerns about their medication abortion, Clayton Alfonso, an OB/GYN at Duke University, said he'll try to evaluate how much she is bleeding and how her body is tolerating the blood loss. But he said it can sometimes be difficult to make those assessments over the phone.

"When you take a patient call, it's always hard because their definition of heavy bleeding could be different from my definition of heavy bleeding," said Alfonso, adding that he usually tries to bring patients into his clinic if he has space on the schedule. "I would much rather see someone than leave someone in limbo at home not knowing what to do."

In states with abortion bans, the emergency room is often the only option for women who want in-person care during their medication abortions. Even if they say they had a miscarriage — a condition that presents with symptoms indistinguishable from a medication abortion — many women in these situations have bad experiences at the hospital, Prine said, encountering physicians who provide inaccurate information or ask suspicious questions about why they're bleeding.

"Your uterus knows what to do."

Prine said she recognizes that the landscape for self-managed abortions is tenuous. The antiabortion movement is ready to seize on any experience with pills that is difficult or complicated, she said, especially the relatively rare cases in which women take pills later in pregnancy.

At the Conservative Political Action Conference last year, prominent antiabortion activist Abby Johnson said women are delivering "fully formed babies" in their bathrooms — a false description of what women see during a medication abortion, even in the second trimester.

"They're passing these babies into the toilet," said Johnson, founder of the antiabortion group And Then There Were None. "Then these women have to make a decision: What do I do with this fully formed baby?... Do I flush my child down the toilet?"

These kinds of incendiary attacks make it hard for abortion rights advocates to discuss the details of a medication abortion later in pregnancy, said Prine and Gomperts — because the specifics could be weaponized by the antiabortion movement.

As a result, Prine said, women who take pills later in pregnancy are sometimes surprised by what they see.

"How much bleeding is normal?"

"Do I push it out?"

A woman struggles to pass her pregnancy

"Should I go to the hospital?"

"I'm totally alone."

At her home in Alabama, Briana waited to take the pills until she'd put all of her children to sleep.

The cramps in her lower back came first, followed by full-body chills and, eventually, contractions more painful than those she remembered from childbirth.

After lying in bed for two hours, Briana felt something "pop" under the comforter, followed by a gush of warm liquid seeping down her legs. She ran to the bathroom, she recalled in interviews and a journal entry, where she felt a mass larger than her palm drop into the toilet.

"This can't be happening," she thought to herself.

Then she looked down to see a bloody umbilical cord dangling between her legs.



When the pills first arrived in the mail a few days earlier, in April 2023, Briana had expected her experience would be more difficult than most. The doctors who administered the medication through Aid Access cautioned Briana that they "do

not like to recommend medical abortions" as far into pregnancy as she would be when the pills reached her, according to emails reviewed by The Post.

Briana felt she had no choice. By the time she found out she was pregnant, she was already 11 or 12 weeks along. The abortion clinic she'd called in a different state, more than a six-hour drive from her home in Alabama, where abortion is banned, was booked for surgical procedures for over a month, busy treating patients from other antiabortion states across the South. She spent nearly two weeks researching her other options, then the pills she ordered took two weeks to arrive.

The 34-year-old was struggling to support the kids she already had.

"I didn't want to take any more away from them ... time, attention, money," said Briana, who estimates that she was 15 or 16 weeks along when she took the pills.

"This can't be happening."

Experts and advocates say it is relatively rare for women to self-manage their abortions well beyond the FDA's 10-week limit, particularly since passage of the shield laws, allowing U.S.-based doctors to mail pills directly into antiabortion states instead of relying on international pharmacies. That change has reduced the shipment time from several weeks to between three and five days.

At the time Briana ordered her medication, over a year ago, Aid Access generally did not send pills to anyone who said they were further than 11 weeks into their pregnancy, Gomperts said. It now allows people to place orders through 12 weeks of pregnancy, because pills reach patients more quickly.

"If we think people might be longer than that, they get an email to make sure they can navigate the situation," said Gomperts, who personally prescribed Briana's medication, according to documentation reviewed by The Post. "Women have agency. They are perfectly capable of making these choices about their own health, and we are there to support them the best we can."

According to data compiled by Aid Access, and shared with The Post, 1 in 20 patients who responded to the organization's survey in January took the pills beyond 11 weeks of pregnancy. One in 100 took the pills beyond 13 weeks. (About 20 percent of people who took the pills responded to the survey.)

Still, Prine said, she has fielded far more of these calls from women later in pregnancy than she would like — averaging one a day on the hotline in the months after the Supreme Court decision. Some of the callers had no idea how

far along they were until they passed the pregnancy, she said. Others knew, but chose to go ahead anyway.

Beyond 12 or 13 weeks, women will see a much more developed fetus, with identifiable features.

“We hear the trauma when we talk to people,” Prine said. “It’s an image you can’t get out of your head.”

How we reported this story

Caroline Kitchener reported this story from four states. She witnessed Ashley’s ultrasound in Texas, watched Linda Prine answer hotline calls in New York, and interviewed Angel and Briana in Oklahoma and Alabama. She also spoke on the phone to women who self-managed their abortions at home.

Alone in her bathroom, Briana had no idea what to do. The Aid Access doctors had told her to expect nausea, vomiting, chills, blood clots and a fetus at least the size of an orange, emails show.

They said nothing about an umbilical cord.

“Do I pull the cord out?” Briana wondered, frantically trying to remember what the doctors had done when she gave birth. “Do I just wait to try to push it out?”

Her boyfriend was sleeping in the next room. Even if she woke him up, she wondered, what could he do? If she went to the emergency room, she said, she felt sure she’d be prosecuted.

Finally, Briana decided to call the number for the Miscarriage and Abortion Hotline she’d seen in an email from Aid Access.

“That’s the placenta you need to push out,” Briana recalled the woman on the hotline saying. “When you feel the next contraction, I want you to push like you’re giving birth.”

Briana said she sat there with her umbilical cord hanging loose for at least 15 minutes before the placenta finally dropped into the toilet.

While there are no major U.S.-based studies on the experience of self-managing an abortion with pills later in pregnancy, international research suggests that women in these situations more frequently seek in-person care. One study conducted with patients in Argentina, Nigeria and Southeast Asia between nine and 16 weeks of pregnancy found that about 24 percent went to a medical facility during or after the experience of taking the pills on their own. Approximately 10 percent required medical intervention to complete the abortion or treat a complication.

One major concern later in pregnancy is that the body won't be able to expel all of the pregnancy tissue, several doctors said.

When the Miscarriage and Abortion Hotline received its first call from a woman who was unable to pass her placenta — at least five weeks further into her pregnancy than the FDA's 10-week limit — a group of hotline doctors started messaging one another, trying to decide what to say to her, Prine said.

One doctor in the group insisted that the woman had to go straight to the ER, but Prine and others disagreed. Worried the woman could face prosecution or mistreatment if she went to the hospital, Prine said, they walked her through her abortion at home, instructing her to take more abortion pills and gently massage her stomach until the placenta came free — the same advice Briana said she received.

"We didn't feel like it was a medical emergency. She wasn't bleeding heavily and she wasn't lightheaded," said Prine, adding that they would have recommended the woman go the ER if a hospital visit was medically necessary.

A woman in that situation could have hemorrhaged or become septic, according to five OB/GYNs interviewed for this article.

"Whenever there is something inside the uterus that is trying to come out and won't come out, the risk of bleeding and infection gets higher with every passing moment," said Keri Garel, an OB/GYN at Boston Medical Center, adding that she would advise someone in Briana's situation to go to the hospital immediately. "At that point, your life is the most important thing."

"Do I pull the cord out?"

As difficult as the situation was, Briana says she is extremely grateful that Aid Access was willing to send her the pills — and that someone on the hotline was

available to talk her through taking them.

"Without the hotline I would have been completely lost and literally completely alone," she said.

"The lady ... stayed talking to me for hours," Briana added. "I wish I knew her name."

Briana stayed in the bathroom that night for more than an hour. She knew she shouldn't look at the fetus, she said, but she couldn't help it. In the toilet bowl, she could make out a head. She remembered thinking that the legs looked long.

"I felt like a monster," she said, reflecting back on that moment.

A year later, Briana said, she is certain she made the right decision for herself and her family. But she wishes someone had told her more about what to expect. If she had known the full extent of what could happen during a medication abortion at 15 or 16 weeks, she said, she probably would have searched harder for an out-of-state clinic with available appointments — and figured out a way to drive six hours or more to Florida, Illinois or North Carolina.

Before *Roe v. Wade* was overturned, Briana could have gone to a clinic less than 30 minutes from her house.

"We can see you tomorrow."

"Here's what you should expect."

A former abortion provider offers some relief

"That website is real."

"You are going to get through this."

"Your uterus looks beautiful."

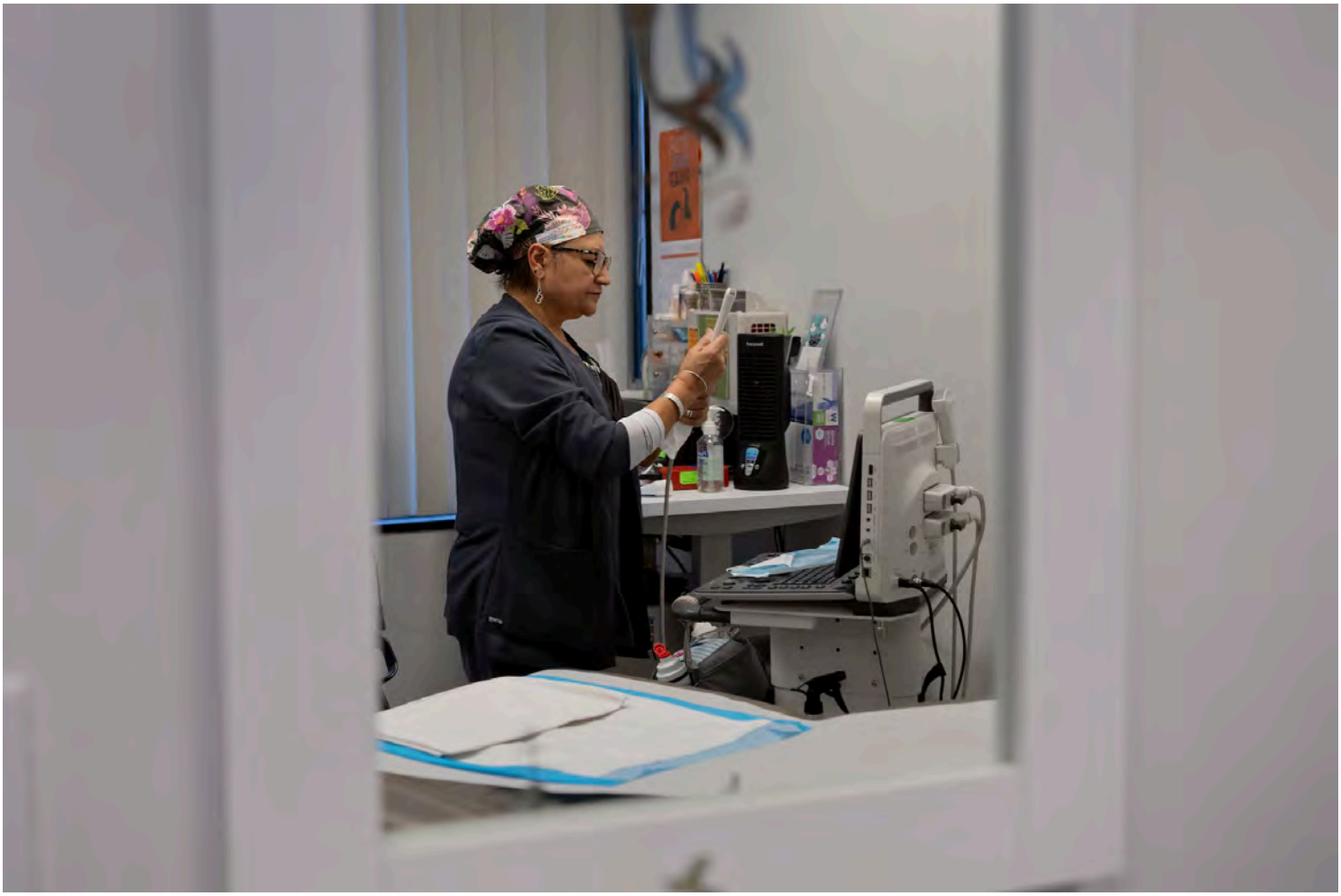
In Houston, a woman lay back on an exam table in a clinic that once offered abortions, hoping to hear that her medication abortion was finally complete.

Ashley, a 25-year-old mother with a baby, opened her legs and stared up at a mermaid mobile hanging from the ceiling, her sweatpants and Converse

sneakers in a heap on the floor.

“Are you ready?” Glenda Lima, the sonographer, asked on a Tuesday morning in mid-February. “There will be a little cold and just a little pressure, okay?”

It was Ashley’s fourth visit in two months to Houston Women’s Reproductive Services, one of a handful of former abortion clinics that have remained open in states with near-total abortion bans. While the staff originally imagined a new version of the clinic that offered ultrasounds and referrals to patients planning to travel out of state for medication and procedures, a large share of the women they serve are now self-managing their abortions with pills they got online.



Glenda Lima cleans ultrasound equipment at Houston Women's Reproductive Services in Texas. (Danielle Villasana for The Washington Post)

As soon as she found out she was pregnant in mid-December, Ashley had ordered pills from Aid Access, which she’d heard about on TikTok. But the whole process seemed a little sketchy, she said. What kind of medical organization collected money through Venmo, she wondered? They were asking for a picture of her driver’s license. What if it was all a scam?

She decided that she needed to talk to someone. Not a disembodied voice on the phone or an anonymous commenter in an online forum — but a real, live person

she could actually meet.

“If I’m putting this in my body,” Ashley recalled thinking to herself, “I need to know I’m going to be okay.”

Ashley struggled to come up with the right terms to Google, she said, wondering if it was even possible to get advice on abortions in a state where abortion is banned. She came across contact information for Houston Women’s Reproductive Services only after first messaging a crisis pregnancy center — an email thread she abandoned when she realized it was actually an antiabortion organization designed to dissuade women from ending their pregnancies.

Kathy Kleinfeld, the administrator of Houston Women’s, responded to Ashley’s panicked message on a Sunday, offering her an appointment for a pre-abortion ultrasound and consultation the next day the clinic was open.

“I was like, ‘Oh my God, I feel like I have been searching for this,’” Ashley said. For the first time since finding out she was pregnant, she said, “I just felt safe.”



Glenda Lima performs an ultrasound for a patient at Houston Women's Reproductive Services. (Danielle Villasana for The Washington Post)



A patient holds her hands while getting an ultrasound at Houston Women's Reproductive Services.

As other Texas clinics moved to New Mexico and Illinois after *Roe* was overturned, Kleinfeld and Lima decided to downsize and stay put, anticipating that some women would continue to seek out ultrasounds, emotional support and general guidance in their home state, services that remain legal under Texas law. If all the abortion clinics shuttered, they said, they knew crisis pregnancy centers would be the only places left to go.

Now, the women see their clinic as a helpful counterpart to the online pill networks: a soothing space with a “relaxation” scented diffuser and three portraits of the late Supreme Court justice Ruth Bader Ginsburg, where Texans

can get the help they need to feel comfortable self-managing their abortions at home.

There are major challenges to providing this kind of care in a state where abortion is illegal. Perhaps the biggest, Lima said, is that women assume there are no abortion resources left in Texas. Those that find them often do so by chance.

Lima said she regularly gets frantic calls and texts from Spanish-speaking patients she's never met before on her cellphone, a number she gives out only to patients she sees in the clinic.

"I ask them, 'How did you get my number?'" she said. "They say, 'A friend of a friend of a friend.'"

"I need to know I'm going to be okay."

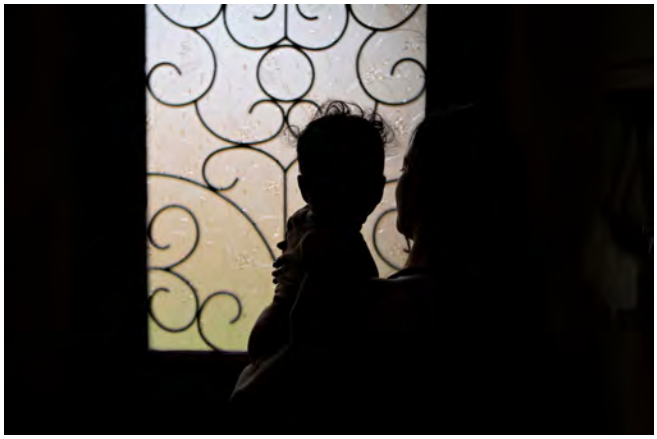
Kleinfeld acknowledges that the very existence of a clinic like theirs — which, unlike some other former abortion clinics that have remained open in states with bans, has no doctors on site and offers no health services other than ultrasounds — is somewhat controversial in the abortion rights community. With abortion rights advocates arguing vehemently that in-person consultations and ultrasounds are entirely unnecessary for a medication abortion, Kleinfeld said, some likely see her clinic as an impediment to women accessing the care they need.

Kleinfeld would never want to see an in-person visit mandated for all patients — most women have no problem handling everything at home, she said. But she has learned that some need the additional hand-holding, especially when they are obtaining pills from unfamiliar sources.

"Not everybody needs an ultrasound, not everyone needs a phone number to call," Kleinfeld said. "But some really do."

Blair Cushing, a family medicine doctor who provided abortions in McAllen, Tex., before the clinic there was forced to close, recently opened a small medical practice near the Mexico border to offer ultrasounds and other support to women who self-manage their abortions. When she meets with patients, she said, they'll often stay to talk for an hour or more — experiencing "information overwhelm" from everything they've read online and desperate for reassurance.

"They're worried because something didn't go the way they were expecting," Cushing said. "They need to decompress about this experience they had and make sure they're okay."



Ashley holds her baby at her home. (Danielle Villasana for The Washington Post)



As soon as she found out she was pregnant in mid-December, Ashley ordered pills from Aid Access.

Ashley first went to Houston Women's Reproductive Services for an ultrasound before she took the pills on Dec. 19 — then returned a week later, wondering why she was still bleeding and experiencing a dull pain in her lower back.

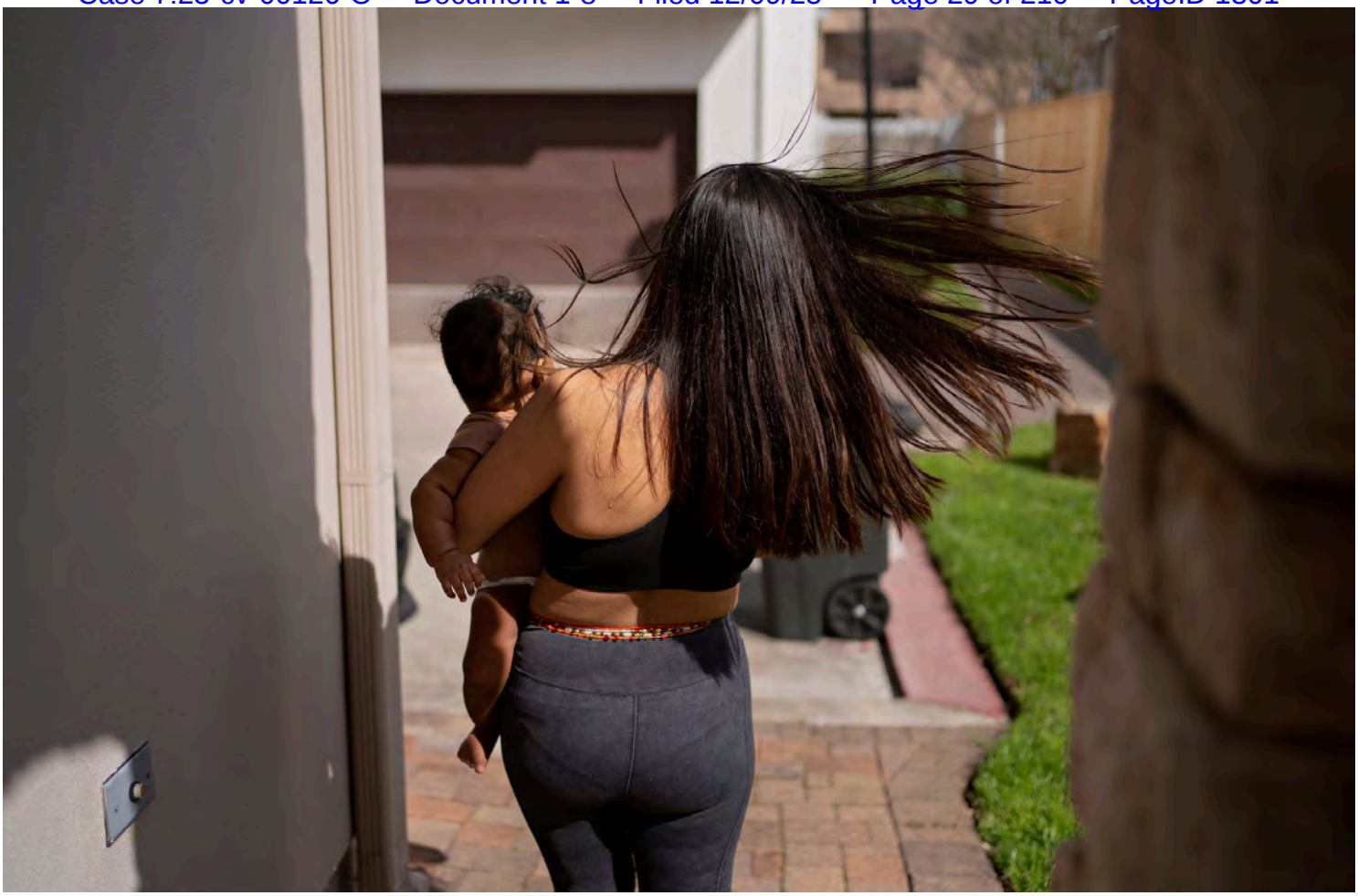
Lima, the sonographer, told Ashley that she still had some blood clots left in her uterus. And while Lima assured her that this was nothing to worry about — the body can typically expel remaining clots without any medical intervention — Ashley wanted to be sure.

She returned to Houston Women's for three more appointments, until Lima was able to confirm that all the clots were gone.

"Your uterus looks beautiful … nice and clean," Lima said at Ashley's final appointment in mid-February. "You're good to go, okay?"

Ashley smiled, closing her eyes as she felt all the muscles in her shoulders finally relax.

"Thank you," she said. "That's all I needed to hear."



Ashley carries her baby outside her home. (Danielle Villasana for The Washington Post)

About this story

Editing by Peter Wallsten. Photo editing by Natalia Jimenez. Copy editing by Thomas Heleba and Martha Murdock. Design editing by Madison Walls. Graphics editing by Emily M. Eng. Graphics reporting by N. Kirkpatrick. Design and development by Agnes Lee. Andrew Tran contributed to this report.

THE U.S. FIGHT OVER ABORTION **HAND-CURATED**

States where abortion is legal, banned or under threat

Sept. 12, 2024



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Caroline Kitchener

Caroline Kitchener is a reporter covering abortion at The Washington Post. She won the 2023 Pulitzer Prize for National Reporting. @CAKitchener

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EXHIBIT 67

C.S.H.B. 3446, House Committee Report, 84th Legis. (Mar. 12, 2015)

EXHIBIT 67

C.S.H.B. 3446, House Committee Report, 84th Legis. (Mar. 12, 2015)

BILL ANALYSIS

C.S.H.B. 3446
By: Laubenberg
State Affairs
Committee Report (Substituted)

BACKGROUND AND PURPOSE

Human trafficking, child pornography, and international sex tourism reportedly generate billions of dollars a year worldwide and there are indications that a significant number of U.S. citizens and foreign nationals are trafficked within the borders of the United States. Texas law already requires certain places of business to post signs that are visible to employees and patrons that provide a toll-free phone number for a national human trafficking helpline. It has been noted, however, that there is no law requiring these postings at an abortion facility despite the fact that many of the women who undergo abortions may be victims of human trafficking, especially sex trafficking. Due to the potentially high number of trafficking victims who undergo abortion procedures, abortion facility employees are uniquely situated to identify and assist victims of sex trafficking. C.S.H.B. 3446 seeks to require signs relating to human trafficking to be displayed at certain abortion facilities.

CRIMINAL JUSTICE IMPACT

It is the committee's opinion that this bill does not expressly create a criminal offense, increase the punishment for an existing criminal offense or category of offenses, or change the eligibility of a person for community supervision, parole, or mandatory supervision.

RULEMAKING AUTHORITY

It is the committee's opinion that rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTION 1 of this bill.

ANALYSIS

C.S.H.B. 3446 amends the Health and Safety Code to require a licensed ambulatory surgical center that performs more than 50 abortions in any 12-month period or a licensed abortion facility to conspicuously display in each patient admission area, waiting room, restroom, and patient consulting room signs that contain a phone number for the Department of Public Safety and a toll-free phone number of a nationally recognized information and referral hotline for victims of human trafficking, as well as the following information: a woman cannot be forced to have an abortion against her will, regardless of her age; if a woman is being forced to have an abortion or being abused, the state is able to help the woman; and human trafficking, including sex trafficking, is a violation of state law. The bill prohibits the signs from containing any information other than that information and prescribes the required sign measurements. The bill requires an applicable center or facility to post a sign in English and a sign in Spanish, as well as any other language in which the political subdivision within which the facility is located is required under the Election Code to provide election materials, if applicable. The bill requires the executive commissioner of the Health and Human Services Commission, not later than December 1, 2015, to adopt rules as necessary to implement and enforce the bill's provisions and establishes that an ambulatory surgical center or abortion facility is not required to comply with the bill's provisions before January 1, 2016.

EFFECTIVE DATE

September 1, 2015.

COMPARISON OF ORIGINAL AND SUBSTITUTE

While C.S.H.B. 3446 may differ from the original in minor or nonsubstantive ways, the following comparison is organized and formatted in a manner that indicates the substantial differences between the introduced and committee substitute versions of the bill.

INTRODUCED

SECTION 1. Subchapter B, Chapter 171, Health and Safety Code, is amended by adding Sections 171.0125 and 171.0126 to read as follows:

Sec. 171.0125. REQUIRED SIGNS AT CERTAIN FACILITIES: AVAILABLE RESOURCES. (a) An ambulatory surgical center licensed under Chapter 243 that performs more than 50 abortions in any 12-month period or an abortion facility licensed under Chapter 245 shall conspicuously display a sign that satisfies the requirements of this section in each patient admission area, waiting room, and patient consulting room.

(b) The sign required by this section must be in English and Spanish and display the following text:

You can't be forced. No one can make you have an abortion against your will, even if you are a minor. In fact, forcing a minor to have an abortion is considered child abuse. If you are a minor being forced into making a particular decision, you can report it by calling the Texas Abuse Hotline at 1-800-252-5400. The call is free and the hotline operates 24 hours per day, 365 days per year.

You and the father. The father of your child must provide support for the child, even if he has offered to pay for an abortion. The Child Support Division of the Office of the Attorney General can help you locate your child's father and determine that he is the father. The Child Support Division can also help establish and enforce child support orders and collect money owed, as well as distribute child support payments. To learn more about child support services, call the Child Support Division at (512) 460-6000.

You and adoption. The law allows adoptive parents to pay costs of prenatal care, childbirth, and newborn care. To learn more about adoption services and the organizations available to assist you, call Woman's Right to Know at (512) 776-6917.

You are not alone. Many agencies are willing to help you carry your child to term and to assist you after your child's birth. This includes providing access to health care services for mother and baby, supplies, healthy food items, nutrition education, and in-home support.

HOUSE COMMITTEE SUBSTITUTE

SECTION 1. Subchapter B, Chapter 171, Health and Safety Code, is amended by adding Section 171.0125 to read as follows:

Sec. 171.0125. REQUIRED SIGNS AT CERTAIN FACILITIES: AVAILABLE RESOURCES. (a) An ambulatory surgical center licensed under Chapter 243 that performs more than 50 abortions in any 12-month period or an abortion facility licensed under Chapter 245 shall conspicuously display signs that satisfy the requirements of this section in each patient admission area, waiting room, restroom, and patient consulting room.

(b) The signs required by this section must contain the following information:

(1) a woman cannot be forced to have an abortion against her will, regardless of her age;

(2) if a woman is being forced to have an abortion or being abused, the state is able to help the woman; and

(3) human trafficking, including sex trafficking, is a violation of state law.

(c) The signs required by this section must also contain a phone number for the Department of Public Safety and a toll-free phone number of a nationally recognized information and referral hotline for victims of human trafficking.

(d) The signs required by this section may not contain any information other than the information described by Subsections (b) and (c).

INTRODUCED	
(See subsection (b) above.)	
(c) The executive commissioner of the Health and Human Services Commission shall adopt rules as necessary to implement and enforce this section.	
Sec. 171.0126. REQUIRED SIGNS AT CERTAIN FACILITIES: HUMAN TRAFFICKING. (a) An ambulatory surgical center licensed under Chapter 243 that performs more than 50 abortions in any 12-month period or an abortion facility licensed under Chapter 245 shall conspicuously display a sign that satisfies the requirements of this section in each patient admission area, waiting room, and patient consulting room. (b) The sign required by this section must be in English and Spanish and display the following text: WARNING: Being forced to engage in sexual activity or forced to obtain an abortion is illegal under Texas law. Call the national human trafficking hotline: 1-888-373-7888. (c) The executive commissioner of the Health and Human Services Commission shall adopt rules as necessary to implement and enforce this section.	(e) The signs required by this section must each be at least 11 inches in width and 17 inches in length. (f) A facility described by Subsection (a) shall post a sign required by this section in English and a sign in Spanish. If the facility is located in a political subdivision that is required to provide election materials in a language other than English or Spanish under Section 272.011, Election Code, the facility shall also post a sign in that language. (g) The executive commissioner shall adopt rules as necessary to implement and enforce this section.
SECTION 2. Not later than December 1, 2015, the executive commissioner of the Health and Human Services Commission shall adopt the rules necessary to implement Sections 171.0125 and 171.0126, Health and Safety Code, as added by this Act.	SECTION 2. Not later than December 1, 2015, the executive commissioner of the Health and Human Services Commission shall adopt the rules necessary to implement Section 171.0125, Health and Safety Code, as added by this Act.
SECTION 3. An ambulatory surgical center or abortion facility is not required to comply with Sections 171.0125 and 171.0126, Health and Safety Code, as added by this Act, before January 1, 2016.	SECTION 3. An ambulatory surgical center or abortion facility is not required to comply with Section 171.0125, Health and Safety Code, as added by this Act, before January 1, 2016.
SECTION 4. This Act takes effect September 1, 2015.	SECTION 4. Same as introduced version.

EXHIBIT 68

Pam Belluck, *Abortion Shield Laws: A New War Between the States*, New York Times (Feb. 22, 2024)

Abortion Shield Laws: A New War Between the States

Doctors in six states where abortion is legal are using new laws to send abortion pills to tens of thousands of women in states where it is illegal.



By Pam Belluck
Pam Belluck spent time with abortion providers sending pills to states that outlaw abortion and talked with patients receiving those pills.

Published Feb. 22, 2024 Updated Feb. 23, 2024

Behind an unmarked door in a boxy brick building outside Boston, a quiet rebellion is taking place. Here, in a 7-by-12-foot room, abortion is being made available to thousands of women in states where it is illegal.

The patients do not have to travel here to terminate their pregnancies, and they do not have to wait weeks to receive abortion medication from overseas.

Instead, they are obtaining abortion pills prescribed by licensed Massachusetts providers, packaged in the little room and mailed from a nearby post office, arriving days later in Texas, Missouri and other states where abortion is largely outlawed.

This service and others like it are operating under novel laws enacted in a half-dozen states — Massachusetts, Washington, Colorado, Vermont, New York and California — that have sought to preserve abortion access since the Supreme Court overturned the nationwide right to abortion in June 2022. The laws have been in use only since the summer and have not been tested in the courts, but they are already providing abortion access to tens of thousands of women in states with bans, especially low-income patients and others who cannot travel.

Called telemedicine abortion shield laws, they promise to protect doctors, nurse practitioners and midwives licensed in those six states who prescribe and send abortion pills to patients in the nearly two dozen states that ban or sharply restrict abortion.

The laws stipulate that officials and agencies of their states will not cooperate with another state's efforts to investigate or penalize such providers — a stark departure from typical interstate practices of extraditing, honoring subpoenas and sharing information, legal experts on both sides of the abortion issue say. Many expect them to ultimately be challenged in federal court.

Abortion opponents see the laws as brazen infringement on state sovereignty.

"You have states not just picking their own strategy but really trying to completely sabotage the governing efforts of their neighboring states," John Seago, the president of Texas Right to Life, said.

"It can't stand, and we can't be content with this new development," he added.



"Some people who might not have gotten an abortion if they had to take off work and go to a clinic, or wait three weeks and all of that, are doing it now," said Dr. Linda Prine, a New York shield-law provider. Ilvy Njiokiktjien for The New York Times

The threat of shield laws is one reason that three states — Idaho, Kansas and Missouri — petitioned to join a case the Supreme Court will hear next month that seeks to bar the mailing of abortion pills and to require in-person doctor visits instead of telemedicine. The petition was denied.

"When you have states actively seeking to circumvent each other's laws, that raises a very real legal problem that will stretch far beyond just the abortion sphere," said Will Scharf, a Republican candidate for attorney general in Missouri, who helped draft anti-abortion legislation when serving as policy director for the state's governor six years ago.

Pills have become the most common abortion method nationally, and abortion rights advocates consider shield laws a crucial way to counter the wave of bans enacted since the Supreme Court's decision in Dobbs v. Jackson Women's Health Organization.

"This might be the most important event since Dobbs on so many levels," said Rachel Rebouché, the dean of Temple University Law School, who has worked with shield law advocates and legislators. "Thousands and thousands of pills are being shipped everywhere across the United States from a handful of providers. That alone speaks to the nature of what mailed medication abortion can do."

Before shield laws were enacted, Aid Access, one of the organizations in the forefront of telemedicine abortion, served patients in states with bans by issuing prescriptions from Europe and shipping pills from a pharmacy in India. Pills could take weeks to arrive, potentially putting patients beyond 12 weeks' gestation, the recommended threshold for taking the medication.

With shield laws, "some people who might not have gotten an abortion if they had to take off work and go to a clinic, or wait three weeks and all of that, are doing it now," said Dr. Linda Prine, a New York shield law provider.

Aid Access providers are now using shield laws to serve about 7,000 patients a month, nearly 90 percent of them in states with bans or severe restrictions, according to Dr. Abigail Aiken, an associate professor at the University of Texas at Austin, who studies Aid Access data.

The shield laws upend the usual telemedicine model, under which out-of-state health providers must be licensed in the states where patients are located.

Beyond providing abortion access to individual patients, the shield-law movement carries broader implications for abortion politics, and supporters are working to enact similar laws in as many states as possible so the approach becomes commonplace, according to Francine Coeytaux, a co-founder of Plan C, a clearinghouse for medication abortion information.

"The shield laws are about a state's legislative and justice system having skin in the game," she said.

Inside the room



Telemedicine abortion shield laws are intended to protect doctors, nurse practitioners and midwives who prescribe and send abortion pills to patients in the nearly two dozen states that ban or sharply restrict abortion. Sophie Park for The New York Times

Carol, who asked to be identified by her middle name to help keep her role private, met me behind the brick building outside Boston and escorted me through a back door, down a warren of hallways. Others who rent offices in the building haven't asked what she does there, she said, adding: "I'm kind of hoping that most people aren't really that curious about what's going on."

At a plain white table, Carol, who has a master's degree in public health, began her routine: checking a spreadsheet of prescriptions; printing out labels with medication information and patients' names; printing address labels with tracking numbers and adding them to the

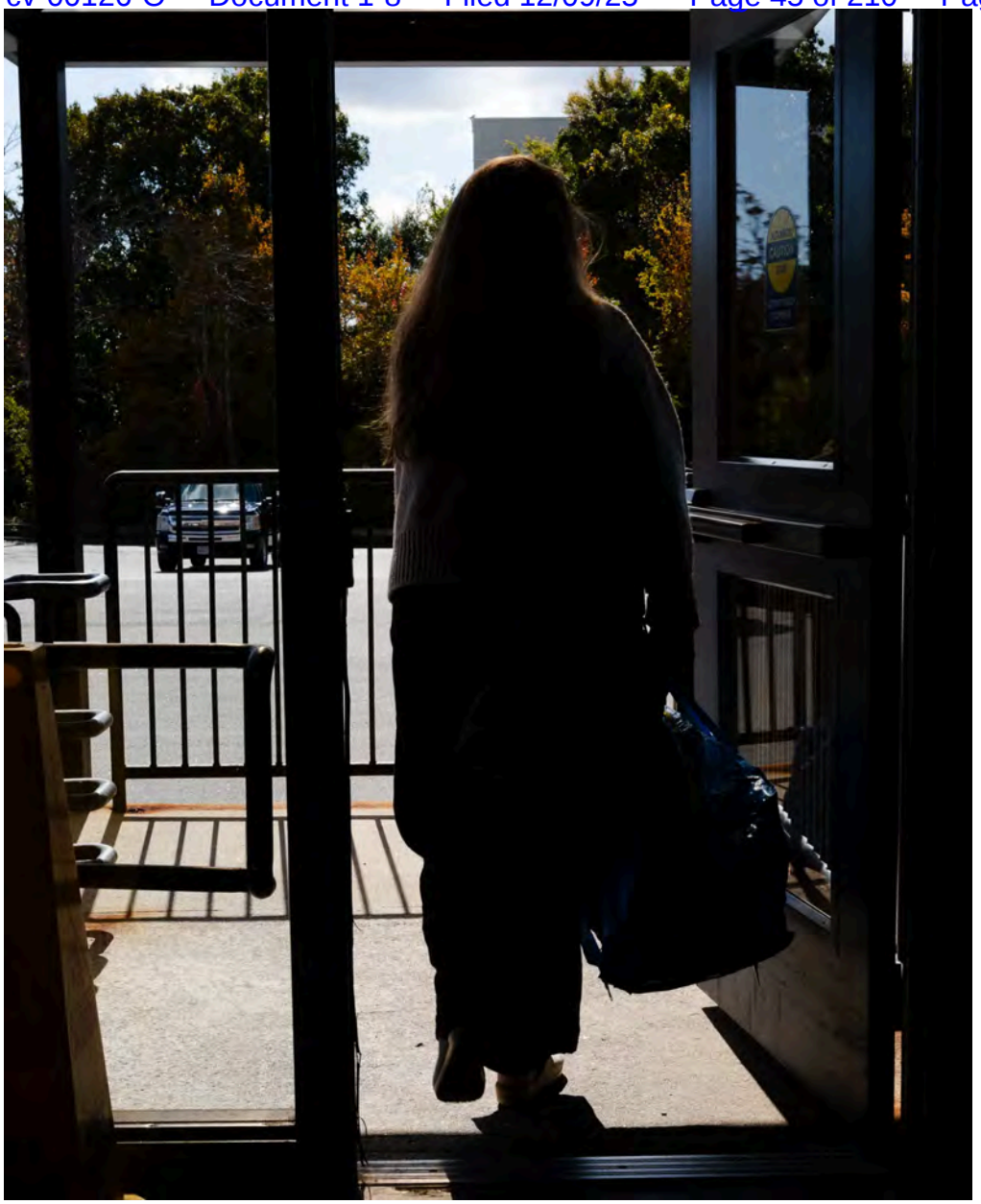
spreadsheet.

Patients contact this service and others online and fill out forms providing information about their pregnancy and medical history. Carol's colleague, Lauren Jacobson, a nurse practitioner, writes prescriptions, evaluating whether patients are medically eligible. They can be up to 12 weeks pregnant and must have no disqualifying medical issues like an ectopic pregnancy or a blood-clotting disorder. Patients and providers can communicate by email or phone if needed.

"We're a free country," said Ms. Jacobson, who sometimes writes 50 prescriptions a day. "So let's put that to the test. Here we are and we're not going to be intimidated, and we have our states backing us."

Carol pulled the two abortion medications from storage boxes: mifepristone, which stops a pregnancy from developing, and misoprostol, taken 24 to 48 hours later to spur contractions to expel pregnancy tissue.

"I don't really consider myself a rule breaker," she said. "So it's funny that here I am sitting in this tiny little closet surrounded by pill bottles."



Carol and others who use shield laws to send abortion pills to patients are taking precautions to protect themselves, including not traveling to states with abortion bans, where they could be more vulnerable to arrest. Sophie Park for The New York Times

The operation resembles a small-scale assembly line, preparing medication for six packages at a time: one mifepristone pill in a manufacturer's prepackaged box and 12 misoprostol tablets counted out by hand from bottles of 100 supplied by a wholesaler. Carol slid the medications into plain envelopes lined with bubble wrapping, along with a 10-page pamphlet from the mifepristone manufacturer and illustrated instructions from Aid Access about taking the medication and expected side effects, like cramping and bleeding.

She drove several miles to a post office to mail the envelopes.

"Getting ready for Christmas?" another customer in the post office asked one day, she recalled.

“Surprise, I’m actually Santa Claus,” she replied cheerfully.

One of Carol’s envelopes arrived at the home of Ashley Dickey in Texas.

Ms. Dickey has two young children and said she had experienced serious postpartum depression after those pregnancies. She said she dissolved in tears when she became pregnant again and concluded that she could not manage another pregnancy and raise another child. “It’s just not good for anybody,” she said.

When she learned she could receive pills by mail, “I was so grateful,” she said, adding, “If I would have had to travel somewhere, it would have been catastrophic, financially and then just emotionally.”



“If I would have had to travel somewhere, it would have been catastrophic, financially and then just emotionally,” said Ashley Dickey, a Texas patient who received abortion

pills from Massachusetts shield law providers. Monumique Monroe for The New York Times

Reaching low-income patients

Supporters say shield laws are already making substantial progress toward an important goal: helping patients who cannot afford — financially or logistically — to travel to another state for an abortion.

“It’s reaching the ones that were impacted the most: low-income, poor people, communities of color, Indigenous,” said Michelle Colón, the executive director of SHERo Mississippi, an organization supporting reproductive rights for people of color.

Nationally, there are three main providers: Aid Access; the Massachusetts Medication Abortion Access Project (called The MAP); and a service called Abuzz, which does not yet serve all states with abortion bans. They charge $150 or $250, though all three services provide pills for reduced prices or even at no cost, based solely on what patients say they can pay.

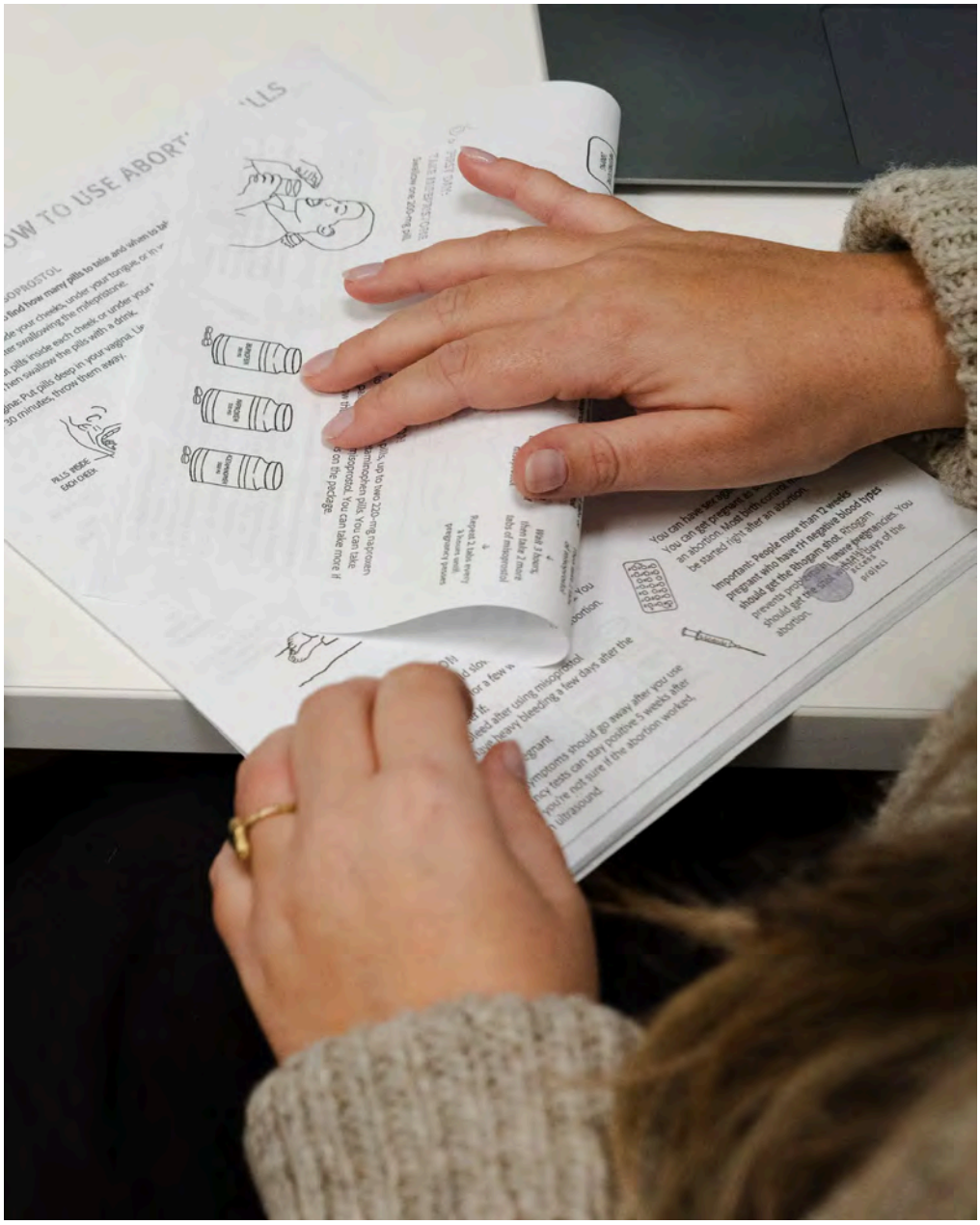
Dr. Rebecca Gomperts, a Dutch physician who founded Aid Access, said over half of its shield-law patients cannot pay full price. About a third of The MAP’s patients can afford only the service’s $5 minimum, said Dr. Angel M. Foster, director of The MAP.

But shield-law providers say it is uncertain whether they can sustain their pay-what-you-can approach. Most providers are absorbing the cost for thousands of patients who can’t pay full price. So far, most abortion funds — organizations that provide financing to help patients obtain abortions — have not given money for sending pills to anti-abortion states, partly because they do not know if shield laws would protect the funds.

“I’ve had several funds say, ‘Our lawyers say we cannot do this,’” said Susan Yanow, a longtime reproductive health activist working with The MAP, who has nonetheless gotten some funds to contribute.

A few funds openly support shield-law activity. “We are here to boldly make a statement,” said Karen Middleton, president of Cobalt Abortion Fund in Colorado, which gives $2,500 a month to that state’s provider. And some advocates are starting funds, including Jodi Jacobson, an activist based in California, who said she wanted to support “providers who are losing money” performing what she called “medical civil disobedience.”

Legal strategizing



Authorities in states with abortion bans have not yet tried to prosecute, sue or otherwise target shield law providers, but some advocates on both sides say it is only a matter of time before that happens. Sophie Park for The New York Times

Several Republican attorneys general from states with strict abortion prohibitions declined requests to discuss shield laws. But Mr. Scharf, who is challenging Missouri's incumbent attorney general in the Republican primary, predicted that the shield laws would almost certainly be challenged in court.

"Constitutional litigation is obviously an option here," he said. "Ultimately, whenever you get attempts like this to circumvent our constitutional system of federalism, that's going to be something that's litigated."

Dr. Seago of Texas Right to Life said taking action against shield-law providers would be "a difficult challenge" that would require "the right case," including a patient "on the receiving side of those illegal activities" who would cooperate with a civil suit or prosecution.

"We can definitely promise that in a pro-life state like Texas with committed elected officials and an attorney general and district attorneys who want to uphold our prolife laws, this is not something that's going to be ignored for long," he said.

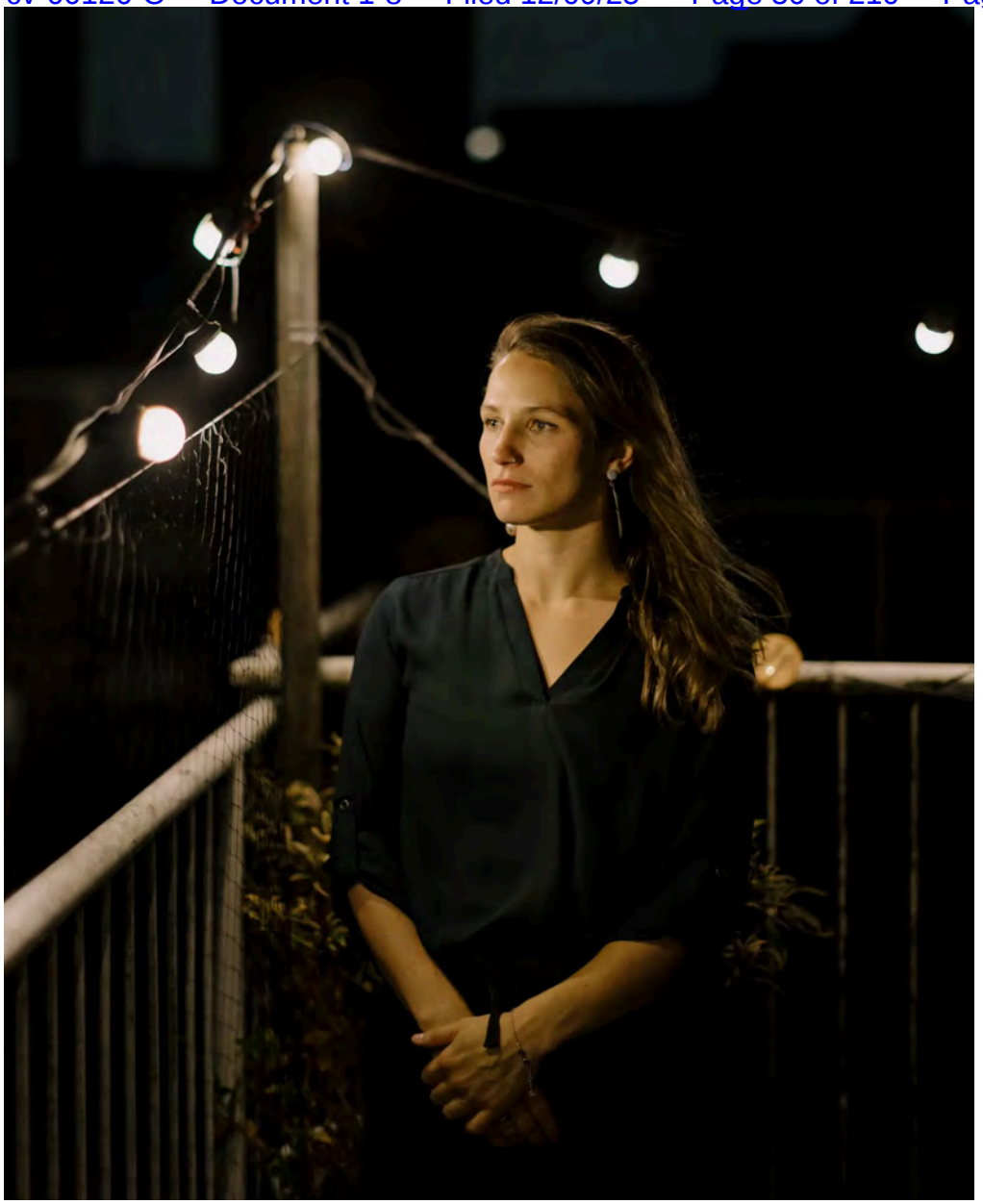
Many shield-law providers are taking precautions, including not traveling to states with abortion bans, where they could be more vulnerable to arrest. Some are not sending pills to states where they have family. Some are creating trusts to protect their assets from civil suits.

"At any moment, I might get a cease-and-desist order, or I might get a lawsuit, or I might get some district attorney coming after me, I have no idea," said Dr. David Wiebe, who operates under Colorado's shield law. "I'm absolutely flying out at full risk here."

The MAP has taken several protective steps. All of its prescribers are within Massachusetts. Pills are stocked and packaged at a separate location by workers hired by Cambridge Reproductive Health Consultants, a nonprofit Dr. Foster leads. "Our model is about distributing risk," she said.

One national mail-order pharmacy, Honeybee Health, based in California, is evaluating whether it can send pills to states with abortion bans under California's shield law, a step that would allow providers in any shield-law state to send their prescriptions to Honeybee and avoid stocking and shipping pills themselves.

Honeybee's co-founder and president, Jessica Nouhavandi, said she hoped to do so, but worried about jeopardizing her business, which dispenses other medications too. If an anti-abortion state like South Carolina pulled her license, "what happens to my thousands of South Carolina patients who get their blood thinners from me?" she said.



“We’re a free country,” said Lauren Jacobson, a nurse practitioner who sometimes writes 50 prescriptions a day. “So let’s put that to test. Here we are and we’re not going to be intimidated, and we have our states backing us.” Ilvy Njiokiktjien for The New York Times

Another unknown is the outcome of the lawsuit by abortion opponents seeking to curtail mifepristone. An appeals court ruling effectively barred the mailing of mifepristone and required in-person doctor visits. The case is now before the Supreme Court.

“If we prevail on that, all these shield laws will be rendered moot at that point because then there’ll be a federal policy prohibiting such a transaction,” said Erik Baptist, senior counsel for the Alliance Defending Freedom, which represents abortion opponents in that case. Some shield law providers say they will look for legal ways to continue.

Texas, which has strict bans, is home to about a third of shield-law patients, including Elizabet, who asked to be identified by her middle name to protect her privacy. She considered traveling to California, where a friend lives, but medication abortion at a clinic there would cost $750, plus transportation expenses.

She was relieved to find Aid Access and to receive pills mailed from Massachusetts. Although abortion bans target providers and not patients, she said she was still nervous about people in Texas finding out.

“That’s been very scary,” she said, “but I was like, you know what, I have to trust it.”

Weeks later, Elizabet said she planned to visit a doctor for birth control, but worried about being asked if she’d taken abortion pills.

Ms. Jacobson, who prescribed her the medication under Massachusetts’ shield law, reassured her, noting that there was no medical reason to disclose having taken abortion pills.

“The symptoms that the abortion pills cause are exactly the same as those that a miscarriage causes, so there is no possible way for a provider, a doctor, to look at you, do any test and know that you took the pills,” she said, adding, “We’ve helped a lot of people navigate situations in places like Texas.”

Pam Belluck is a health and science reporter, covering a range of subjects, including reproductive health, long Covid, brain science, neurological disorders, mental health and genetics. More about Pam Belluck

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A version of this article appears in print on , Section A, Page 1 of the New York edition with the headline: New Shield Laws Allowing Women Abortion Access

EXHIBIT 69

MAP - Frequently asked questions

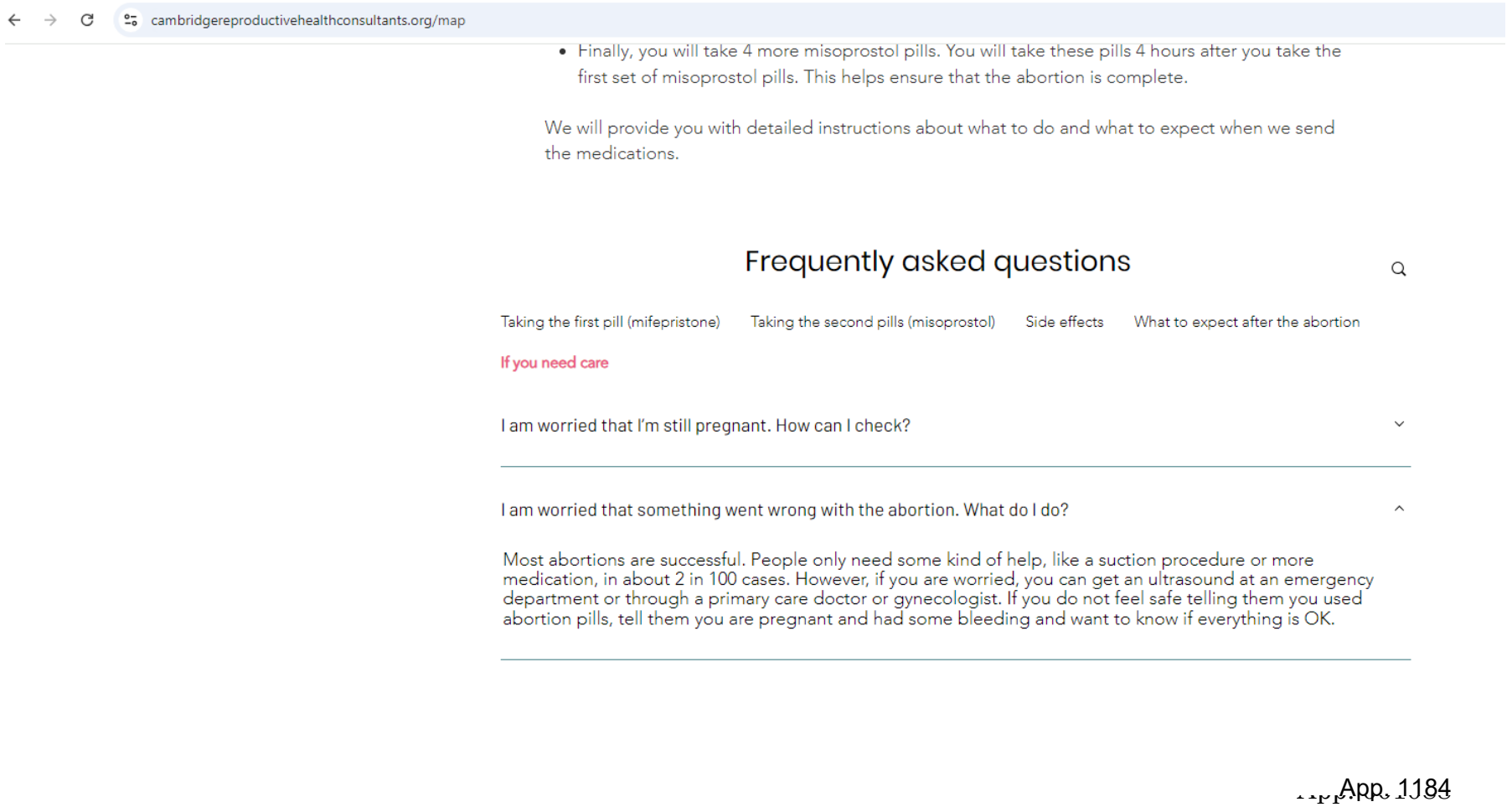

cambridgereproductivehealthconsultants.org/map
Finally, you will take 4 more misoprostol pills. You will take these pills 4 hours after you take the first set of misoprostol pills. This helps ensure that the abortion is complete.
We will provide you with detailed instructions about what to do and what to expect when we send the medications.
Frequently asked questions
Taking the first pill (mifepristone)
Taking the second pills (misoprostol)
Side effects
What to expect after the abortion
If you need care
I am worried that I'm still pregnant. How can I check?
I am worried that something went wrong with the abortion. What do I do?
Most abortions are successful. People only need some kind of help, like a suction procedure or more medication, in about 2 in 100 cases. However, if you are worried, you can get an ultrasound at an emergency department or through a primary care doctor or gynecologist. If you do not feel safe telling them you used abortion pills, tell them you are pregnant and had some bleeding and want to know if everything is OK.

EXHIBIT 70

Abuzz

abuzz

Need abortion care at home?

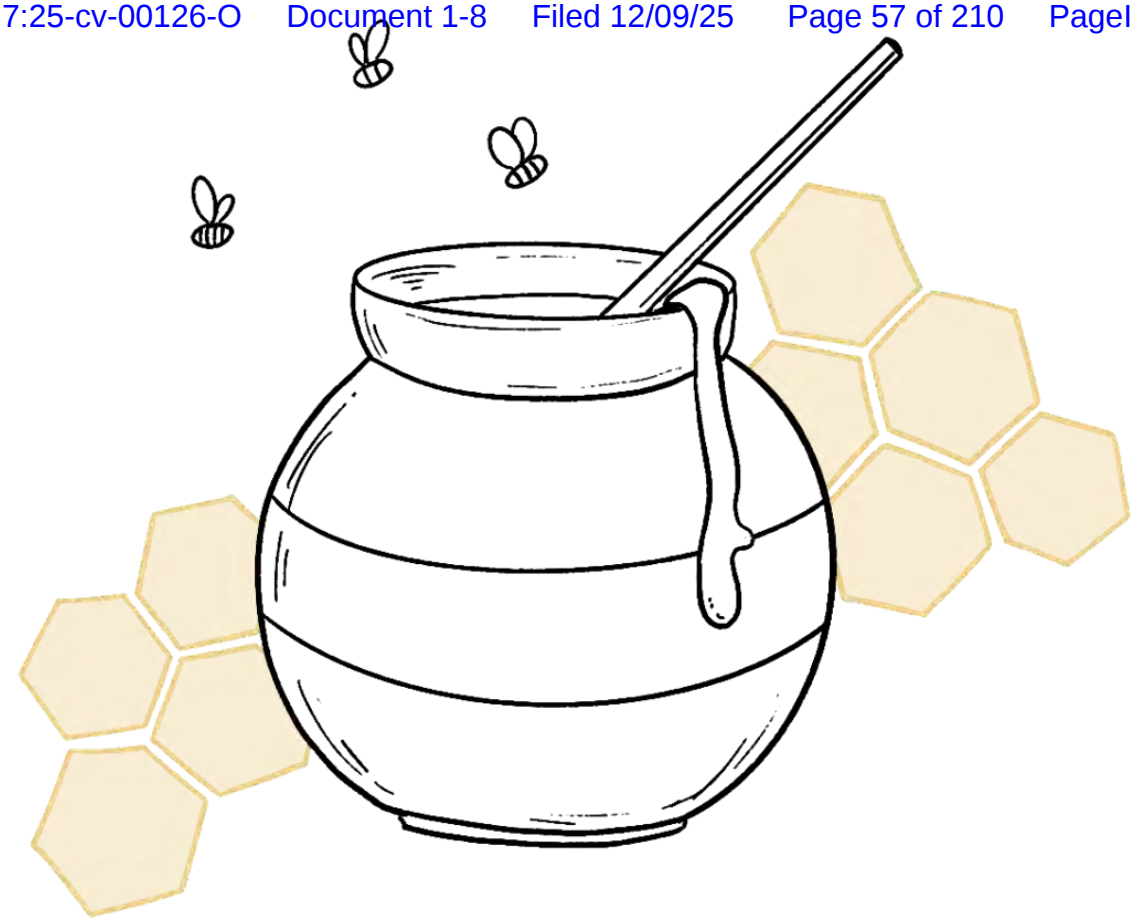
Get access today





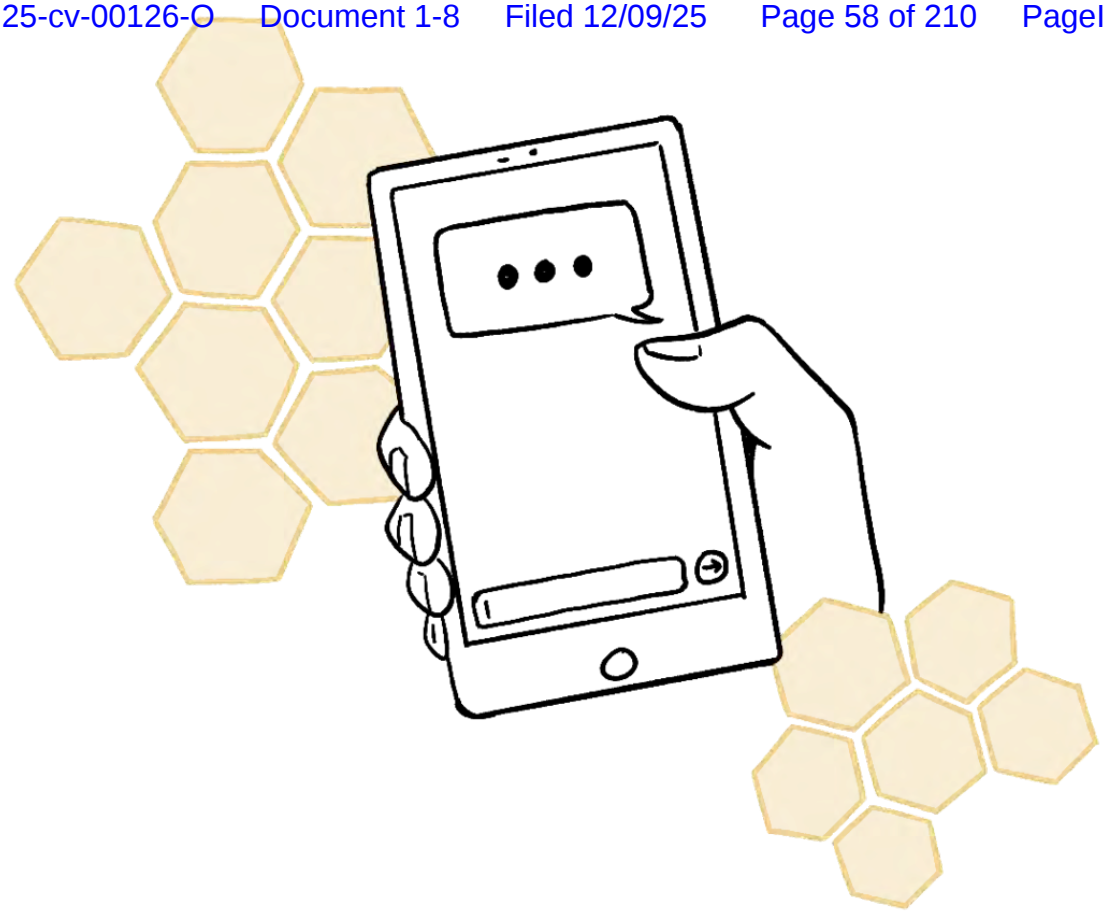
Fast, discreet shipping.

Packages arrive in 2-5 days. Medications are shipped in a plain mailing envelope.



Affordable care for everyone.

Accessing safe and affordable healthcare is a fundamental right. Services are available for $0-150 sliding scale.



The support you need, when you need it.

An experienced medical team is here to answer your questions, provide support, and guide you through the process.

Abuzz may be able to help you if...



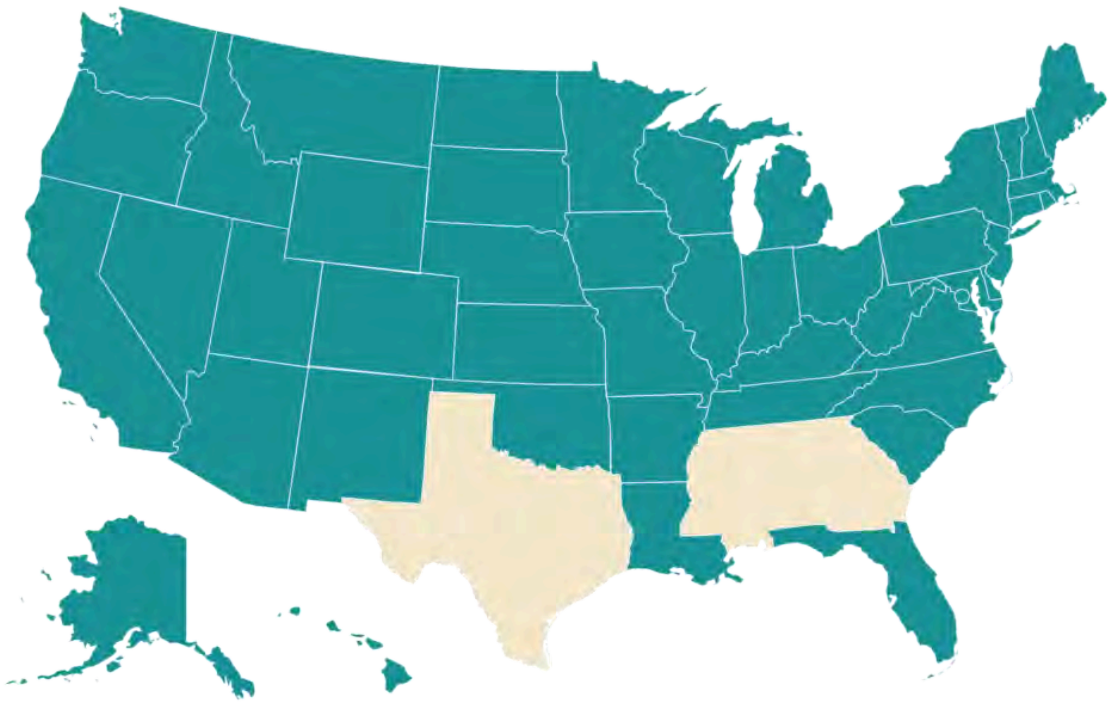
You're less than 13 weeks pregnant.

You must be less than 13 weeks pregnant to access abortion through Abuzz. Remember that pregnancy is measured from the first day of your last menstrual period, which is around two weeks before conception.

→ How do I estimate the length of my pregnancy?

You're comfortable with virtual abortion care.

In most cases, providers do not require a phone call or video visit. After you fill in the form, a clinician will arrange payment with you and review your information. If you're approved to receive abortion pills by mail, your pills will be shipped out in 1-2 business days.



You have a mailing address in one of our states.

Options for at-home abortion pill access will vary based on your location. Click below to find options in your state or territory.

Still have questions? Check out our FAQ

abuzz

Abuzz: Abortion Pill Access At Home

About Us

How it Works

FAQ

Terms of Use

Privacy Policy

Provider Payments

Donations allow us to help all pregnant people, regardless of their ability to pay. Please consider supporting our work.

DONATE

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EXHIBIT 71

Abuzz FAQ

abuzz

Frequently Asked Questions*

Services | About Abortion Pills | Before Taking Abortion Pills | How to Use Abortion Pills | During An Abortion With Pills | After An Abortion With Pills

Services

I can't afford $150. Can I still get help? –

Yes, you can still get help! Just let your provider know what you can afford when you fill out the form.

Can I get abortion pills even if I'm not pregnant? –

Yes, clinicians offer abortion pills "just in case" you do get pregnant. These are sometimes called "advance provision" or "pills for future use."

Do I have to have a video visit or phone call? –

In most cases, a phone or video call is not required. Everything is done through the intake form. You will receive a phone number so that you can contact the medical team for any follow up questions. We are here to support you if you choose.

What happens after I ll out the form? –

We will connect you with a provider that is best suited to support your care. The provider will arrange payment with you and review your file. They might ask you some follow up questions. If you are eligible to receive services, they will mail you abortion pills.

How do I get started? –

Fill in the form here.

About abortion with pills

What comes in the abortion pill kit? –

The abortion pill kit has two medicines: mifepristone and misoprostol. The combination of mifepristone and misoprostol is very effective and has the fewest side effects.

How do the abortion pills work? –

Mifepristone stops the pregnancy from growing. Misoprostol makes the uterus contract and push out the pregnancy just like a natural miscarriage.

How effective are abortion pills? –

The combination of mifepristone and misoprostol has been shown to be 98% effective at ending a pregnancy.

Is there a difference between the generic (mifepristone) and brand (Mifeprex) versions of mifepristone? –

There is no difference between them.

Are abortion pills safe? –

They are very safe – safer than Tylenol and safer than driving in a car! The risk of severe, life-threatening complications requiring hospitalization is less than 1%.

If abortion pills are so safe, why are they so restricted? –

Restrictions on abortion pills have nothing to do with medical safety or effectiveness. The restrictions are made by politicians who are against abortion.

Will the abortion pills affect my ability to get pregnant in the future? –

No, abortion pills do not affect your future fertility. You can still get pregnant again.

I have an Rh negative blood type. Will I need Rhogam if I am less than 12 weeks when I take the abortion pills? –

No, Rhogam is only needed for people with Rh negative blood *after* 12 weeks.

Do abortion pills increase the risk of infection? –

Infections from abortions are very rare. They occur in less than 2% of all abortions and usually are easily treated with antibiotics when they do occur.

How far in pregnancy can I use abortion pills? –

The clinicians we refer to will send the pills to people up to 12 weeks and 6 days pregnant. If you are 13 weeks pregnant or more, you can find services here.

What is an ectopic pregnancy and how would I know if I had one? –

Ectopic (tubal) pregnancies are located outside of the uterus. The risk of having an ectopic pregnancy is very low (less than 2%), but if it bursts it is a medical emergency. The only way to know for sure if you have an ectopic pregnancy is by ultrasound. If you are pregnant and have any of the following signs of a ruptured ectopic pregnancy, you should go to the hospital right away: severe abdominal pain on one side, dizziness, lightheadedness, feeling very weak. There is a higher risk of ectopic pregnancy if you have an IUD or history of ectopic pregnancies.

Will the pills work if I have an ectopic pregnancy? –

The abortion pills will NOT work for an ectopic pregnancy. If you take abortion pills and do not have any bleeding within 24 hours after taking misoprostol, you should speak to your abortion pill provider right away. They may recommend an ultrasound to check the location of the pregnancy.

Can I use abortion pills if I have an IUD in place? –

It is very rare to become pregnant with an IUD in place. If you are pregnant with an IUD, there is a higher risk of it being an ectopic pregnancy. Ectopic pregnancies are dangerous because they can burst suddenly and cause severe internal bleeding. While an ultrasound is not required, it would show the location of the pregnancy and the IUD. You don't need to have the IUD taken out before taking abortion pills. They will still work (unless it is an ectopic pregnancy) and a risk is that the IUD may come out with the pregnancy. Since you have become pregnant, it also means you will need to have the IUD replaced after the abortion since it is no longer working correctly.

I got an abortion pill kit for future use. How long is it good for? –

You can store the pills for at least two years (and probably longer) in a cool, dry, dark place. It's not recommended to store them in the bathroom because the heat and humidity can make the pills less

effective.

Can I receive just misoprostol? –

Using mifepristone and misoprostol together is considered the “gold standard” protocol for abortion with pills. Typically, clinicians prefer to prescribe the two medications together as they have fewer side effects and the process is easier. If you cannot take or do not want to take mifepristone, you can fill in the online form and ask your clinician about a misoprostol-only abortion.

Can I ll an abortion pill prescription at my local pharmacy? –

Local pharmacies in the U.S. are allowed to dispense mifepristone after getting certified. You can locate a pharmacy here. Some clinicians may be able to send a prescription for you to fill at a local pharmacy. At this time, Abuzz does not offer this service.

Before taking abortion pills

What should I do before taking abortion pills? –

Before taking pills, it is helpful to do a pregnancy test to confirm you’re pregnant. This avoids taking pills unnecessarily and prevents confusion. If you don’t want to take a pregnancy test, you don’t have to. You should also estimate how far along the pregnancy is. Pregnancies are measured starting from the first day of your last period (and not from conception or when you had sex). You can figure out how far along the pregnancy is using your last period in a **pregnancy calculator like this one** or by getting an ultrasound.

What kind of pregnancy test should I use before taking the pills? –

Almost any pregnancy test will work. Dollar store tests work great. We do not recommend using any digital (positive/negative or +/-) pregnancy tests because we have noticed many people having false positives (a positive test result when they are not actually pregnant).

Do I need to get an ultrasound before taking abortion pills? –

No, getting an ultrasound is not required for most people. You do not need to get an ultrasound as long as your provider can figure out how far along your pregnancy is and you do not have signs of an ectopic pregnancy.

How should I get ready to take my abortion pills? –

1. Read our information on how to take the pills, what you might see and feel, and how to identify signs of complications.
2. Have a plan for where and when you will take the pills. You will want to be in a comfortable place and have access to a bathroom for up to 12 hours after taking misoprostol (the second medicine).
3. Have a plan for how to get emergency medical care in the unlikely event that you need it. It can be good to have a support person (in-person or virtually) in case you need help – especially the day you take misoprostol because this is when you'll have the most cramping/pain and bleeding.
4. Have on hand whatever you usually use to help with your periods (ex: large overnight pads, painkillers, anti-nausea medicine, heating pads, comfortable clothes, snacks, netflix/movies, etc).

How to use abortion pills

How should I take the abortion pills? –

Check out the instructions. How you take the abortion pills depends on how far along the pregnancy is. You can figure out how far along the pregnancy is based on your last period or by getting an ultrasound. There are many different ways to take the pills and most work well. The World Health Organization recommends:

Less than 9 weeks	• Swallow 1 mifepristone 200mg pill orally • Wait 1-2 days • Take 4 misoprostol 200mcg pills under the tongue, in the cheek, or in the vagina. If you don't start bleeding after 24 hours, take another 4 pills.
9-11 weeks	• Swallow 1 mifepristone 200mg pill orally • Wait 1-2 days • Take 4 misoprostol 200mcg pills under the tongue, in the cheek, or in the vagina. 4 hours later, take another 4 misoprostol 200mcg pills.
12+ weeks	• Swallow 1 mifepristone 200mg pill orally • Wait 1-2 days • Take 2 misoprostol 200mcg pills under the tongue, in the cheek, or in the vagina every 3 hours until the pregnancy tissue is out.

How long do I have to wait to take misoprostol (the second medicine)? –

We recommend taking misoprostol 1-2 days (24-48 hours) after mifepristone because this will be the most effective.

How do I take misoprostol (the second medicine)? –

Misoprostol can be taken in 3 different ways – vaginally, buccally, or sublingually. Vaginally means inserting the medicine with your fingers into the vagina. Buccally means holding the medicine in your cheeks like how a chipmunk holds food. Sublingually means holding the medicine under your tongue. If you take the misoprostol sublingually or buccally, after 30 minutes you can swallow whatever remains of the pills.

What is the difference between putting the misoprostol (the second medicine) under your tongue, in your cheek, or in the vagina? –

In areas where abortion is restricted, it can be safer to put the misoprostol in your cheek or under your tongue. After 30 minutes you can swallow or spit out anything that is left. Using the medicines in your cheeks or under your tongue can give you more side effects (nausea, vomiting, diarrhea). Using the medicines in the vagina gives you less side effects, but the pills could be seen during a vaginal exam. If this is a concern for you, we recommend that you use the pills in your cheek or under your tongue.

What can I take for nausea? –

You can take over the counter anti-nausea medicine like Unisom or Dramamine. Other things that can help with nausea include ginger tea, chewing gum, and sucking on hard candies. A prescription for anti-nausea medication can be sent if needed.

What can I take for pain? –

1. It's most effective to wait until you feel some pain before taking painkillers (but do not wait until the pain is unbearable). You can take over-the-counter painkillers like ibuprofen (Motrin/Advil) and acetaminophen (Tylenol). You can take 600-800mg ibuprofen every 6-8 hours with food. You can take 1000mg of acetaminophen every 6 hours. You can also take ibuprofen and acetaminophen together. If you do not want to use ibuprofen, you can try taking naproxen (Aleve) 550mg every 12 hours. To be more comfortable during the process, you can also try using a hot water bottle or heating pad on the belly, listening to music, having a support person, being someplace private, etc.

Why do I start with fewer misoprostol pills when I'm 12+ weeks pregnant? –

The farther along you are, the fewer misoprostol pills you need for each dose. After 12 weeks, people should take 1 mifepristone followed by 2 misoprostol pills repeated every 3 hours until the pregnancy passes.

Why do I have extra pills and what should I do with them? –

Extra misoprostol pills are sent in case:

1. You vomit after taking the pills
2. You don't bleed enough after taking the pills
3. You have too much bleeding after taking the pills

Please keep any extra misoprostol for at least 2 months. This way you will have it on hand in case you experience a complication and are advised to take it.

What do I do with my extra pills? –

Please keep any extra misoprostol for at least 2 months. This way you will have it on hand in case you experience a complication and are advised to take it.

What if I throw up after taking the abortion pills? –

As long as you can keep the mifepristone (first medicine) down for at least 30 minutes, it will most likely be effective. If you vomit less than 30 minutes after taking mifepristone, it might not be as effective, so contact us for further information.

As long as you keep the misoprostol (second medicine) in your mouth for at least 20 minutes, that should be enough time for the medication to absorb and be effective. If you vomit less than 20 minutes after taking the misoprostol by mouth, it's recommended to take anti-nausea medication, wait a few hours, and try again.

During an abortion with pills

What happens after taking the abortion pills? –

Most people don't have any symptoms after taking mifepristone (the first medicine). Some people might have light bleeding or nausea. The main symptoms of bleeding and cramping usually begin after taking the misoprostol (the second medicine).

How much bleeding and cramping will I have? –

Every person is different, and there is a range of normal bleeding and cramping. . Most people have bleeding and cramping that is heavier than a period and can include blood clots the size of lemons. Some people only have light bleeding. It usually starts 4-6 hours after taking the misoprostol (the second medicine) and starts to slow down within 1 day. Some people have mild pain, and other people have very intense cramps.

What if I start bleeding/having a miscarriage before I use the abortion pills? –

Signs of a miscarriage don't always mean you had a complete miscarriage so it is recommended that you still use the abortion pills to make sure the pregnancy passes fully.

What are the side effects of misoprostol (the second medicine)? –

The side effects of misoprostol include nausea, vomiting, headache, diarrhea, fever, and chills. These are usually temporary and go away on their own. If the fever (more than 101 degrees) continues for more than 24 hours after taking misoprostol, please contact your abortion pill provider because this can be a sign of infection.

How much bleeding is too much? −

It is normal to have heavy bleeding and blood clots. If you are soaking 2 large overnight pads per hour for 2 hours in a row (4 pads in 2 hours) that is too much bleeding. You should seek medical attention right away if this happens. Sometimes providers recommend taking 2 more misoprostol pills to slow the bleeding down while waiting for medical attention.

What are signs of a complication? −

If you have very heavy bleeding (soaking 2 large overnight pads per hour for 2 hours in a row), fever for over 24 hours since taking misoprostol, or severe pain that is not relieved by painkillers, these are signs of severe medical complications, and you should seek medical attention right away.

Will anyone be able to tell that I took abortion pills? −

No, there are no tests to detect that you took abortion pills by mouth. The only way for the providers to know is if you tell them or if you took the pills vaginally and they see them on an internal exam. You do not need to say that you took abortion pills.

If I have to go to the hospital, what should I say? −

The treatment for a miscarriage and abortion are the same, so you can just say something like “I’m bleeding but it doesn’t feel like my usual period. I’m afraid something is wrong” or “I’m pregnant and bleeding. I’m scared there’s something wrong” and you should get the care you need.

After an abortion with pills

How do I know if the abortion pills worked? −

Most people can tell if the pills worked by what they experience and how they feel. Some signs that the abortion pills worked can include: bleeding (light or heavy), cramping after taking the pills, passing clots and/or tissue, and no longer feeling pregnant. Pregnancy tests can stay positive for up to 5 weeks after a successful abortion, so they are not reliable before that time. If you still feel pregnant, you should contact your abortion pill provider.

What if I have little or no bleeding after taking the abortion pills? −

This could be a sign that the pills didn't work, so you need to talk to your abortion pill provider for further guidance.

How long will I bleed after taking abortion pills? −

Bleeding should start to slow down after the pregnancy passes. However, light bleeding and/or spotting can continue off and on for up to 6 weeks. If you have been bleeding more than 6 weeks, contact your abortion pill provider.

What if I have vaginal odor after using the pills? −

Your vagina needs time to adjust to the changing hormones after ending the pregnancy, so any odor changes can be normal. Burning or pain from the discharge are reasons to seek medical attention.

When can I get pregnant again after an abortion? −

You can get pregnant as soon as 1 week after your abortion. If you want to prevent pregnancy, it is important to start birth control soon after your abortion.

When can I start birth control after my abortion? −

You can start most methods right away. If you start within 1 week, you are protected from pregnancy right away. Here is a guide to starting birth control after an abortion.

When can I start exercising or return to work/school after an abortion with pills? −

Everybody is different. Most people are able to return to normal activities the day after you finish taking misoprostol (the second medicine).

When can I have sex again after an abortion? −

This is up to you and what feels right for your body. You can have sex again whenever you feel ready.

* Nothing on this website is to be construed as medical advice. Please consult with a trusted healthcare professional before making any medical or healthcare decisions.

Abuzz: Abortion Pill Access At Home

About Us

How it Works

FAQ

Terms of Use

Privacy Policy

Provider Payments

Donations allow us to help all pregnant people, regardless of their ability to pay. Please consider supporting our work.

DONATE

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EXHIBIT 71a

Abuzz - How It Works

abuzz

X Quick Exit

How It Works

The process is simple, con dential, and designed to meet your needs.

1. Fill in the form.

The form asks a few basic questions to help the clinician know if you are eligible to get abortion pills by mail.

You will also be asked to upload a copy of your photo ID (if you do not have one, please let us know) and sign a consent form.

Fill in the form →

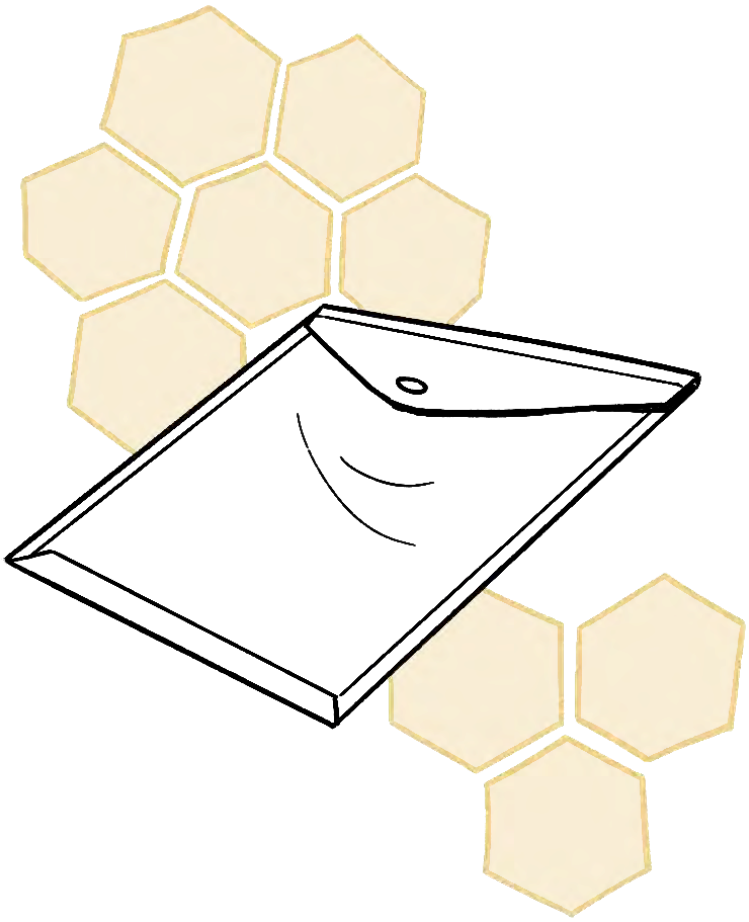
2. Check your email.

You'll get instructions for making a payment and signing into the secure portal. Follow those instructions to complete your request.

3. Review

A US-licensed clinician will review your eligibility for an at-home abortion with pills within 1-2 business days. In most cases, Abuzz providers do not require a phone/video call. If your provider has more questions, they will contact you via the portal.





4. Receive and use abortion pills at home

Your FDA-approved medications (mifepristone and misoprostol) will be sent by mail. Shipping takes 1-5 business days. Detailed instructions and support are provided. Clinicians are available to answer your questions 7 days a week.

Still have questions? Check out our FAQ

→Go to the FAQ

abuzz

Abuzz: Abortion Pill Access At Home

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Provider Payments

Donations allow us to help all pregnant people, regardless of their ability to pay. Please consider supporting our work.

DONATE

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EXHIBIT 72

Declaration of Ann Dalton

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

STATE OF MISSOURI, *et al.*,

Intervenor-Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants,

DANCO LABORATORIES, LLC,

Intervenor-Defendant, and

GENBIOPRO, INC.,

Intervenor-Defendant.

Case No. 2:22-cv-00223-Z

DECLARATION OF ANN DALTON

I, Ann Dalton, hereby declare and swear as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth here, and am competent to make this declaration.

2. I currently work in Florida's Agency for Healthcare Administration (AHCA) as the Assistant Deputy Secretary for Medicaid Policy and Quality.

3. In my role with AHCA, I am familiar with the administration of the Florida Medicaid program.

4. The statements in this declaration are based on my professional knowledge and experience.

5. When a provider seeks coverage for medical services, it submits a claim to Florida Medicaid.

6. Claims typically include information regarding services rendered, diagnosis codes, and payment amounts.

7. In my role with AHCA, I am familiar with Florda Medicaid claim records, and in preparing this declaration, Agency staff reviewed a subset of paid claim amounts for Calendar Years 2020 and 2022.

8. As a matter of State policy, Florida Medicaid does not provide coverage for elective abortions. However, Florida Medicaid does provide coverage for treatment and follow-up care at hospitals following abortion *complications*, including complications from abortifacients like mifepristone.

9. Often, the cost to Florida for providing such coverage is not quantified, or is difficult to identify, in the medical records due to a range of factors, including coding variances.

10. Nonetheless, through a review of a subset of Florida's Medicaid records, Agency staff has identified the below coverage costs to the State of Florida provided for treatment and follow-up care at hospitals following chemical abortion complications.

11. The review was initiated in April 2025. First, AHCA identified Medicaid diagnosis codes associated with mifepristone complications. AHCA then sent letters to approximately 500 healthcare providers requesting medical records for approximately 1,000 recipients with Florida Medicaid claims filed under those diagnosis

codes. AHCA requested that the records be delivered within 14 days after receipt of the notification. Many healthcare providers did not meet this deadline, and some have not responded. Many records received by AHCA required decryption. Once records were received and decrypted, AHCA narrowed its search by uploading the records into a document review software and filtering by keyword searches. The remaining records were manually reviewed by certified nurses to determine whether treatment was related to complications from a chemical abortion. The records described below were identified in July 2025. The review is ongoing.

12. In Calendar Year 2020, Florida Medicaid expended $543.73 in total funds to reimburse UF Health Shands Hospital for services provided to a Medicaid recipient in January 2020. Based on a review of the records documenting the services provided, AHCA staff concluded that the services were provided for the patient's treatment and follow-up care for medical complications caused by a chemical abortion.

13. In Calendar Year 2022, Florida Medicaid expended $433.39 in total funds to reimburse the Jackson Health System for services provided to a Medicaid recipient in March 2022. Based on a review of the records documenting the services provided, AHCA staff concluded that the services were provided for the patient's treatment and follow-up care for medical complications caused by a chemical abortion.

* * *

I declare that the foregoing is true and correct to the best of my knowledge, information, and belief.

Executed August 21, 2025.

/s/
Ann Dalton

EXHIBIT 73

Declaration of Julie Webster

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

STATE OF MISSOURI, *et al.*,

Intervenor-Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants,

DANCO LABORATORIES, LLC,

Intervenor-Defendant, and

GENBIOPRO, INC.,

Intervenor-Defendant.

Case No. 2:22-cv-00223-Z

DECLARATION OF JULIE WEBSTER

I, Julie Webster, hereby declare and swear as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth here, and am competent to make this declaration.

2. I currently work in Florida's Agency for Healthcare Administration (AHCA) as an Operations & Management Consultant Manager in the Division of Health Quality Assurance.

3. I am a registered nurse licensed in the State of Florida.

4. The statements in this declaration are based on my professional knowledge and experience.

5. In July 2025, I was asked to review medical records that had been collected from hospitals by AHCA's Division of Medicaid. These records were requested based on a review of paid Medicaid claims in which I was not involved. Upon reviewing the records, I concluded that two of the records reflected instances in which hospitals in Florida provided services for patients' treatment and follow-up care for medical complications caused by chemical abortions.

6. In the first instance, I reviewed records related to services provided to a patient by UF Health Shands Hospital in January 2020. The patient presented at UF Health Shands Hospital with fever, abdominal pain, nausea, and vomiting for the previous two days. The patient was seen at Bread & Roses, an abortion clinic, six days before reporting to the hospital, when she was pregnant at approximately six weeks' gestation. The abortion clinic performed an elective chemical abortion. The patient was given one tablet of mifepristone in the clinic and four tablets of misoprostol to take at home, which she completed. She passed large clots and fetal tissue followed by light bleeding for a few days. The day before reporting to the hospital, the patient developed nausea, vomiting, and abdominal pain with a fever of 103 degrees at home. She took Tylenol but continued to feel worse and could not tolerate food or drink by mouth. The patient denied upper respiratory infection symptoms, diarrhea, or recent sick contacts. The hospital administered laboratory testing, an ultrasound, IV fluids, and antibiotics for suspected endometritis. By the third day of treatment, the patient was tolerating intake, had improved pain, and was stable and ready for discharge.

7. In the second instance, I reviewed records related to services provided to a patient by the Jackson Health System in March 2022. The patient presented to the emergency department at the Jackson Health System with left flank pain for the previous 13 days. The patient was seen at Total Women's Clinic, an abortion clinic, 16 days before reporting to the hospital, when she was pregnant at seven weeks' gestation. The abortion clinic performed an elective chemical abortion. The patient was given one tablet of mifepristone in the clinic and two tablets of misoprostol to take at home, which she completed. She experienced heavier bleeding over the next two days and believed she saw the passage of tissue. Her flank pain started laterally, travelling down to her right lower quadrant. The hospital administered laboratory tests, an ultrasound, pain medications, and a pelvic exam. Tissue from the patient's cervical os and vaginal vault was removed and sent to pathology for evaluation. Pathology determined it was degenerated chorionic villi in a background of purulent exudate consistent with inflamed/infected products of conception.

* * *

I declare that the foregoing is true and correct to the best of my knowledge, information, and belief.

Executed August 21, 2025.

/s/ Julie Webster
Julie Webster

EXHIBIT 74

We Take Care of Us
FAQ

Frequently asked questions

About medication abortion
Before medication abortion
During medication abortion
After medication abortion
About our care

Resources
How to take abortion pills

EXIT

ABOUT medication abortion

Who is eligible for medication abortion?

Is medication abortion safe?

Is medication abortion effective?

If medication abortion is safe, why am I hearing about abortion restrictions in the news?

Is abortion legal? Can I get in trouble for having or taking abortion pills?

I'm in a restrictive state, how can I access abortion pills safely?

BEFORE medication abortion

- How do I confirm that I'm pregnancy?
- How do I know how many weeks pregnant I am?
- How do I find out about my options?
- How does medication abortion work?
- When during pregnancy is medication abortion an option?
- Will abortion pills affect my ability to get pregnant in the future?
- My blood type is Rh negative. Do I need to take Rhogam if I have a medication abortion?
- What is ectopic pregnancy? How do I know if I have one?
- I have an IUD. Is medication abortion an option for me?
- Do I need an ultrasound?
- How should I prepare for a medication abortion?

EXIT

DURING medication abortion

- How do I take abortion pills?
- What is the best way to take misoprostol?
- What should I expect after taking mifepristone?
- What should I expect after taking misoprostol?
- What if I vomit after taking the medication?
- Can I eat and drink as usual during my medication abortion?
- How can I manage my symptoms after taking abortion pills?
- How do I know if my bleeding is normal?

What should I do if I think I'm having a complication?

AFTER medication abortion

How do I know if the abortion pills worked?

How long will my bleeding last?

Is it normal to continue to have cramps?

When can I return to my usual work, school and/or exercise routine?

When can I have sex again after taking abortion pills?

When can I get pregnant again after taking abortion pills?

When can I start taking birth control?

How do I know if I have an infection?

What should I do if I have misoprostol pills left over?

EXIT

ABOUT our care

Who are the providers?

What is telehealth? Is it safe and private?

How much does care cost?

Do you take insurance?

I can't pay $150 for an abortion. Is financial assistance available?

Do I have to schedule a video visit?

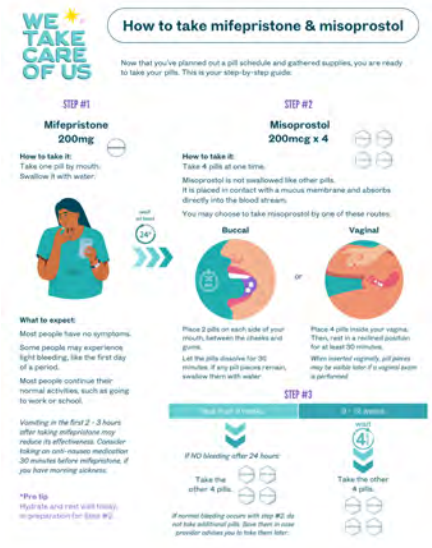
No. A video visit is not required. Most of the care we provide is asynchronous. The first step is completing an online intake form. When completing the form, you tell us what contact method you would like to use for ongoing coordination of your care. Options include a secure

messaging app, text and email. If you would like to have a video visit to ask questions, that option is also available.

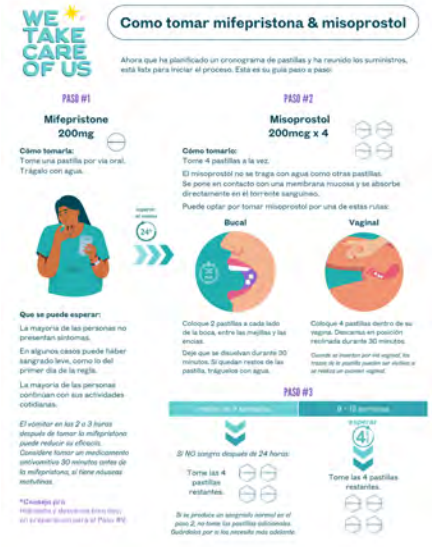
For some care services, such as perimenopause and menopause care, we may recommend a video visit as the best way to work with you to understand your priorities and goals, and develop your plan of care.

Is support available if I have questions?

How to take abortion pills



Click to download



Haga clic para descargar

EXIT

Resources

- Medical Support
- Emotional Support
- Legal Support
- Security



EXIT

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EXIT

Frequently asked questions

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AFTER medication abortion

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When can I get pregnant again after taking abortion pills?

When can I start taking birth control?

How do I know if I have an infection?

What should I do if I have misoprostol pills left over?

EXIT

ABOUT our care

Who are the providers?

We Take Care of Us is a cooperative run by Certified Nurse Midwives (CNMs). We are primary healthcare providers for individuals who have a uterus; from menarche, during the reproductive years and throughout menopause. CNMs focus on health promotion, wellness care, gynecologic and family planning services, as well as childbearing. Our midwives specialize in providing whole-person, trauma-informed and gender-expansive care. We are here to accompany you on your journey toward health and well being.

What is telehealth? Is it safe and private?

How much does care cost?

Do you take insurance?

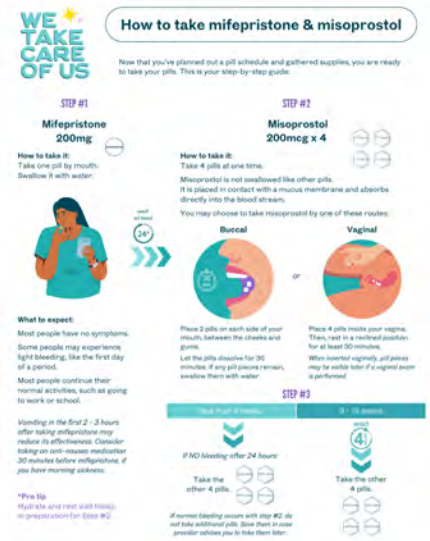
I can't pay $150 for an abortion. Is financial assistance available?

Do I have to schedule a video visit?

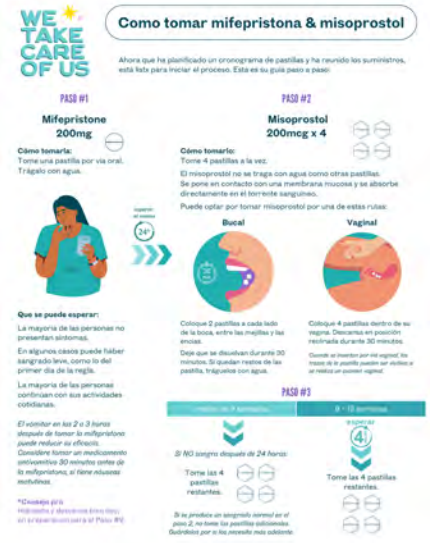
Is support available if I have questions?

EXIT

How to take abortion pills



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EXIT

Resources

- Medical Support
- Emotional Support
- Legal Support
- Security



EXIT

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EXHIBIT 74a

We Take Care of Us

Community Supported Abortion



Our Community Supported Abortion program provides medication abortion during the first 12 weeks of pregnancy, throughout the United States. Sliding scale pricing ranges from $150 - $600. You choose a payment amount that fits your economic and social situation. Additional assistance is available to those who need it.

GET STARTED EMPIEZA AHORA

How it works:

- Complete a 10-15 minute online intake request

  This form asks a series of screening questions to ensure that medication abortion is a safe option for you. We review your intake within 24 hours.

- Make your selected sliding scale payment
- Abortion pills are delivered to your door
- Receive ongoing support and accompaniment

The legal context of abortion care is different in every state and policies are in flux. Find up-to-date information about your state's abortion laws, and the potential risks of receiving abortion pills by mail in your state here.

Abortion pills in advance

Get abortion pills when you're not pregnant to have on hand just in case. If you decide to use them in the future, our midwives will be available to accompany you. Complete a quick intake request to get started.

PILLS IN ADVANCE PASTILLAS POR ADELANTADO



Period pills

Is your period late, but you haven't taken a pregnancy test? Period pills may help reestablish your period, even if you prefer not to confirm pregnancy. Complete a quick intake request to get started.

PERIOD PILLS PASTILLAS PARA EL PERIODO

EXIT

perimenopause

Perimenopause and menopause have long been overlooked by the medical community. Unfortunately, this leaves many providers unprepared to respond to your symptoms and concerns during this time of life.

We Take Care of Us is different. We are up-to-date on the evidence and the available treatment options. We work with you to develop an individualized plan of care. Then we follow up and make adjustments as needed, to maximize your quality of life.

Get started with our online intake request. We follow up in 24-48 hours.
Sliding scale: $80-$200 consult fee.

Other care offerings:

EXIT

Emergency Contraception

Emergency Contraception (EC) can be used to prevent pregnancy within the first 5 days after unprotected penis-in-vagina sex. We can order EC if you've had unprotected sex in the last 72 hours, or just want to have EC available for future use.

Sliding scale: $10-$60 consult fee, plus the cost of your medication.

Fill out this brief intake form and we'll follow up within 24 hours.

GET STARTED NOW EMPIEZA AHORA

Emergency Contraception

Contraception Counseling and Prescriptions

Vaginal & Urinary Tract Infections

Sexual Health, Wellness & Education

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EXHIBIT 75

Plan C – Where people get abortion pills online in Florida



Where People Get Abortion Pills Online in Florida

Abortion access in Florida is restricted after 6 weeks of pregnancy. But, abortion pills are still available by mail from providers outside of Florida, before and after the 6-week mark. Options below.

Show my options ↓

Have legal questions? →

Pregnancy Calculator →

If you live in this state and are seeking an abortion, you may qualify to participate in a paid research study about abortion access. **Click here to learn more.**



Did you know you can order abortion pills ahead of time, just in case?

View Options

Options for getting pills

We group providers based on the type of service they offer.

How do I choose from these provider types?

Online clinics that mail pills

For people who want abortion pills by mail and follow-up support from a clinician.

💵 $0–150+ 🚚 1–5 days

🧑🏾 Clinician support

💊 FDA-approved medications

Medically safe, possible legal risk

Websites that sell pills

For people who want abortion pills by mail without consulting a clinician.

💵 $58 and up 🚚 3–6+ days

💊 Generic medications

ⓘ Medically safe, possible legal risk

See 10 results ↓

Community networks that mail pills

For people who can't afford other services and want free pills mailed by volunteers.

💵 Free 🚚 5–14 days

💊 Generic medications

ⓘ Medically safe, possible legal risk

See 2 results ↓

Stay safe: Read our digital privacy tips ›
Quick Exit (esc)

For people who have access to transportation and would prefer to pick up abortion pills in person from an abortion clinic.

💵 Pricing varies 🧑🏾 Clinician support

💊 FDA-approved medications

See results ↓

Filter Results

- ☐ Accepts insurance
- ☐ Accepts Medicaid
- ☐ Sliding scale pricing
- ☐ Get pills in advance
- ☐ Se habla español

Stay safe: Read our digital privacy tips ›
Quick Exit (esc)

Online Clinics That Mail Pills

US-Based Online Clinics

Online clinics are US-licensed clinicians who ship pills to you after a brief online form or phone/video visit. Follow up support is available.

Showing 6 of 6 results Sort by: **Price**

Abuzz

Price	Delivery	Ages
$0–150	**1–5 days**	**16+**

Pills by mail with clinician support
For pregnancies up to 13 weeks

- Get pills in advance
- Financial assistance available
- Medically safe, possible legal risk

MORE INFORMATION REQUEST PILLS

The MAP: Cambridge Reproductive Health Consultants

Price	Delivery	Ages

Get pills in advance

Financial assistance available

Medically safe, possible legal risk

MORE INFORMATION REQUEST PILLS

Aid Access

Price	Delivery	Ages
$150 or less	2–5 days	All

Pills by mail with clinician support
For pregnancies up to 14 weeks

Get pills in advance

Financial assistance available

Medically safe, possible legal risk

MORE INFORMATION REQUEST PILLS

Community Supported Abortion, by We Take Care of Us

Price	Delivery	Ages
$5–$300+	2–5 days	All

Stay safe: Read our digital privacy tips ›
Quick Exit (esc)

Get pills in advance

Financial assistance available

Medically safe, possible legal risk

MORE INFORMATION REQUEST PILLS

Choices Rising

Price	Delivery	Ages
$150	2–5 days	15+

Pills by mail with clinician support (Hablamos Español)

For pregnancies up to 12 weeks

Get pills in advance

Medically safe, possible legal risk

MORE INFORMATION REQUEST PILLS

A Safe Choice

Price	Delivery	Ages
$150	1–5 days	All

Pills by mail with clinician support

Stay safe: Read our digital privacy tips ›
Quick Exit (esc)

MORE INFORMATION REQUEST PILLS

International Online Clinics

These services are provided by clinicians licensed in the US or abroad who mail pills after the patient completes a brief online or video visit. Pills provided are generic versions.

Showing 2 of 2 results

Abortion Pills in Private

Price	Delivery	Ages
$95	**3–6 business days**	**16+**

Pills by mail with clinician support (Hablamos Español)
For pregnancies up to 11 weeks

No financial assistance available

Medically safe, possible legal risk

MORE INFORMATION REQUEST PILLS

Women on Web

For pregnancies up to 12 weeks

- Get pills in advance
- Financial assistance available
- Medically safe, possible legal risk

MORE INFORMATION REQUEST PILLS

Why are online clinics listed if my state does not allow telehealth for abortion?

How do I choose a provider?

What if I have medical questions?

Back to top

Websites That Sell Pills

Stay safe: Read our digital privacy tips ›
Quick Exit (esc)

(some provide up to 14 misoprostol tablets). It may not be necessary to use all of these tablets, but doctors recommend having extra pills on hand in case you need them.

Important: These websites may not follow strict digital security protocols. Read our digital privacy tips to learn how to protect yourself when ordering or searching for abortion pills online.

Read the FAQs below for more information on how these sites work.

Showing 4 of 10 results

Sort by: **Price**

Private Emma

Price	Delivery	Ages
$59	**3–6 business days**	**All**

1 mifepristone plus 14 misoprostol
For pregnancies up to 12 weeks

- Get pills in advance
- Financial assistance available
- Medically safe, possible legal risk

MORE INFORMATION REQUEST PILLS

Privacy Pill Rx

Price	Delivery	Ages
$59–79	**10–12 business days**	**All**

Stay safe: Read our digital privacy tips ›
Quick Exit (esc)

MORE INFORMATION REQUEST PILLS

Life Easy On Pills

Price	Delivery	Ages
$60–80	**3–6 business days**	**All**

1 mifepristone plus 14 misoprostol

Get pills in advance

Medically safe, possible legal risk

MORE INFORMATION REQUEST PILLS

Abortion Privacy

Price	Delivery	Ages
$60–80	**3–6 business days**	**All**

1 mifepristone plus 14 misoprostol

Get pills in advance

Medically safe, possible legal risk

See all 10 websites that sell pills

What are websites that sell pills?

Are these websites legit?

How many pills do I need?

What if I have medical questions?

Back to top

Community Networks That Mail Pills

These are community-based (mostly volunteer) networks in the US that ship generic abortion pills for free. The pills often come repackaged in plastic baggies. Request pills by email.

These services are for confirmed pregnancies only. To learn about services that offer pills in advance, visit plancpills.org/in-advance).

Price **$0** Delivery **5–12 days** Ages **All**

Community network that mails pills - FOR CONFIRMED PREGNANCIES ONLY

Medically safe, possible legal risk

MORE INFORMATION REQUEST PILLS

DASH

Price **$0** Delivery **5–14 days** Ages **All**

Community network that mails pills - FOR CONFIRMED PREGNANCIES ONLY

Medically safe, possible legal risk

MORE INFORMATION REQUEST PILLS

Back to top

In-Person Clinics

Clinics offer abortion pill pickup and other in-person abortion care options. To find the nearest clinic to Florida, use any of these search tools:

I Need an Abortion

A comprehensive, regularly updated, and personalized resource for abortion seekers in the US.

VISIT WEBSITE

Learn about potential legal risk

Learn about potential legal risks of accessing pills from alternative suppliers by reading the FAQ below, "Can someone get in trouble for using abortion pills?"

You can also contact the free, confidential Repro Legal Helpline (online or at 844-868-2812) to discuss your specific situation.

Can someone get in trouble for using abortion pills?



Have feedback about Plan C or a provider?

Let us know

Stay safe: Read our digital privacy tips ›
Quick Exit (esc)



Live Phone & Text Support

For Medical Questions

The M+A Hotline

Free, confidential support from expert clinicians. They don't sell pills.

CALL OR TEXT VISIT WEBSITE

For Logistical & Emotional Support

Reprocare Healthline

Free, confidential peer-based support for getting and using abortion pills.

CALL OR TEXT VISIT WEBSITE

For Legal Questions

ReproLegal Helpline

Free, confidential legal information from expert lawyers.

Stay safe: Read our digital privacy tips ›
Quick Exit (esc)



Automated Support

NEW

Charley the Chatbot

A free, secure chatbot that helps identify nearby local clinics, online providers and support services.

VISIT WEBSITE

Frequently Asked Questions

Answers to common questions about how abortion pills work and how people access them.

READ FAQ

ALL SUPPORT & RESOURCES →



Sign up for our newsletter to get the latest updates and opportunities to take action, delivered straight to your inbox.

Your Email

Sign Up

Plan C is a project under the fiscal sponsorship of Possibility Labs, a 501c3 organization. Our generous donors make this critical work possible.

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PLAN C
Abortion Pills
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Español

EXHIBIT 76

Plan C – Where people get abortion pills online in Texas

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PLAN C

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Plan C Guide > Texas



Where people get abortion pills online in Texas

Abortion access in Texas is restricted, but abortion pills are still available by mail from providers outside of Texas. Options below.

- Show my options ↓
- Learn about potential legal risk →
- Pregnancy Calculator →

⚠ **Please note:** Plan C does not sell pills. Use this guide to find an abortion pill provider.

Stay Safe: Read our digital privacy tips ›

Quick Exit (esc)



Online clinics that mail pills

For people who want abortion pills by mail and follow-up support from a clinician.

- $150 or less
- 1-5 days
- Clinician support
- FDA-approved medications
- Potential legal risk

See 8 results ↓



Websites that sell pills

For people who want abortion pills by mail without consulting a clinician.

- $30 and up
- 3-9 days
- Generic medications (from India)
- Potential legal risk

See 13 results ↓



Community networks that mail pills

For people who can't afford other services and want free pills mailed by volunteers.

- Free
- 5-10 days
- Generic medications (from India)
- Potential legal risk

See 1 result ↓



In-person clinics

For people who have access to transportation and would prefer to pick up abortion pills in person from an abortion clinic.

- $500 or more
- Clinician support

Stay Safe: Read our digital privacy tips ›

Quick Exit (esc)

⚠ **Learn about potential legal risks of accessing pills from alternative suppliers by reading the FAQ below, "Can I get in trouble for using abortion pills?"**

You can also contact the free, confidential Repro Legal Helpline (online or at 844-868-2812) to discuss your specific situation.

Can I get in trouble for using abortion pills?

The short answer is: it depends, and it's complicated.

Legal risk can depend on:

- where you live,
- your identity: race, ethnicity, income level, etc.
- and how far along you are in pregnancy.

In the end, it's up to each person to make their own decision about risk. Click the headings below for more information about these risks.

Where someone lives makes a difference.

What if a state totally bans abortion?

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PLAN C

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Have Legal Questions?

The **Repro Legal Helpline** provides free and confidential legal advice that can help people better understand the laws and legal risk they may face. Contact them **online** or call **844-868-2812**.

For more analysis of potential legal risk, **read this article**.

How do I choose from these provider types?

Here are a few factors to consider when choosing a provider type:

What kind of support do you want?

How much will it cost?

How long will it take to get pills?

Other important factors

Stay Safe: Read our digital privacy tips ›

Quick Exit (esc)

PLAN C

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Online clinics that mail pills



US-based online clinics

Online clinics are US-licensed clinicians who ship pills to you after a brief online form or phone/video visit. Follow up support is available.

Why are online clinics listed if my state does not allow telehealth for abortion?

This is possible because some states have "shield laws" in place that protect clinicians when they provide telehealth care to someone in another state. **Read our FAQ** about potential legal risks of getting abortion pills by mail and taking them in a state that restricts access. If you want to speak to someone about legal risk, contact the **Repro Legal Helpline**.

For more information about shield laws, **read this article**.

How do I choose a provider?

People usually choose an online clinic based on what kind of telehealth care they are comfortable with. Some providers require a phone or video visit while other providers communicate with you through text or email.

Stay Safe: Read our digital privacy tips ›

Quick Exit (esc)

What if I have medical questions?

Online clinics usually offer medical support during and after your abortion. The format of this care depends on the provider. Some providers use phone or video visits (we call this a "Virtual visit with provider") while others communicate through text or email (we call this "Online consultation by form").

You can also get free medical support from **The Miscarriage and Abortion Hotline**, which provides confidential medical information and support by phone and text to anyone in any state.

Important: If you live in an abortion restrictive state and are traveling to another state to receive telehealth care, the provider will not be able to provide care to you if you tell them you have returned to the restrictive state.

Filter by:

☐ Accepts insurance ☐ Accepts Medicaid ☐ Sliding scale pricing ☐ Get pills in advance ☐ Se habla español

Showing 5 of 5 results

Sort by: **Price**

AID ACCESS

Price	Delivery	Ages
$150 or less	**2-5 days**	**All**

ARMADILLO CLINIC

Price	Delivery	Ages
$200 or less	**2-5 days**	**18+**

CAMBRIDGE REPRODUCTIVE HEALTH CONSULTANTS

Price	Delivery	Ages

Stay Safe: Read our digital privacy tips ›
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Financial assistance available

Learn about the potential legal risk of using this service

MORE INFORMATION | REQUEST PILLS

Learn about the potential legal risk of using this service

MORE INFORMATION | REQUEST PILLS

Get pills in advance

Financial assistance available

Learn about the potential legal risk of using this service

MORE INFORMATION | REQUEST PILLS

WE TAKE CARE OF US

Price	Delivery	Ages
$150–$600	**1–5 days**	**All**

Pills by mail with clinician support (hablamos español)

For pregnancies up to 12 weeks

Get pills in advance

Financial assistance available

Learn about the potential legal risk of using this service

MORE INFORMATION | REQUEST PILLS

A SAFE CHOICE

Price	Delivery	Ages
$150	**1–5 days**	**All**

Pills by mail with clinician support

For pregnancies up to 13 weeks

Get pills in advance

Learn about the potential legal risk of using this service

MORE INFORMATION | REQUEST PILLS

International online clinics

ivacy tips ›
Quick Exit (esc)

Showing 3 of 3 results

ABORTION PILLS IN PRIVATE

Price **$90** | Delivery **8–14 days** | Ages **16+**

Pills by mail with clinician support

For pregnancies up to 11 weeks

No financial assistance available

Learn about the potential legal risk of using this service

MORE INFORMATION | REQUEST PILLS

WOMEN ON WEB

Price **$120 or less** | Delivery **3–5 business days** | Ages **All**

Pills by mail with clinician support (Hablamos Español/falamos Português)

For pregnancies up to 12 weeks

Get pills in advance

Financial assistance available

Learn about the potential legal risk of using this service

MORE INFORMATION | REQUEST PILLS

TELEFEM MEXICO

Price **$200** | Delivery **3 days** | Ages **All**

Pills by mail with clinician support, Hablamos Español--SHIPS TO MEXICO ADDRESSES ONLY, BUT CAN BE PICKED UP ALONG U.S. BORDER AT COURIER LOCATIONS

For pregnancies up to 10 weeks

No financial assistance available

MORE INFORMATION | REQUEST PILLS

Back to top

Websites that sell pills

privacy tips ›
Quick Exit (esc)

our digital privacy tips to learn how to protect yourself when ordering or searching for abortion pills online.

Read the FAQs below for more information on how these sites work.



What are websites that sell pills?

Websites that sell pills are e-commerce websites that sell and ship pills to addresses in all U.S. states. They do not require a prescription for the medications, do not require you to upload your ID, and do not provide a medical consultation or any kind of support.

Are these websites legit?

Yes, these websites are legit. They sell generic abortion pills that are not regulated or inspected by the US government. Plan C regularly tests these websites by buying pills from them. The services we list in our guide all shipped pills to a home address. The pills were real (based on laboratory testing). But, we do not operate these sites, and cannot guarantee they will be reliable in the future.

Important: These websites may not follow strict digital security protocols. Read our **digital privacy tips** to learn how to protect yourself when ordering or searching for abortion pills online.

How do I choose one of these websites?

Stay Safe: Read our digital privacy tips ›
Quick Exit (esc)

We suggest you check their website and pick the one that you feel most comfortable ordering from. If you are not sure what pills to order, read the FAQ below, "What kind of kit do I order?".

What kind of kit do I order?

Most of these websites sell abortion pills in a blister pack called an MTP Kit. These kits usually contain 5 pills: 1 dose of mifepristone (1 pill) and 1 dose of misoprostol (4 pills). Sometimes these packs will be listed under different names, or will be sold in bulk quantities, which may seem confusing. What is important is that you get the correct dosage for your pregnancy. Read the next section "How many pills do I need?" for dosage information.

Important note about payment: It is very common for these websites to email or call soon after they get your order to request a different form of payment. They often say the credit card did not go through. They often ask the buyer to use a PayPal account in a person's name or in the name of another business. These payment requests do seem unusual, but they worked every time we tested them.

The pills usually arrive by the US Postal Service. They usually do not require a signature.

How many pills do I need?

If you are *under* 9 weeks pregnant you usually need 1 mifepristone pill and 4 misoprostol pills. **People who are more than 9 weeks pregnant may need additional misoprostol pills (4 or 8 pills) to complete the abortion.** Many of these websites sell misoprostol pills separately (sometimes called Cytotec or Cytolog), which can be added to your order.

Stay Safe: Read our digital privacy tips ›

Quick Exit (esc)

PLAN C

Find Pills FAQ Support & Resources Get Involved About Plan C Donate Español

What if I have medical questions?

Websites that sell pills do not offer medical support. If you have medical questions during your abortion, you can get support and have your questions answered by contacting **The Miscarriage and Abortion Hotline**. This hotline provides free, confidential medical information and support by phone and text. Often they can help you address a problem without needing to go to a clinic or hospital.

If you are experiencing complications and feel the need to seek care from a health care provider at a clinic or hospital, you should do so. Your clinician does not need to know that you have used abortion pills to provide appropriate follow up care. Clinicians also can't tell you've taken abortion pills unless you tell them, or if you inserted the misoprostol vaginally and the pills did not fully dissolve. Many people use misoprostol orally to prevent this possible detection.

Some people who have told their clinician that they used abortion pills have faced legal prosecution. This is why many people just say they are having a miscarriage. The symptoms after taking abortion pills are the same as a miscarriage, and **blood tests do not reveal any differences between a miscarriage and a medication abortion**.

You can also get free, nonjudgmental emotional support before, during, and after your abortion from the folks at **All-Options Talkline**, **Exhale**, **Faith Aloud**, or **Reprocare**.

Showing 4 of 13 results

Sort by: **Price**

LIFE EASY ON PILLS **HOME ABORTIONRX** **PRIVATE EMMA**

Stay Safe: Read our digital privacy tips ›

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PLAN C

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Get pills in advance

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

Get pills in advance

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

Get pills in advance

Financial assistance available

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

MEDSIDE 24

Price	Delivery	Ages
$44	**3-6 business days**	**All**

Pills by mail

Get pills in advance

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

See all 13 websites that sell pills

Stay Safe: Read our digital privacy tips ›

Quick Exit (esc)

Community networks that mail pills



These are networks of volunteers in the US that ship generic abortion pills for free. The pills often come repackaged in plastic baggies. You will need to request pills by email.

What are community support networks?

These are networks of community-based volunteers who ship generic abortion pills to people in the U.S. with confirmed pregnancies. They believe in a model of community care and ship pills for free. The pills often come repackaged in plastic or mylar baggies.

What if I have medical questions?

Community support networks sometimes offer emotional or medical support through secure texting apps. You can also get support and have your medical questions answered by contacting **The Miscarriage and Abortion Hotline**. This hotline provides free, confidential medical information and support by phone and text. Often they can help you address a problem without needing to go to a clinic or hospital.

Stay Safe: Read our digital privacy tips ›

Quick Exit (esc)

Find Pills FAQ Support & Resources Get Involved About Plan C Donate Español

and the pills did not fully dissolve. Many people use misoprostol orally to prevent this possible detection.

Some people who have told their clinician that they used abortion pills have faced legal prosecution. This is why many people just say they are having a miscarriage. The symptoms after taking abortion pills are the same as a miscarriage, and **blood tests do not reveal any differences between a miscarriage and a medication abortion**.

You can also get free, nonjudgmental emotional support before, during, and after your abortion from the folks at **All-Options Talkline**, **Exhale**, **Faith Aloud**, or **Reprocare**.

Showing 1 of 1 results

LAS LIBRES

Price	Delivery	Ages
$0	**5–12 days**	**All**

Community network that mails pills

⚠ Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

Stay Safe: Read our digital privacy tips ›

Quick Exit (esc)

In-person clinics



Clinics offer abortion pill pickup and other in-person abortion care options. To find the nearest clinic to Texas, use any of these search tools:

I Need an Abortion

A comprehensive, regularly updated, and personalized resource for abortion seekers in the US.

VISIT WEBSITE

Texas: Abortion Clinic Guide

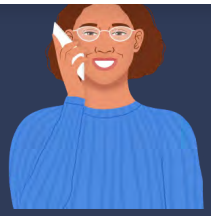
Information about Texas abortion clinics, nearby clinic options, and financial assistance from local support resources.

VISIT WEBSITE

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Stay Safe: Read our digital privacy tips ›

Quick Exit (esc)



Live phone & text support

For Medical Questions

The M+A Hotline

Free and confidential support from a clinician at the Miscarriage + Abortion Hotline. (M+A does not sell pills)

CALL OR TEXT ↗ VISIT WEBSITE

For Logistical & Emotional Support

Reprocare Healthline

Free and confidential help understanding how to get pills and how to use them.

CALL OR TEXT ↗ VISIT WEBSITE

For Legal Questions

ReproLegal Helpline

Connect with a lawyer for free and confidential legal information.

CALL OR TEXT ↗ VISIT WEBSITE



Automated support

NEW

Charley the Chatbot

Provides users with personalized abortion options, including information about different

Frequently Asked Questions

Get answers to common questions about how abortion pills work and how to access them.

Stay Safe: Read our digital privacy tips ›

Quick Exit (esc)



Get the Plan C Newsletter

For breaking developments in abortion pill access and opportunities to take action.

Your Email

Sign Up

Plan C is a project under the fiscal sponsorship of the National Women's Health Network, a 501c3 organization. Our generous donors make this critical work possible.

Find Pills →

FAQ

- Finding Abortion Pills
- About Abortion Pills
- Using Abortion Pills
- Can I get in Trouble for Using Abortion Pills?

Support and Resources

- Quick Resource List
- Medical + Emotional Support
- Legal Support
- Financial Support
- Abortion Pill Instructions
- Abortion Care Apps
- Other Options for Getting an Abortion

Get Involved

- Plan C Community
- Take Action
- Stickers & Flyers
- Plan C Merch
- Social Media Toolkit
- Partner with Us
- For Medical Professionals
- Work with Plan C
- Donate

About Plan C

- Mission
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- Research & Learning
- PLAN C: The Documentary
- 2023 Annual Report
- Media inquiries
- Contact Us

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Abortion Care Network

EXHIBIT 77

Plan C – About Us



About Us

Plan C is a public health creative campaign on abortion pill access, started in 2015 by a small team of veteran public health advocates, researchers, social justice activists. Read about our values here.

Plan C works to transform access to abortion in the US by normalizing the self-directed option of abortion pills by mail.

Our Vision: A near future in which the ability to end an early pregnancy is directly in the hands of anyone who seeks it.

Read more about our work in the 2024 Annual Report.

We Work in 4 Ways:

- **Conducting research** and publicly sharing information about how people are accessing abortion pills in the US, including domestic and global evidence about safety and efficacy of medication abortion;
- **Building collaborative relationships** with providers, reproductive health and justice organizations, and technology innovators who share our vision of demedicalizing pills by mail;
- **Calling for universal access to abortion pills**, de-stigmatizing and normalizing the modern option of self-managing an abortion at home, and
- **Centering the transformative nature of abortion pills** and building on decades of their safe self-use, to move agency over abortion back to the individuals who seek them.



Press & Media

Plan C in the Press

Media inquiries

Who We Are

Plan C is a public health creative campaign, started in 2015 by a small team of veteran public health advocates, researchers, social justice activists and digital strategists.

Our team holds an array of identities. Some have children, others are childless by choice. Some have had abortions and others have not. This diversity of experiences informs what and how we do our work.

Our Values

Work With Us

History of the Plan C Campaign

Founded in 2015 to do research and share information on abortion pills by mail in the U.S., Plan C is a fiscally sponsored project of Possibility Labs, a 501c3 nonprofit organization.



2 min video

The Story of Plan C

Watch our animated history of the abortion pill.

Timeline

1990's

In the mid 1990s, Elisa Wells and Francine Coeytaux were on the team to bring Plan B, the "morning after pill," over the counter – a long but successful journey catalyzing business, FDA and public goals. (Read *From Secret to Shelf, 1999*).

2013

In 2013, Coeytaux, then at Public Health Institute, coordinated a meeting with National Women's Health Network and Ipas to bring together reproductive justice organizations to discuss how to move the issue of self-managed care forward. A key revelation was that misoprostol was available online in the United States, which Wells and others outlined in an unpublished paper called *Surfing for Abortion*.

2015

In 2015, Wells and Coeytaux prepared an analysis for the Reproductive Health Technologies Project about how the lessons learned from emergency contraception could be used to spread awareness of abortion pills as a self-managed method in the United States. During these years, Coeytaux and Wells were also working internationally and witnessing the expansion of access to abortion pills through pharmacies in many countries, and the positive impact that access was having on reducing maternal mortality.

In late 2016, we noticed online vendors selling "abortion kits." We researched and tested these vendors and published this research in the journal *Contraception*, as well as on our website as the Plan C Report Card, documenting what we knew to be reliable online sources of pills.

Over the next three years, our website grew and the Plan C data and team were featured in major publications worldwide.

2018

In 2018 we collaborated with UCSF on a study to demonstrate the feasibility and acceptability of online access to abortion pills throughout California. But the FDA refused to approve the study, for the same reason the restrictions remain in place—politics. Instead, we took our idea to the state of Washington, where a respected clinic ran with it instead.

By now, dozens of online vendors were selling abortion pills, most from within the United States. This was unprecedented. But still there were so many people reaching out to reproductive health organizations, asking for help in self-managing their abortion--and no US organization was able to step up. So AidAccess.org came online to serve the US from the Netherlands, initially helping around 1,000 people/month with medically-supported at-home abortion care. By operating from outside the US, they were able to sidestep the politics of abortion for the time being.

2019

By 2019 the Plan C website was receiving upwards of 50,000 hits/month, from all over the US, with over half of those visitors seeking out the Report Card. The work of the Plan C team was featured in major press and led to speaking engagements at events like Essence Festival and the Cycles+Sex Conference (now allbodies.com). The Plan C team meanwhile spent time incubating and advising new telehealth providers as they considered coming

2020

In April 2020, as the global pandemic hit, Plan C sent a call-out to medical providers across the nation, asking them to step up and consider providing telemedicine and pills shipped directly to patients during the pandemic's state of emergency. Hundreds responded to the call, and a handful found ways to launch their new services from permissive states. In collaboration with the University of Washington, Plan C developed a Toolkit to assist them as they began to revolutionize access to early abortion across the U.S. by mailing pills.

In July 2020, a judge's ruling allowed mifepristone to be mailed. Clinics and telehealth startups fast-tracked the adoption of new protocols that reduced the need for blood tests and physical exams, opening the door to rapid expansion of online abortion care.

2021

In January 2021, on one of the deadliest days of the pandemic, SCOTUS ruled to reinstate restrictions on mifepristone by mail, creating chaos for telehealth abortion providers and those seeking this new form of care. Aid Access continued to mail pills to patients across the U.S. and providers considered how much they were willing to risk to provide patient-centered care in a public health crisis. Plan C continued to share information about alternate routes of access to pills, including online pill vendors and Aid Access.

In April of 2021, the court once again removed restrictions against mailing, but left other barriers in place: blocking mife from pharmacies and keeping burdensome provider registration processes in place. Telehealth abortion care came online with full force.

In summer of 2021, Texas announced passing the first "aid and abet" abortion ban, deputizing citizens to target helpers of abortion access with civil suits. In response, Plan C contacted local Texas partners

in Plan C's online reach, with Plan C accounts reposted far and wide: AOC's tweet about Plan C garnered more than 8M views.

2022

In May 2022 the U.S. media "leaked" the *Dobbs* decision, alerting the public and organizations of what was to come. Unfortunately, the repro movement and governmental administrations were unable to coordinate or mobilize a response or defense.

Six weeks later, the *Dobbs* decision effectively overturned the protections of *Roe v. Wade*. Plan C responded on social media, in the press and in community with partner organizations sharing information on alternate routes of access and resources for self-managed abortion (including advance provision and mail forwarding. Abortion access was now a human rights imperative and our harm reduction response garnered a groundswell of support, with people amplifying our information about self-managed abortion far and wide.

Nevertheless, tens of millions of people in the U.S. were impacted by not only clinics closing and providers withdrawing from care, but also consistent misinformation and censorship of health info online.

In late 2022, Plan C was recognized in MIT's 2022 Technology Review and won the Anthem/Webby awards Gold Award for non-profit websites.

2023

In Winter 2022/2023 we began a research and messaging development process to support new communications campaign called "Know Your Plan C / Conoce a Tu Plan C:" learning from grassroots organizations and audiences in six restricted states (Florida, Georgia, Kentucky, Mississippi, Oklahoma, and Texas) and rolling out content to those states designed to be educational, approachable, action-oriented, and empowering.

with additional creators and expand the campaign's reach to other states.

2023's breakthroughs came in the form of "Shield Laws:" passed in six states to protect providers in mailing pills over state lines, into states with bans. These shield laws also provide protections for people traveling into permissive states for abortion services. Existing and new telehealth services immediately operationalized these laws, serving thousands of people with pills by mail every month, even in states that ban abortion. Plan C's Guide to Pills is a critical mechanism to help people know about the availability of these services and we have been actively fundraising for these providers, who offer a sliding scale model that ensures that no one is denied access to care due to inability to pay.

The Plan C co-founders were named as part of Fast Company's Most Creative People in Business 2023. This recognition aligned with Plan C's long standing goal for abortion pills to be in mainstream culture.

With a looming SCOTUS ruling on mifepristone, continued state bans and a digital landscape rife with misinformation and censorship, Plan C's work is far from done. But in just seven years, Plan C has helped to accelerate the demedicalization of medication abortion, changing the narrative and normalizing the method across the U.S. as well as catalyzing partners and services that represent a new era of access and self-care.

Have a question not answered here?

Contact us

"I love this project, thank you for giving me hope."

"I've used Plan C and it saved my life. Now I go around teaching about safe sex to high schoolers in the summer."

"I'm a dude but I stand with y'all. I have 3 sisters and an amazing wife and I learned so much from them...my way of helping y'all is putting these [stickers] everywhere ♥."

Plan C at Sundance for the documentary screening, Jan 2023.



Want to stay updated on abortion pill news?

Sign up for our newsletter to get the latest updates and opportunities to take action, delivered straight to your inbox.

Your Email

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EXHIBIT 78

Plan C – 2023 Annual Report

2023 Annual Report

Activities, Financials & Impact



From the Co-founders



What a journey this year (and decade) has been.

From the initial question we posed nearly 10 years ago - why aren't people in the US talking about abortion pills? - to a campaign to spread this information widely, we've watched as Plan C has grown into a national resource, a recognized creative force, a documentary, and a movement of self-directed access in the face of harmful bans to care.

It has been a journey that has required tenacity and grit, sensitivity and humility. The past year we harnessed the talents of our deeply skilled and imaginative team to spread the word that - in the devastating aftermath of Roe - abortion pills are still available by mail in every state.

We can't imagine any other way to participate in this historic and challenging moment, and we remain so grateful to be able to share good news: abortion pills are real, available, and inevitable.

Thank you for being on the journey with us.

Onward,

Amy Merrill Elisa Wells

Amy Merrill & Elisa Wells
Co-Founders & Co-Directors

Who we are and what we do

Plan C is a public health information campaign and a catalyst for direct access to abortion pills by mail in the US.

Since 2015, Plan C has led the way in normalizing self-directed abortion care in the US, actively increasing awareness of safe and effective abortion pills (mifepristone and misoprostol). We share evidence-based information on how the method works, where it's found online and by mail, and how people are accessing pills and free confidential support services, from any state.

At Plan C our #1 tool is plancpills.org, where we maintain a comprehensive Guide to Pills, which includes tested and vetted sources of pills available through both mainstream and alternate routes, FAQs and referrals to free and confidential support hotlines - information that centers the end user in their decision, allowing them to make the decision that is best for them, especially in states with harmful bans.

As a creative campaign, Plan C works with artists, brands and media to make the method more known and available and tell new stories about abortion access and autonomy over reproductive outcomes.

Plan C operates under a vision of pills in hands: disentangling the method from politics and moving agency over abortion back to the individual.

Learn more at plancpills.org.



2023 & looking ahead

In spite of bans and restrictions, more people are getting abortions across the country, avenues to access abortion pills are increasing, and providers, community support networks, and websites are providing pills by mail options that are more affordable, more convenient and faster than ever.

Public support for abortion is as high as ever.

The public is on our side: recent data show 9 in 10 people in the US support abortion access.

Over the last two years, abortion has been a winning issue on state ballots, including California, Kansas, Kentucky, Michigan, Montana, New York, Ohio, and Virginia.

Messaging from the abortion pill access movement is becoming even bolder.

Alongside a handful of movement partners, we're getting the word out about abortion pill access in restricted states in even more direct ways.

And with the 2024 elections on the horizon, we'll be working to elevate abortion pills in the political conversation and inspire our community to vote.

Shield laws are expanding access to abortion pills by mail.

Six states - California, Colorado, Massachusetts, New York, Vermont, and Washington - have passed "Shield Laws" to protect providers as they offer telemedicine abortion and ship pills to all 50 states. This is a historic development in policy efforts to protect abortion access.

Supporting shield law providers.

Shield laws are not a total or permanent solution, but right now they're a game-changer for abortion pill access. We will continue to secure funding for shield provider care, to ensure equitable access no matter what the abortion seeker's financial situation. We're also helping to spread the word about shield law provision: still a relatively unknown development.

More providers are coming on board to supply abortion pills.

Shield laws have been operationalized by Aid Access and US-based telehealth abortion startups Abuzz and Cambridge Reproductive Health Consultants, shipping pills over state lines into restricted states to thousands per month, with sliding scale costs and 2-5 day ship times.

Catalyzing, supporting, and incubating the abortion pill ecosystem.

We know how important the ecosystem of services, hotlines and funds is together, and we'll continue to bolster mechanisms for access to abortion pills and sources of self-managed pills, information and support.

There are more avenues to access abortion pills.

Creating diverse routes of accessing abortion pills is vital to protecting this form of care, especially in light of ongoing bans and potential SCOTUS decisions.

Online vendors are selling pills for as low as $25. Providers are now supplying abortion pills in advance of need, and new "period pill" services send people the same medications for a late period, no pregnancy test required.

Keeping abortion pills visible.

To keep the momentum going on these exciting developments and capture the public's enthusiasm for abortion, we're expanding our media engagement work: leveraging the PLAN C documentary, building our presence online and at in-person events, activating our community, and exploring creative partnerships.

We also update our Guide to Pills as things change.

Plan C by the numbers

1.8M

Total Visitors to the Plan C website in 2023. Traffic to the Plan C website doubled in the year after Roe fell.

300K

Total click-offs from the Plan C website to other sites: this represents people finding the resources they seek.

40M

Total impressions on social media platforms, both paid and organic.

20B

Total impressions from press and media articles and interviews
(yes, that B is for billion!).

123K

Total social media followers on Plan C's active platforms.

1.4M

Stickers and flyers distributed this year.

147

Number of events featuring Plan C representatives, materials or talks.

We also forged 18 on-campus partnerships this year.

$382,810

Total money given by Plan C to partner organizations: to catalyze access, awareness, and support for on-the-ground efforts around pills by mail.

Key Campaigns & Updates

The Plan C Documentary Premieres at Sundance

Shot over the past four years by award-winning filmmaker Tracy Droz Tragos, PLAN C is a documentary capturing the work of the Plan C campaign and the work of activists and providers who began to mail abortion pills, during the pandemic and in the face of crumbling reproductive rights & access across the US.

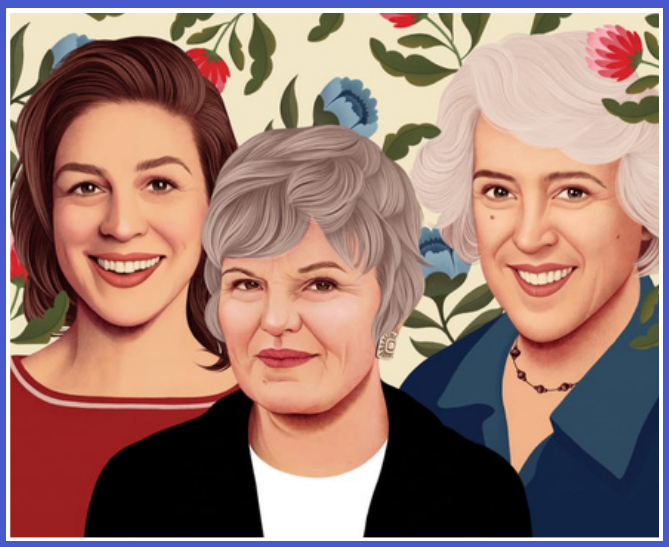
See more at plancmovie.com.



Plan C Co-Founders named in Fast Company's Most Creative People in Business 2023

The Plan C co-founders were named as part of Fast Company's Most Creative People in Business list for 2023. This recognition aligned with Plan C's longstanding goal for abortion pills to be in mainstream culture. It credits our team's ongoing work at the intersection of creativity, innovation and public health.

Read the announcement here.

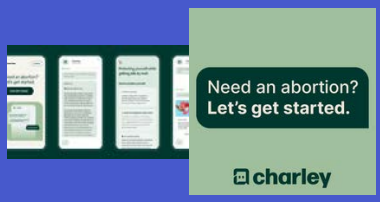


Key Campaigns & Updates, continued

"Know Your Plan C" Campaign Rollout

This year, Plan C launched a new multi-state information campaign to ensure that people know about abortion pills by mail developed with comprehensive research from nonprofit communications agency Public Good Projects and ongoing substantive input from state and local partners. So far the campaign has drawn more than 30M impressions across six states that restrict or ban abortion through radio, digital audio, social media, and Hulu ads.

Visit KnowYourPlanC.com to view the campaign.



The Abortion Chatbot Will See You Now

This fall, alongside ineedana.com, the Miscarriage and Abortion Hotline, and other reproductive health and advocacy experts, Plan C advised on the development of new online chatbot, Charley: designed to provide abortion seekers with personalized, direct and comprehensive information about their options, including care methods, nearby clinics, accessing abortion pills, and referrals to support services.

Visit www.chatwithcharley.org to give it a try.



Fighting Digital Suppression, in Coalition

After years of fighting censorship and information suppression online, Plan C joined forces with larger efforts to create solidarity amongst international sexual and reproductive health and research organizations that experience similar challenges.

In 2023, Plan C was an active participant in this coalition to fight Big Tech's suppression of online abortion information, alongside Amnesty International, Women on Web, Reproaction, Center for Intimacy Justice, and Women First Digital at RightsCon, Netroots, the UN General Assembly and online.

Plan C SMA 101 Workshops + ABCs of SMA

The Plan C Community facilitated monthly online information sessions that drew participation from school groups, activist groups, medical students, and community organizations. The sessions shared information about abortion pills, resources to support abortion seekers, and how to get more involved in advocating for access to pills by mail, with guest speakers from If/When/How, Amnesty International, National Abortion Federation, and Women on Web.

The sessions were an essential entry point for volunteers, supporters and partners.
Learn more at plancpills.org/community.

What they're saying

"

Everything about this process was amazing.

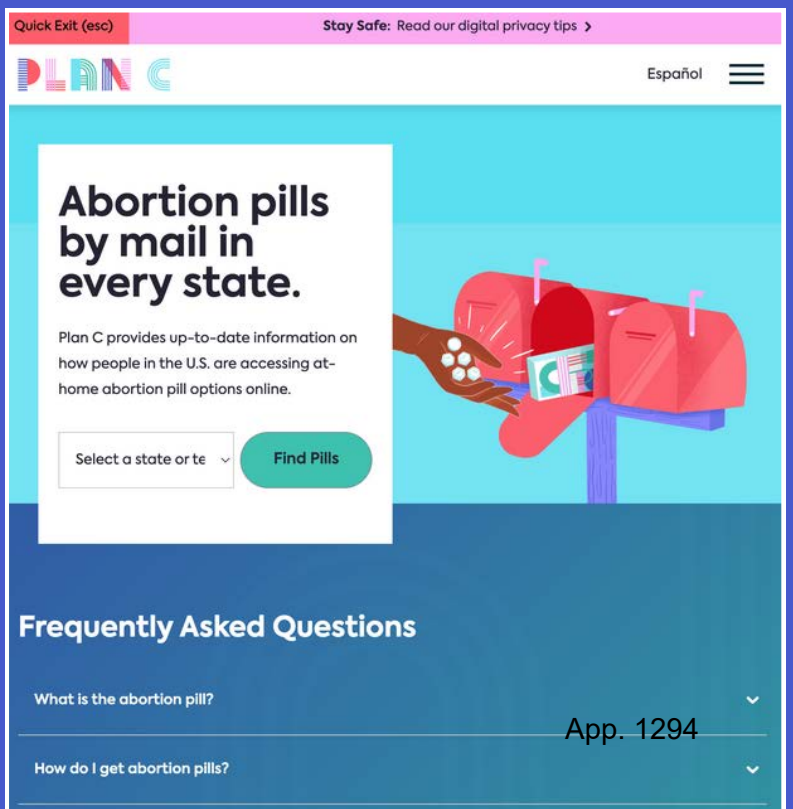
I could do everything at home, in private. Everything was fast, efficient - the people I spoke to were so caring and non judgemental."

"

I believe that this not only is, but should be, the future of abortion access in our country.

It allows for patient-centered care, and removes a piece of the process that revolves around stigma.

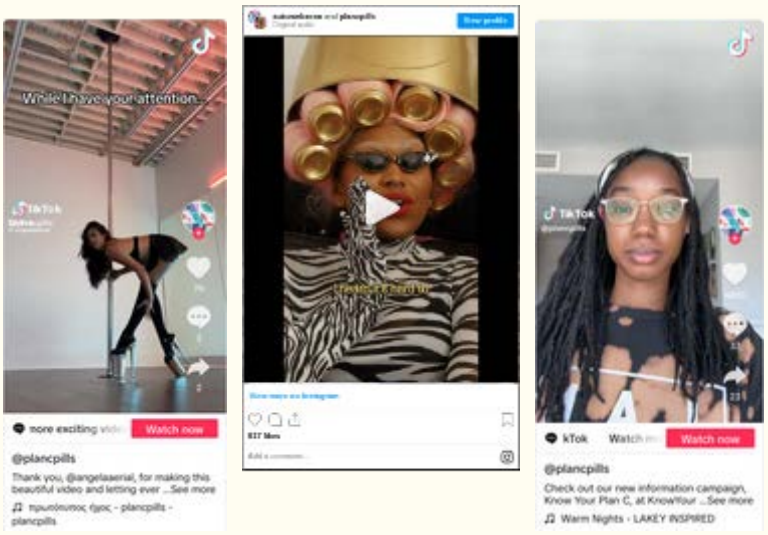
It allows that patient to directly access the services they need without having to confront stigma in the face."



Creative Partnerships

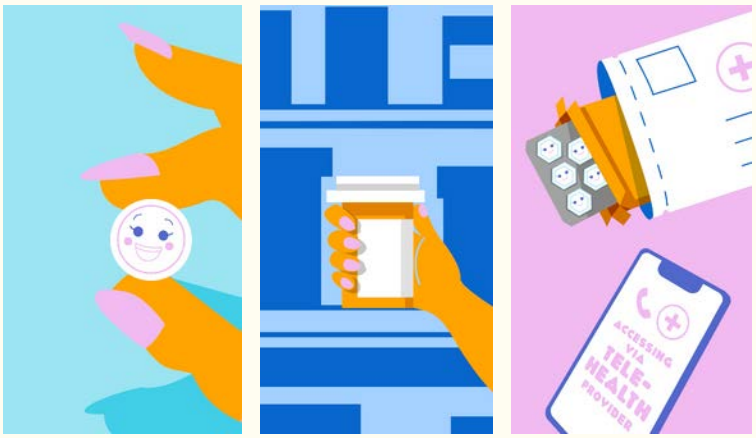
Check us out on TikTok

Our TikTok following has grown by 11k followers this year thanks to great content by our Partnerships Manager and collaborations with creators like @angelaaerial.



Mife + Miso: Animated Series

We worked with Runaway Train Productions and Reel Black Studios to create a series of 4 educational animations with mife + miso pills as the "heroes" of the story. Topics included miso-only protocols, the M+A Hotline, and the availability of pills in advance. Find the videos on our website here.



Day of A at SXSW

The Plan C team took SXSW with a post-Roe panel alongside Planned Parenthood and Center for Reproductive Health and Day of A, an event in coordination with the PLAN C documentary and Future Front TX in support of local partners, which drew hundreds of guests.



Creative Partnerships, continued

Our first artist-in residency, Autumn Breon

Plan C partnered with artist Autumn Breon on video content and the launch of her Care Machine: a free vending machine stocked with reproductive and beauty resources. Works appeared at the Crenshaw Dairy Mart and Miami Art Basel, and will continue in 2024 at Frieze and other art & culture festivals.



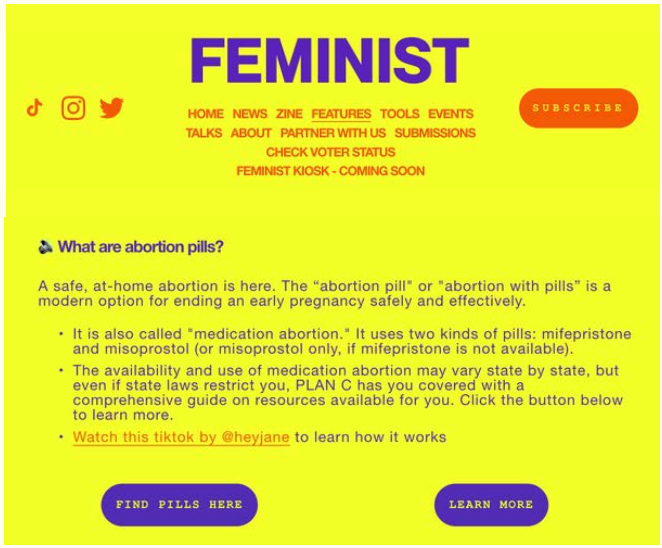


The Power of Music

Plan C was beneficiary of Demi Lovato's new pro-abortion song launch: 'SWINE' which garnered major press. The team also aligned with artist/musician Amanda Palmer and Runway Productions on a short film about abortion pills by mail set to Amanda's song, "Voicemail for Jill."



Creative Partnerships, continued



Featured in Feminist

With a social media following of 6M+, Feminist knows how to engage the public around issues that matter: and their info page is a model example of how brands and groups can feature abortion pill info alongside other resources, for audiences who want
to know.

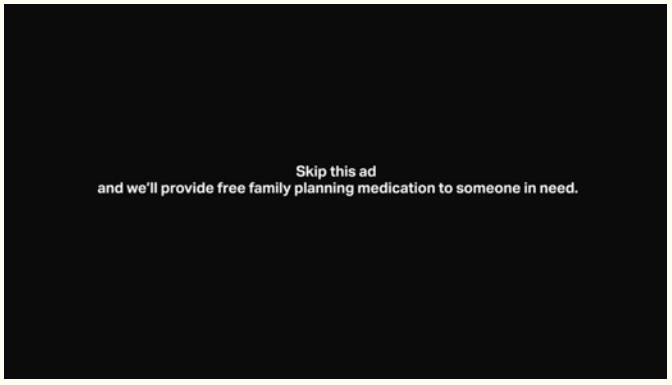
Visit the page on feminists.co here.

Partnering with brands

Plan C partnered with brands August and Stix on campaign SyncPeriodsNotData to call out digital surveillance via a clever pregnancy test package containing additional reproductive health and abortion information.

Plan C also partnered with agency 72andsunny on Made By Choice: a YouTube campaign where viewers could watch the abortion ad, or skip it and trigger a donation to fund pills, with the message: you have a choice.





A Tech-First Approach to Abortion Access



Plan C leverages technology, digital tools, and creative content to share information and change the narrative.

Technology Challenges:

Digital Suppression.

Our content on social media is routinely suppressed or blocked by social media companies. Plan C has been shadowbanned, we've reported fake Plan C accounts and copycat websites, and our content has been routinely blocked from followers' feeds. In February 2023, we led a digital campaign calling out Instagram and Meta for suppressing our account and shadow banning our content.

Ad Blocks.

Since July 2022 our account has been blocked on Google Ads. Meanwhile Google allows crisis pregnancy centers aka "fake clinics" to advertise on search, under abortion keywords (even when they don't provide abortions) and Google reportedly made $10M in ad revenues from these CPCs in the past year. in the past year. Plan C ads on Meta often get rejected as well, which leads to exhaustive appeals with their policy team, delaying or blocking the flow of critical public health information at this urgent moment in history.

"Anti" bots.

Recently we discovered and tracked artificially-enhanced results for keyword "abortion pill," likely designed by anti-abortionists to inflate their own CPC listings. On days when the bot was active, Plan C's listing was pushed far down the search results page.

Tech, continued...

Shadow-ban (verb):

To block (a user) from a social media site or online forum without their knowledge, typically by making their posts and comments no longer visible or with limited visibility to other users.

Censorship (noun):

The suppression of speech, public communication, or other information.

Digital suppression (verb):

The restraint of an idea, information, or activity online by institutions with power.

Tech, continued...

How We're Overcoming These Challenges:

Search Engine Optimization (SEO):

Our world-class SEO lead helps ensure that our website and Guide to Pills rises to the top of organic search results, above deceptive resources and meeting the individual in their moment of need as they search for abortion information.

In 2023 we also embarked upon a UX and development process to improve the Plan C Guide to Pills, incorporating user feedback to make information more understandable and digestible, improve the backend databases of providers and services, and ensure high levels of digital security and privacy along the way.

In one year:

- Organic traffic landing on the Guide's state pages increased by 26%.
- Google visibility of the Guide's state pages increased by 448%.
- Plan C ranked #1 in search for 122 keywords (previously 20 keywords).

Breaking Through Censorship & Suppression:

This past year we partnered with Amnesty International, Women on Web, Reproaction, Center for Intimacy Justice, and Women First Digital in a coalition to fight against digital suppression of sexual and reproductive health information and collectively troubleshoot issues faced. We also gave a grant to OARS, who runs the Reddit /abortion page, answering thousands of questions each month from anonymous abortion seekers in need of for support.

We're also bringing issues to coalitions like Techies for RJ and the Charley Chatbot team. In 2024 we will continue to build power in coalition, to solve problems and share resources across the many organizations experiencing similar challenges in the face of ensuring ongoing access to abortion.

Strategic Paid Ads Approach:

We continue to prioritize digital paid advertising to reach target audiences and restricted states, especially with the launch of our "Know Your Plan C" campaign. This has been one of Plan C's most successful strategies in reaching harder-to-reach members of target audiences.

We've been steadfast and creative in getting ads on platforms like Facebook, Instagram, TikTok, and Hulu and have been proud to partner with companies like iHeart Media who value and support our public health message.

> **"You can't stop people from going on the internet. How are you going to stop them?"**
>
> *Francine Coeytaux, Plan C cofounder, in opening scene of new documentary PLAN C*

Press Highlights

Rolling Stone

Here's What Happens If Trump Judge Ends Access To Critical Abortion Drug Nationwide

Elisa Wells, co-founder and co-director of Plan C, an organization that helps individuals obtain abortion pills, says regardless of Kacsmaryk's decision, women will still have options.

The New York Times

Inside the Online Market for Overseas Abortion Pills

This New York Times piece brought huge visibility to the option of obtaining abortion pills through ecommerce websites, informed heavily by Plan C's research over the past 10 years.

The Washington Post

The abortion bot will see you now

This overview of our collaboration on Charley describes the bold new abortion bot that helps abortion-seekers find access to vetted health care resources, from any state.

abc NEWS

Plan C on ABC News

This episode of ABC News addressed the proliferance of online pill vendor sites, as a real and available option for people in states with bans.

teen VOGUE

Abortion Pills Are in My Medicine Cabinet. They Should Be in Yours Too

Cofounder & Digital Director Amy Merrill wrote a widely-viewed op-ed for Teen Vogue to spread the word about Plan C's "No Roe. Get Pills in Advance" advance provision information campaign.

The Dallas Morning News

Texans still getting abortion pills by mail with out-of-state help

This Dallas Morning News interview reached millions of people in Texas. It was picked up by MSN for enormous amplification, translated for the Spanish language community in Texas, and led to further coverage of Plan C's work on the local news stations in-state.



Savage Love podast with Elisa Wells

Co-Director Elisa Wells appeared on Dan Savage's Savage Love Cast, a personal highlight for members of Plan C who are fans of the show.

COSMOPOLITAN

This Documentary About the Fight for Abortion Information and Access Is One of the Must-Sees of 2023

Cosmopolitan was one of the scores of publications that wrote about the PLAN C documentary premiere and release. This was one of the major ways Plan C showed up in entertainment and culture news in 2023.

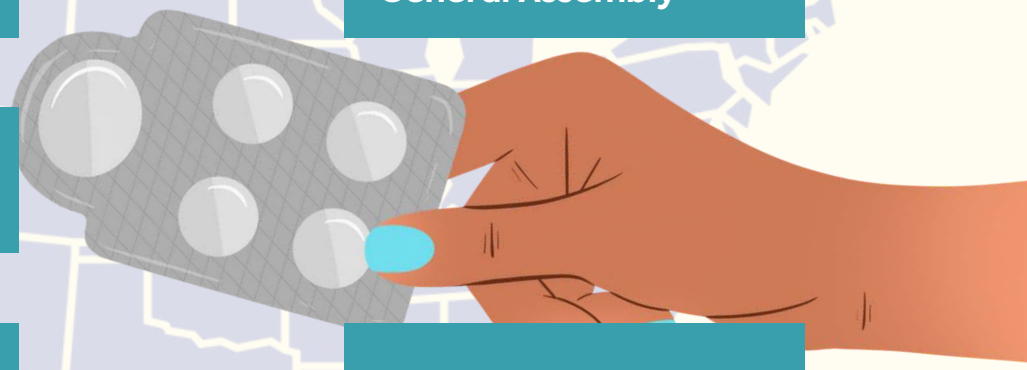




Plan C at Sundance Film Festival, January 2023

Conferences

- Nexus Summit
- SXSW
- RightsCon
- United Nations General Assembly
- NOW National Conference
- Abortion Camp by SYA
- Creating Change
- CES Vegas
- NetRoots



Changing the Narrative

One of our big realizations in 2023 was that so many people still don't know about abortion pills by mail, or how to access them from all states.

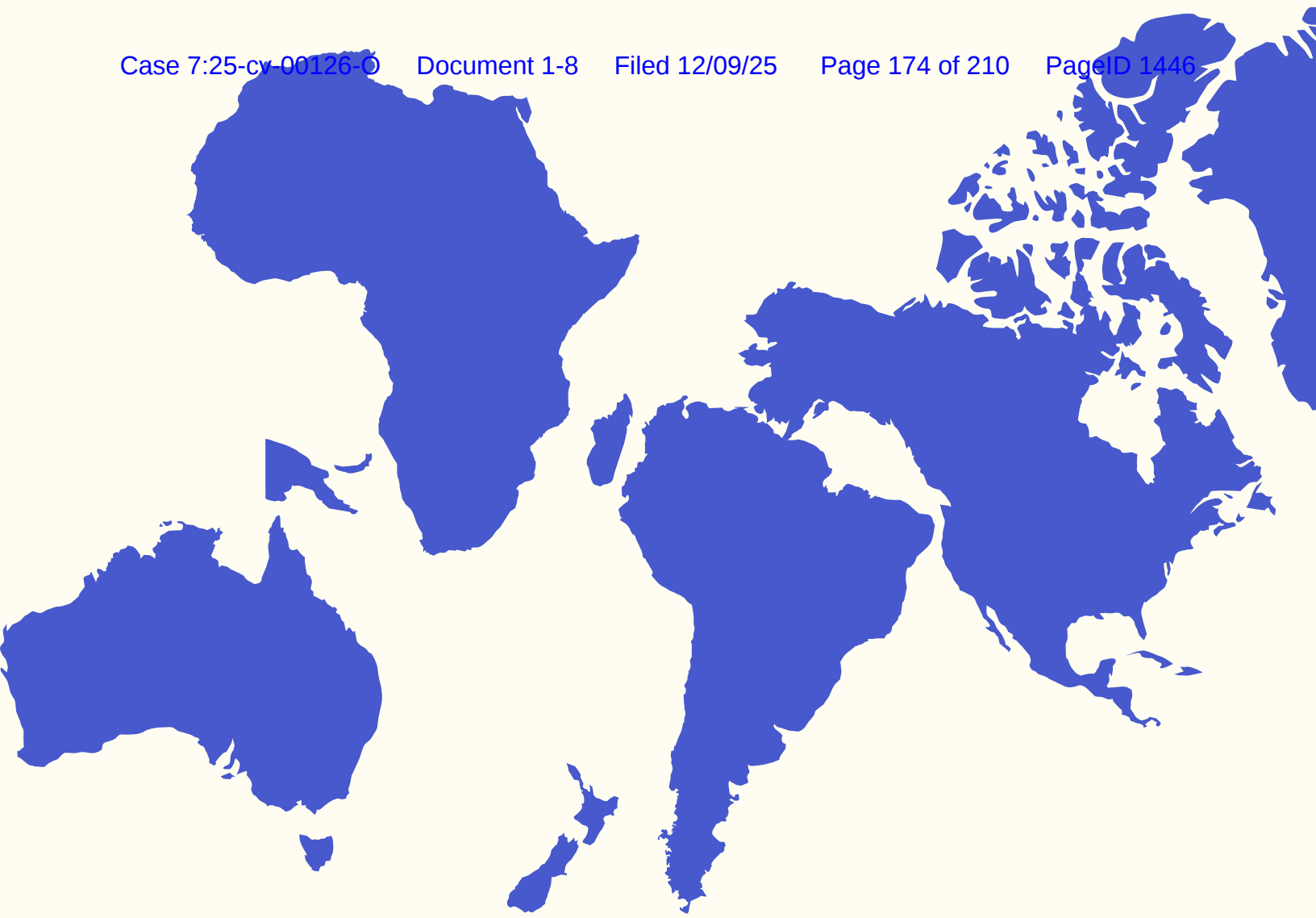
Plan C is committed to continuing to show up in spaces related to reproductive rights & access and also mainstream pop culture. We do this to share information, and also to expand the general public's current notion of what is an abortion: from self-managed, to miscarriage management, to "period pills," to getting pills in advance, we are describing a paradigm shift, one that contains a spectrum of experiences and needs, and introduces the transformative potential of abortion pills to meet those needs for people living in a post-Roe US.



Day of A

A Day of Action in Austin, TX - March 2023

In partnership with Future Front Texas we produced an activation during SXSW that brought hundreds of people through... highlighted local orgs and destigmatized abortion and shared information on how Texans could still access abortion pills by mail, despite bans to local access and care.



This is a global movement.

- Abortion pills are endorsed by the World Health Organization as an essential medication.
- They are used by millions worldwide every year, and are available over the counter in many countries.
- In India, abortion pills used outside of health facilities account for over 70% of all abortions.
- In the US, we have seen great progress in catching up - but we still have a long way to go.
- There is much to learn from the international movement and from countries who have lived under abortion bans for a long time. Plan C is committed to showing up in global coalition, and exchanging learnings and practices with groups, activists and researchers from other countries.

2023 Impact & Financial Highlights

Starting with Texas' SB8 in the fall of 2021, the Plan C campaign has experienced generous upticks in donations and commitments. People and organizations wanting to fund abortion access recognize the potential of sharing information about abortion pills by mail, and channel their outrage and passion toward our work.

We are always happy to talk to donors about the measurable results of their donations: in materials created and distributed, resources shared, ad views, cost-per-clicks and website visitors, administrative and team support.

We also know that we are dealing in not just numbers but in paradigm shifts, introducing concepts of self-directed care and empowering others with information so they can then spread it further. Because of this will never truly see the extent of our impact.

One of our core strategies is to support other activists and organizations with not just information and collaboration, but with funding to do the work. This past year we gave over $350,000 to other organizations making a difference in abortion pill access for restricted states and across the US.

We also talked to our donors and partners about how they can fund this landscape as well.

We believe in supporting the multi-faceted ecosystem working to ensure holistic support for self-directed abortion, and that a rising tide lifts all ships.

We are endlessly grateful for the support of our donors and foundation partners, to enable us to do this critical work as such a poignant moment in history.

Together we are making change and showing up for people in need of abortion care.

2023 BUDGET

Administrative: Travel, Team & Consulting Fees	$1,233,789
Grants to Partners	$361,451
Paid Ad Placements	$353,435
Creative Partners	$104,325
Stickers & Outreach Materials	$131,020
Telecom, Software & Website	$130,466
Fiscal Sponsorship Fees (10%)	$278,459
Total Expenses	$2,592,945

Our Vision & Values



Since 2015 our vision has stayed the same: abortion pills in the hands of the person who seeks them, full stop. We are laying the groundwork for over-the-counter access: disentangling this safe and effective option from politics, and moving agency over abortion back to the individual.

The efforts described in this report fall under two major goals, namely that:
1. People Know (about the pills), and
2. People Have Access (to pills).

These two concepts are what drive us.

Our team of public health researchers, social justice activists and digital strategists is dedicated to centering the abortion seeker in the work, and leading and collaborating from values of self-determination, equity and justice.

Read more at plancpills.org/about.

Where we're headed

In this report we've described our recent work in context of the current domestic and global landscape. At Plan C we are structured like a campaign, designed to be nimble and responsive to the moment. When we achieve our mission, we will go "out of business."

Unfortunately in the US, our work is far from complete.

We are energized and equipped to show up clear and focused in 2024: building on previous successes, in deep service to abortion seekers, in support of activists and partners, and under the same shared vision of pills in hands.

We will continue to provide research-based information about where to obtain medication abortion, both mifepristone and misoprostol, as the landscape continues to change. We will lead creative campaigns and outreach, with a focus on restricted states, push back against censorship and bullying, and cultivate partnerships to build power in coalition.

At Plan C we believe abortion is basic health care and a human right. We believe everyone deserves full, legal access to this safe and effective medication through clinics, telehealth, and self-managed sources in every zip code in the US.

We aren't slowing down yet.

> **"We hear all the time from our patients that Plan C was an incredible resource and helped them connect to trustworthy care.**
>
> *Telehealth company HeyJane*

Thank you.

The support of our donors, our partners and our community and makes this work possible.

Have a question, idea or offering?
Reach out at info@plancpills.org.

Visit us online at plancpills.org
@plancpills on Instagram, TikTok, Facebook and Twitter.

"Nobody can stop us from getting abortions when we are informed about how and where to get them."

– comment on Plan C Instagram, Summer 2023

EXHIBIT 79

Free Medication Abortion

FREE MEDICATION ABORTION

In a restricted state? Looking for information on safe abortion access? We're here for you.

Scroll down for a list of providers!

Abortion pills by mail are a reality even in states with restrictions.

Please use a privacy app like Duck Duck Go
when looking at abortion resource sites like ours.

En Español

This site is an information sourc ***s not give medical or legal advice or sell abortion pills.***

*For references to free, trusted, community support providers for people with **confirmed** pregnancies, find your state and corresponding contact email below.*

**See below notes for how states and providers are identified.*

*For your **safety** and the providers' safety, we encourage you to set up a secure, free email account on **protonmail** to use when contacting them.*

***iCloud email** is not compatible with our system.*

Please note,** these services may take up to **14 days** to arrive after request. If it is not possible to wait 14 days (may come sooner, USPS service is out of their control) **please visit PlanCPills.org for alternative providers.

INCLUDE IN YOUR EMAIL :

-The name of the person receiving the medication

-Your full mailing address

-Estimated number of weeks gestation

-The first day of your last menstrual period

-The date of your positive pregnancy test

***PLEASE CONFIRM YOUR INFORMATION HAS THE CORRECT ADDRESS** - only one kit is shipped per request and the most frequent reason for non-delivery is an incorrect address or missing address information. Make sure to include ALL information - name, street, city, state, zip code and apartment number if available.*

Current Coverage by State

^Alabama - sjog2010@proton.me

^American Samoa - AccessInformation13@proton.me

Arizona - IdahoAccess@proton.me

***Arkansas - ARTogether@proton.me**

^Florida - FLCompanionRequest@proton.me

^Geo[illegible]essInformation13@proton.me

^Guam - AccessInformation13@proton.me

Idaho - IdahoAccess@proton.me

^Indiana - AccessMidAmerica@proton.me

^Iowa - AccessMidAmerica@proton.me

^Kansas - AccessMidAmerica@proton.me

^Kentucky - AccessMidAmerica@proton.me

^Louisiana - AccessInformation13@proton.me

^Mississippi - AccessInformation13@proton.me

^Missouri - AccessMidAmerica@proton.me

Nebraska - IdahoAccess@proton.me

^Nevada - AccessInformation13@proton.me

^New Hampshire - AccessMidAmerica@proton.me

^North Carolina - AccessMidAmerica@proton.me

North Dakota - IdahoAccess@proton.me

^Northern Mariana Islands - AccessInformation13@proton.me

^Ohio - AccessMidAmerica@proton.me

Oklahoma - IdahoAccess@proton.me

^Pennsylvania - AccessMidAmerica@proton.me

^South Carolina - AccessInformation13@proton.me

South Dakota - IdahoAccess@proton.me

^Tennessee - AccessMidAmerica@proton.me

^*Texas - TexasAccess@proton.me

^US Virgin Islands - AccessInformation13@proton.me

^Utah - AccessInformation13@proton.me

^Virginia - AccessMidAmerica@proton.me

^West Virginia - AccessMidAmerica@proton.me

^Wisconsin - AccessMidAmerica@proton.me

^Wyoming - AccessInformation13@proton.me

ⓘ above contact information is provided for community support groups that follow verified protocols (listed below) to ensure consistency and security for all clients regardle

States prefaced wi :risk (*) follow different mailing protocols.
Free Medication Abortion Home What We Stand For How to Use Abortion Pills

States prefaced with (^) follow different dosing protocols.

See coverage tab for full list of community networks.

1) Client response provided within 24 hours, seven days a week
2) Medicines shipped by USPS priority mail in discreet packaging with no tracking. (unless prefaced with an asterisk (*))
3) Kits in states prefaced by (^) all contain one (1) 200 mg Mifepristone and 16 - 200 mcg Misoprostol for pregnancies 20 weeks and under (as recommended by MAHotline). Those without (^) contain (1) 200 mg Mifepristone and 12 - 200 mcg Misoprostol.
4) Choice for clients of loose, unidentifiable pills or foil, blister packs depending on their security concerns and community provider stock. Loose is sent default if no choice is made or other inventory is not available.
5) Access to a personal, trained companion available for all clients and automatically assigned for clients over 14 weeks
6) Service for all gestations
7) No personal data retained or collected
8) Clinicians available on request

Residents of other states may find abortion funding assistance through the National Network of Abortion Funds.
PlanCPills lists all vendors, including for-profit, for all states and territories.

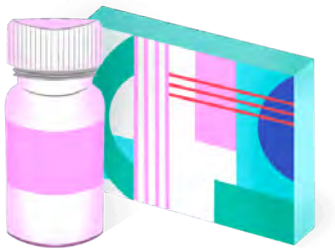
EXHIBIT 80

Plan C - Websites that Sell Pills

Stay Safe: Read our digital privacy tips ›
Quick Exit (esc)

‹ GO BACK

Websites That Sell Pills



These websites sell abortion pills but do not include any additional support. You can still get free medical support for your abortion from the M+A Hotline.

Important: These websites may not follow strict digital security protocols. Read our digital privacy tips to learn how to protect yourself when ordering or searching for abortion pills online.

Read the FAQs below for more information on how these sites work.

What are websites that sell pills?

Websites that sell pills are e-commerce websites that sell and ship pills to addresses in all U.S. states. They do not require a prescription for the medications, do not require you to upload your ID, and do not provide a medical consultation or any kind of support.

Are these websites legit?

Yes, these websites are legit. They sell generic abortion pills that are not regulated or inspected by the US government. Plan C regularly tests these websites by buying pills from them. The services we list in our guide all shipped pills to a home address. The pills were real (based on laboratory testing). But, we do not operate these sites, and cannot guarantee they will be reliable in the future.

Important: These websites may not follow strict digital security protocols. Read our **digital privacy tips** to learn how to protect yourself when ordering or searching for abortion pills online.

How do I choose one of these websites?

We suggest you check their website and pick the one that you feel most comfortable ordering from. If you are not sure what pills to order, read the FAQ below, "What kind of kit do I order?".

What kind of kit do I order?

Most of these websites sell abortion pills in a blister pack called an MTP Kit. These kits usually contain 5 pills: 1 dose of mifepristone (1 pill) and 1 dose of misoprostol (4 pills). Sometimes these packs will be listed under different names, or will be sold in bulk quantities, which may seem confusing. What is important is that you get the correct dosage for your pregnancy. Read the next section "How many pills do I need?" for dosage information.

Important note about payment: It is very common for these websites to email or call soon after they get your order to request a different form of payment. They often say the credit card did not go through. They often ask the buyer to use a PayPal account in a person's name or in the name of another business. These payment requests do seem unusual, but they worked every time we tested them.

The pills usually arrive by the US Postal Service. They usually do not require a signature.

How many pills do I need?

If you are *under* 9 weeks pregnant you usually need 1 mifepristone pill and 4 misoprostol pills. **People who are more than 9 weeks pregnant may need additional misoprostol pills (4 or 8 pills) to complete the abortion.** Many of these websites sell misoprostol pills separately (sometimes called Cytotec or Cytolog), which can be added to your order.

Read this guide for instructions on how to take abortion pills and for recommended dosages. If you don't know how many weeks pregnant you are you can use our **pregnancy calculator**.

What if I have medical questions?

Websites that sell pills do not offer medical support. If you have medical questions during your abortion, you can get support and have your questions answered by contacting **The Miscarriage and Abortion Hotline**. This hotline provides free, confidential medical information and support by phone and text. Often they can help you address a problem without needing to go to a clinic or hospital.

If you are experiencing complications and feel the need to seek care from a health care provider at a clinic or hospital, you should do so. Your clinician does not need to know that you have used abortion pills to provide appropriate follow up care. Clinicians also can't tell you've taken abortion pills unless you tell them, or if you inserted the misoprostol vaginally and the pills did not fully dissolve. Many people use misoprostol orally to prevent this possible detection.

You can also get free, nonjudgmental emotional support before, during, and after your abortion from the folks at **All-Options Talkline**, **Exhale**, **Faith Aloud**, or **Reprocare**.

Can I get in trouble for using abortion pills?

The short answer is: it depends, and it's complicated.

Legal risk can depend on:

- where you live,
- your identity: race, ethnicity, income level, etc.
- and how far along you are in pregnancy.

In the end, it's up to each person to make their own decision about risk. Click the headings below for more information about these risks.

Where someone lives makes a difference.

Many states allow legal access to abortion pills through clinics or telehealth services. People who get pills in states where these services are legal should face no legal risk.

Pills are available by mail in all states, even in states that ban clinic-based abortion care. This is possible because some states have "shield laws" that protect clinicians when they provide telehealth care to someone in another state. People in all states can also get abortion pills from alternate suppliers like international online clinics, community networks, and websites that sell pills. We mark alternate suppliers with an alert icon ⚠ in our **Guide** to let you know that they may have legal risk.

To understand the potential legal risks of using alternate suppliers, you can contact the ReproLegal Helpline, a free legal resource that can help answer your questions: visit **reprolegalhelpline.org** or call or text 844-868-2812.

What if a state totally bans abortion?

Some states have laws against abortion. These laws mean that with limited exceptions medical providers and clinics in those states can't do an abortion procedure or provide abortion pills.

A ban that blocks providers from offering care does not necessarily block a person from using pills on their own. However, a person who self-manages their abortion can face legal risk: people in the US are criminalized for all kinds of reasons, with outsized impact on certain identities or socioeconomic backgrounds.

People in states that ban abortion can still get abortion pills by mail from telehealth providers in "shield law" states (see above) or alternate suppliers, like international online clinics, websites that sell pills, and community networks that mail them for free.

instance if they are not free to leave their home or do not want to risk going through an immigration checkpoint (which can be within 100 miles of any US border).

The **Repro Legal Helpline** provides free and confidential legal advice that can help people better understand the laws and legal risk they may face. Contact them **online** or call **844-868-2812**.

How big is the legal risk?

This is a really hard question to answer.

We have some information about what has happened in the past. From 2000 to 2020, at least 61 people who have self-managed an abortion or have helped someone else **were arrested or prosecuted.** During that same time, many people self-managed abortions (tens of thousands or more).

It is unclear how new abortion laws will affect future criminalization of people for self-managing an abortion.

Those who are already at greater risk of criminalization because of their race, gender identity, economic status, or other factors may have a higher risk of prosecution.

The **Repro Legal Helpline** provides free and confidential legal advice that can help people better understand the laws and legal risk they may face. Contact them **online** or call **844-868-2812**.

Why have some people gotten in legal trouble?

Have Legal Questions?

The **Repro Legal Helpline** provides free and confidential legal advice that can help people better understand the laws and legal risk they may face. Contact them **online** or call **844-868-2812**.

For more analysis of potential legal risk, **read this article**.

Showing 14 of 14 results

Sort by: **Price**

PILL PULSE

Price	Delivery	Ages
$29	**3-6 business days**	**All**

Pills by mail

LIFE EASY ON PILLS

Price	Delivery	Ages
$30-50	**3-6 business days**	**All**

Pills by mail

Stay Safe: Read our digital privacy tips ›
Quick Exit (esc)

MORE INFORMATION REQUEST PILLS

MORE INFORMATION REQUEST PILLS

HOME ABORTIONRX

Price	Delivery	Ages
$33	12-19 business days	All

Pills by mail

Get pills in advance

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

PRIVATE EMMA

Price	Delivery	Ages
$35	3-6 business days	All

Pills by mail

For pregnancies up to 12 weeks

Get pills in advance

Financial assistance available

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

MEDSIDE 24

Price	Delivery	Ages
$44	3-6 business days	All

Pills by mail

Get pills in advance

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

HOME ABORTION PILLSRX

Price	Delivery	Ages
$45	3-6 business days	All

Pills by mail

Get pills in advance

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

YBYCMEDS

Price	Delivery	Ages
$46	3-6 business days	All

Pills by mail

Get pills in advance

PRIVACY PILL RX

Price	Delivery	Ages
$120	3-6 business days	All

Pills by mail

Get pills in advance

SAFE PHARMACY

Price	Delivery	Ages
$198	3-6 business days	All

Pills by mail

Get pills in advance

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

ABORTION PILLS RX

Price	Delivery	Ages
$230	4-6 business days	All

Pills by mail

Get pills in advance

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

GENERIC ABORTION PILLS

Price	Delivery	Ages
$291	3-6 business days	All

Pills by mail

Get pills in advance

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

ABORTION RX

Price	Delivery	Ages
$299	3-6 business days	All

Pills by mail

Get pills in advance

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

ONLINE ABORTION PILL RX

Price	Delivery	Ages
$470	3-6 business days	All

Pills by mail

Get pills in advance

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS

ABORTION PRIVACY

Price	Delivery	Ages
$470	3-6 business days	All

Pills by mail

Get pills in advance

Learn about the potential legal risk of using this service

MORE INFORMATION REQUEST PILLS



Live phone & text support

For Medical Questions

The M+A Hotline
Free and confidential support from a clinician at the Miscarriage + Abortion Hotline. (M+A does not sell pills)

CALL OR TEXT VISIT WEBSITE

For Logistical & Emotional Support

Reprocare Healthline
Free and confidential help understanding how to get pills and how to use them.

CALL OR TEXT VISIT WEBSITE

For Legal Questions

ReproLegal Helpline
Connect with a lawyer for free and confidential legal information.

CALL OR TEXT VISIT WEBSITE



Automated support

NEW

Charley the Chatbot

Provides users with personalized abortion options, including information about different abortion care methods, nearby clinics,

Frequently Asked Questions

Get answers to common questions about how abortion pills work and how to access them.



Get the Plan C Newsletter

For breaking developments in abortion pill access and opportunities to take action.

Your Email

Sign Up

Plan C is a project under the fiscal sponsorship of the National Women's Health Network, a 501c3 organization. Our generous donors make this critical work possible.

Find Pills →

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Disclaimer: This is not legal or medical advice and does not substitute for the representation of an attorney or the advice of a doctor. No attorney client relationship has been formed by reviewing this material.

Abortion Care Network

EXHIBIT 81

Ryan T. Anderson & Jamie Bryan Hall, T*he Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event*, Ethics & Public Policy Center (Apr. 28, 2025)

LIFE AND FAMILY INITIATIVE

ETHICS AND PUBLIC POLICY CENTER
Shaping Policy, Renewing Culture.

The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event

Jamie Bryan Hall, Director of Data Analysis, Ethics and Public Policy Center
Ryan T. Anderson, President, Ethics and Public Policy Center

April 28, 2025

Summary

- This largest-known study of the abortion pill is based on analysis of data from an all-payer insurance claims database that includes 865,727 prescribed mifepristone abortions from 2017 to 2023.
- 10.93 percent of women experience sepsis, infection, hemorrhaging, or another serious adverse event within 45 days following a mifepristone abortion.
- The real-world rate of serious adverse events following mifepristone abortions is at least 22 times as high as the summary figure of "less than 0.5 percent" in clinical trials reported on the drug label.
- The FDA should immediately reinstate its earlier, stronger patient safety protocols to ensure physician responsibility for women who take mifepristone under their care, as well as mandate full reporting of its side effects.
- The FDA should further investigate the harm mifepristone causes to women and, based on objective safety criteria, reconsider its approval altogether.

Danco Laboratories markets Mifeprex as "the safe and effective abortion pill," but our research shows that mifepristone abortion, as currently practiced in the U.S., is not safe and effective.[1] The manufacturer and the FDA rely on the results of 10 clinical trials with a total of 30,966 participants, less than 0.5 percent of whom reportedly experienced serious adverse reactions. In contrast, we analyzed real-world insurance claims data for 865,727 prescribed mifepristone abortions, broadly representative of women who obtain mifepristone abortions in the U.S. today, and we find a serious adverse event rate of 10.93 percent—at least 22 times as high as the summary figure reported on the drug label. In light of this research, we urge the FDA to reinstate earlier, stronger patient safety protocols and reconsider its approval of mifepristone altogether. Women deserve better than the abortion pill.

Our Key Findings

10.93 percent of women experience sepsis, infection, hemorrhaging, or another serious or life-threatening adverse event within 45 days following a mifepristone abortion, far greater than the summary figure of "less than 0.5 percent" in clinical trials reported on the drug label. *Figure 1, next page.*

[1] Danco Laboratories, "The Safe and Effective Abortion Pill | Mifeprix (mifepristone)," https://www.earlyoptionpill.com (accessed April 14, 2025)

Figure 1

Serious Adverse Events by Category

	Number with adverse events	Serious adverse event rate
Sepsis	824	0.10%
Infection	11,707	1.34%
Transfusion	1,257	0.15%
Hemorrhage	28,658	3.31%
Hospitalization (related to the abortion)	5,699	0.66%
ER visit (related to the abortion)	40,960	4.73%
Ectopic pregnancy	3,062	0.35%
Other life-threatening adverse events (cardiac, pulmonary, thrombosis, anaphylaxis, surgery)	1,956	0.22%
Repeated (surgical) abortion	24,563	2.84%
Other abortion-specific complications	49,169	5.68%
Overall	94,605	10.93%

Note: The overall serious adverse event rate of 10.93% is adjusted for the fact that some women suffer from adverse events in multiple categories.

Simply stated, mifepristone, as used in real-world conditions, is not "safe and effective."

Our real-world post-market observational study of mifepristone is, to our knowledge, the most comprehensive study of chemical abortion safety ever conducted in the U.S.:

- We identify and include 865,727 prescribed mifepristone abortions, 28 times as many as were included in all FDA-cited clinical trials combined.
- Our dataset is more recent, no earlier than 2017, while the FDA approval of mifepristone relies entirely on data from more than a decade ago.
- The women in our dataset are broadly representative of the women who obtain mifepristone abortions in the U.S.; they are not a prescreened group of generally healthy women recruited into various clinical trials conducted at different times around the world.
- The women in our dataset receive (or fail to receive) pre- and post-abortion healthcare of the real-world quality that prevails in the U.S. today, not the carefully controlled regimen of care that ordinarily prevails in a clinical trial.

Policy Implications

The FDA should reinstate the original patient safety protocols that were required when mifepristone was first approved. Doing so will likely reduce the harms to women and permit better monitoring to determine whether this drug should remain on the market:

- Prescribing mifepristone and misoprostol for the termination of pregnancy should require at least three in-person office visits by the patient—as originally required by the FDA.
- Mifepristone should be prescribed only by physicians—as originally required by the FDA—who have read and understood the prescribing information.
- Mifepristone should be administered only in a clinic, medical office, or hospital, by or under the supervision of a physician, able to assess the gestational age of an embryo and to diagnose ectopic pregnancies—all of which was originally required by the FDA.
- Physicians must be able 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.
- Healthcare providers should be required once again to report to the FDA (and manufacturers of mifepristone) all serious adverse events resulting from the use of mifepristone.
- Mifepristone should only be prescribed to a woman who is confirmed by a physician to be in the first seven weeks of pregnancy—as originally required by the FDA.

Background on FDA Approval and Regulation of Mifepristone

Mifepristone was developed by the French pharmaceutical company Roussel Uclaf S.A. and brought to the United States at the urging of President Clinton and after Congressional pressure. The FDA approved it under a little-used approval process for "certain new drug products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments."[2] Thus, to grant approval in this manner, the FDA had to consider an unwanted pregnancy a "serious or life-threatening illness" and find that mifepristone was more effective than surgical abortion in treating it. The FDA's decision cites minimal data: clinical trials with only 859 participants in the U.S. and 1,800 in France.[3]

The original FDA-approved drug label for Mifeprex (the brand name of mifepristone) from September 2000 indicated use of the drug for "the medical termination of intrauterine pregnancy through 49 days' pregnancy."[4] It required several modest safeguards for women's health:

> Treatment with Mifeprex and misoprostol for the termination of pregnancy requires three office visits by the patient. Mifeprex should be prescribed only by physicians who have read and understood the prescribing information. Mifeprex may be administered only in a clinic, medical office, or hospital, by or under the supervision of a physician, able to assess the gestational age of an embryo and to diagnose ectopic pregnancies. Physicians must also be able 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.[5]

During the Obama and Biden administrations, the FDA chipped away at these initial safeguards, risking women's health in order to increase access to abortion. Under the current Risk Evaluation and Mitigation Strategy (REMS) in effect since 2023:

1. a mifepristone abortion now requires as a little as one telehealth visit with any approved healthcare provider (not necessarily a physician),
2. a woman may self-administer drugs obtained from a mail-order pharmacy, and
3. the prescriber need not report any adverse events unless he or she knows that a patient has died. *Figure 2.*

Figure 2

Weakening FDA Safeguards for Mifepristone

	2000 Clinton Initial Approval	2016 Obama REMS Changes	2023 Biden REMS Changes
Required number of in-person visits	3	1	0
Maximum gestational age (LMP)	7 weeks	10 weeks	10 weeks
Drugs prescribed only by physician	✓	✗	✗
Drugs dispensed only in office	✓	✓	✗
Drugs taken only in office	✓	✗	✗
Required in-office follow-up	✓	✗	✗
Required reporting of adverse events	✓	✗	✗

2 Alliance for Hippocratic Medicine v. FDA, Complaint, https://adflegal.org/wp-content/uploads/2022/11/Alliance-for-Hippocratic-Medicine-v-FDA-2022-11-18-Complaint.pdf
3 Mifeprex (mifepristone) drug label, September 2000, page 3, https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.pdf
4 Mifeprex (mifepristone) drug label, September 2000, page 6, https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.pdf
5 Mifeprex (mifepristone) drug label, September 2000, page 14, https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.pdf

The current FDA-approved drug label refers to the results of 10 clinical trials with a total of 30,966 participants, less than 0.5 percent of whom reportedly experienced serious adverse reactions.[6] But these figures are based entirely on data from trials taking place more than a decade ago.

The Increasing Market Share of Chemical Abortion

Increased access to chemical abortion has coincided with a rapid increase in its prevalence. Chemical abortions—the vast majority of which are performed using a combination of mifepristone and misoprostol—now account for roughly two-thirds of all abortions in the United States. *Figure 3.*

In fact, Danco Laboratories boasts that more than 5 million U.S. women have used its abortion pill since it was approved in 2000.[7] Thus, it has become increasingly important to understand the risks and harms to women from chemical abortion in general and from mifepristone in particular.

How We Identified Mifepristone Abortions

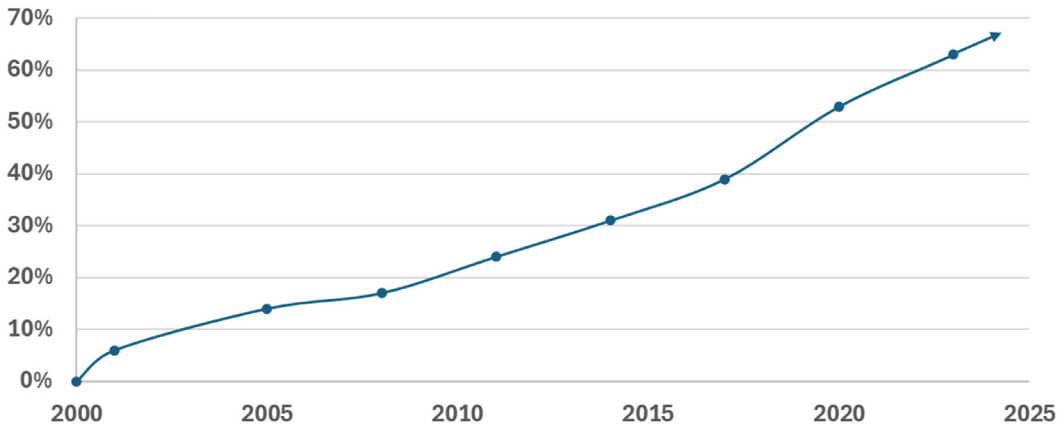
In our data, a mifepristone abortion was identified in one of three ways:

1. procedure code S0199: medically induced abortion by oral ingestion of medication including all associated services and supplies,
2. a prescription for mifepristone (with or without misoprostol within the next 3 days), or
3. a diagnosis code for elective termination or unwanted pregnancy, along with other billing coding consistent with manufacturer instructions for reimbursement for a mifepristone abortion for a given state and insurer combination.[8]

Following this method, we identified a total of 865,727 mifepristone abortions prescribed for a total of 692,873 women from 2017 to 2023. This includes 566,446 women, each of whom had one such abortion, and 126,427 women with multiple such abortions.

Figure 3

Chemical abortion has increased rapidly since approval in 2000 and now accounts for approximately two-thirds of all abortions.



Source: Guttmacher Abortion Provider Census and Monthly Abortion Provision Study,via https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020

6 Page 7 of the drug label states, "Serious adverse reactions were reported in <0.5% of women. Information from the U.S. and non-U.S. studies is presented in Table 2." Table 2 on page 8 indicates that some categories of serious adverse reactions were observed at higher rates in some trials, but this is never discussed in the text, leaving only the previous statement with which to interpret the table. See Mifeprex (mifepristone) drug label, January 2023, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s026lbl.pdf

7 Danco Laboratories, "The Safe and Effective Abortion Pill | Mifeprex (mifepristone)," https://www.earlyoptionpill.com (accessed April 14, 2025)

8 Danco Laboratories, "Mifeprex State Payer Policies," https://www.earlyoptionpill.com/how-do-i-get-mifeprex/state-payer-policies (accessed April 14, 2025)

How We Identified Serious Adverse Events

We followed the official FDA definition of "serious adverse event."[9] To do so, we identified relevant ICD-10 diagnosis codes and CPT/HCPCS procedure codes for adverse events from multiple sources:

- CDC Severe Maternal Morbidity (SMM) indicators,[10]
- CMS Diagnosis-Related Group (DRG) 770 and 769 codes,[11]
- FDA Adverse Events Reporting System (FAERS) reports (interpreted and translated into diagnosis and procedure codes by the doctors on our team),[12] and
- a small number of (mostly gynecological) codes suggested by our doctors.

These codes were then graded by a team of physicians using the the NIH Common Terminology Criteria for Adverse Events (CTCAE version 5), which categorizes adverse events by severity on a 5-point scale.[13] We included CTCAE Grade 3 (severe) and Grade 4 (life-threatening). We did not include Grade 1 (mild) or Grade 2 (moderate). (Grade 5 is death, which would count as a serious adverse event under the FDA definition but could not necessarily be observed in the insurance claims data. We hope to show the rate of death in a subsequent report.)

For reporting, we have grouped the relevant diagnosis and procedure codes as follows:

1. The mifepristone label divides serious adverse events into six categories identified in the clinical trials: sepsis, infection, transfusion, hemorrhage, hospitalization, and emergency room visit. Only those hospitalizations and emergency room visits with abortion-related diagnosis and procedure codes are included in our analysis.
2. FAERS received reports of various events that our doctors judge to be life-threatening and have grouped into broad categories: ectopic pregnancy, surgery, cardiac, pulmonary, thrombosis, and anaphylaxis.
3. Repeated (surgical) abortion procedures are considered serious adverse events.
4. Other abortion complications include codes specifically related to an abortion or miscarriage, as well as life-threatening mental health diagnoses, etc.

We consider only serious adverse events that occurred within 45 days following the abortion. This is conservative, as some adverse events may present later (and studies relied on by the FDA used a timeframe as long as 72 days). Additionally, the likelihood of a subsequent pregnancy within this timeframe is negligible, which ensures that adverse events are related to the abortion rather than to a subsequent pregnancy.

Our Data

Our team has purchased access to a commercially available all-payer health insurance claims database including de-identified data for all U.S. patients during the years 2017 to 2023. It includes information on hospital and office visits, diagnoses, procedures, and prescriptions processed through private health insurance, Medicaid, Medicare, TRICARE, and the Department of Veterans Affairs (VA). The data excludes transactions for which the insurer is also the provider (as is the case with some HMOs and much VA care), as well as cash pay transactions (which are disproportionately common for abortion). This dataset provides longitudinal tracking of medical diagnoses, procedures, and prescriptions for each patient and is widely used in academic and regulatory research.

9 FDA, "What is a Serious Adverse Event?," https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event
10 CDC, "Identifying Severe Maternal Morbidity (SMM)," https://www.cdc.gov/maternal-infant-health/php/severe-maternal-morbidity/icd.html
11 CMS, "ICD-10-CM/PCS MS-DRG v37.0 Definitions Manual," https://www.cms.gov/icd10m/version37-fullcode-cms/fullcode_cms/P0287.html
12 FDA, "FDA Adverse Events Reporting System (FAERS) Public Dashboard," https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f-7f1c25ee/sheet/33a0f68e-845c-48e2-bc81-8141c6aaf772/state/analysis
13 NIH, "Common Terminology Criteria for Adverse Events (CTCAE)," https://ctep.cancer.gov/protocolDevelopment/electronic_applications/ctc.htm

Our Research Project Team

Our research project was conducted and validated by a team of data scientists, analysts, and engineers, with assistance from our clinical team of board-certified obstetricians and gynecologists. Members have a history of academic research and peer-reviewed publication.

Conclusion

Our research shows unequivocally that mifepristone abortion, as currently practiced in the U.S., is considerably more dangerous to women than is represented on the FDA-approved drug label. The FDA should immediately reinstate its earlier, stronger patient safety protocols to ensure physician responsibility for women who take mifepristone under their care, as well as mandate full reporting of its side effects. The FDA should further investigate the harm this drug causes to women and, based on objective safety criteria, reconsider its approval altogether. Women deserve better than the abortion pill.

This paper is the first in a series investigating women's health and abortion using real-world data.

ETHICS AND PUBLIC POLICY CENTER

Shaping Policy, Renewing Culture

EXHIBIT 82

Declaration of Dr. Ingrid Skop

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF DR. INGRID SKOP

I, Ingrid Skop, a citizen of the United States and a resident of San Antonio, Texas, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I am a board-certified obstetrician and gynecologist working for OB Hospitalist Group with privileges in the Baptist Hospital System.
3. I also serve as a Senior Fellow and Director of Medical Affairs at the Charlotte Lozier Institute.
4. I am a member of Plaintiff American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG), where I served as a member of the board from 2018-2020. I am also a member of the Christian Medical & Dental Associations.
5. I received my medical degree from Washington University School of Medicine in 1992 and completed my residency in obstetrics and gynecology at the University of Texas Health Sciences Center at San Antonio in 1996.
6. My current practice involves delivering babies and performing surgeries in a hospital setting as an obstetric hospitalist. In my prior 25-year career in a large single-specialty OB/GYN practice, I also provided clinic-based obstetric and gynecologic care to women and girls.

7. I have provided written and oral expert testimony about chemical abortion to several state legislatures and to the United States Congress.

8. I have also published the peer-reviewed articles "Chemical Abortion: Risks Posed by Changes in Supervision" and "Medical Abortion: What Physicians Need to Know" in the Journal of American Physicians and Surgeons.

9. The articles I published reflect the research I have performed on the risks associated with unsupervised chemical abortion—a practice that is becoming more common.

10. A chemical abortion includes providing patients with a combination of two drugs. One drug—mifepristone—blocks hormonal support, killing the unborn child, while the other—misoprostol—induces uterine contractions to expel the unborn child and the pregnancy tissue.

11. The drugs mifepristone and misoprostol may cause serious complications for the women and girls who take them.

12. In my practice, I often treat patients who are admitted through the hospital's emergency department with complications from chemical abortions.

13. In my practice, I have cared for several dozen women in the emergency department who were totally unprepared for the pain and bleeding they experienced due to chemical abortion.

14. In my experience caring for women who have gone through chemical abortion, the doctors who prescribed or administered chemical abortion drugs

to these women often did not adequately prepare them for the drugs' effects, so these women could not have truly achieved informed consent.

15. At least a dozen patients have expressed significant emotional distress to me when they viewed the body of their unborn child in the toilet after the chemical abortion.

16. I have treated patients who have experienced trauma and emotional distress because of complications from chemical abortion. Those women were not anticipating that complications were possible and likely did not have sufficient informed consent to proceed with chemical abortion.

17. In my practice, I have cared for at least a dozen women who have required surgery to remove retained pregnancy tissue after a chemical abortion. Sometimes this includes the embryo or fetus, and sometimes it is placental tissue that has not been completely expelled.

18. I have cared for approximately five women who, after a chemical abortion, have required admission for a blood transfusion or intravenous antibiotics or both.

19. Complications from chemical abortion are not uncommon. In fact, chemical abortions involve more complications than surgical abortions.

20. The FDA's actions in 2016 and 2021 have increased the frequency of complications from chemical abortion.

21. Given my experience, I expect to see and treat more patients presenting with complications from chemical abortion.

22. For example, in one month while covering the emergency room, my group practice admitted three women to the hospital. Of the three women admitted in one month due to chemical abortion complications, one required admission to the intensive care unit for sepsis and intravenous antibiotics, one required a blood transfusion for hemorrhage, and one required surgical completion for the retained products of conception (*i.e.*, the doctors had to surgically finish the abortion with a suction aspiration procedure).

23. In my office, I treated one young woman who had been bleeding for six weeks after she took the chemical abortions drugs given to her by a doctor at a Planned Parenthood clinic. After two follow-ups at Planned Parenthood, during which she was given additional misoprostol but not offered surgical completion, she presented to me for help. I performed a sonogram, identified a significant amount of pregnancy tissue remaining in her uterus, and performed a suction aspiration procedure to resolve her complication.

24. I have also cared for minor women below the age of 18 who have obtained chemical abortion drugs. Although mifepristone has not been studied specifically in minor women, the FDA has negligently allowed their provision to this special age group, assuming their response will be the same as adult women.

25. The FDA's actions deregulating mifepristone and expanding access to unsupervised chemical abortion harm women and their doctors, including me. Concerns about "unsafe, back-alley abortions" were used to overturn all

state abortion restrictions in 1973 and they are being recycled today to allow the abortion industry to continue perpetuating dangerous abortion methods. Yet, a clear-eyed look at the FDA's actions allowing unsupervised "mail-order abortions" shows that they are now promoting illegal, unsafe "chemical coat hangers" to the women they falsely say they want to protect.

26. The FDA's actions harm women, including my patients, because without proper oversight, chemical abortions can become even more dangerous than when they are supervised.

27. The FDA's actions harm women, including my patients, because clinics and physicians prescribing or dispensing chemical abortion drugs, or websites that provide these drugs through mail order delivery without any physician involvement, often underprepare women for the severity and risks of chemical abortion, and they often provide insufficient or no follow-up care to those women. Many women are inadequately prepared for the effects of the drugs, the severity of the pain and bleeding they will experience, the human tissue they will expel, and some are unaware that they have complicating factors such as ectopic implantation, more advanced gestation than estimated, and Rh-negative blood type. These patients are being abandoned because in many cases there is no doctor-patient relationship, so they often present to overwhelmed emergency rooms in their distress, where they are usually cared for by physicians other than the abortion prescriber.

28. Unsupervised chemical abortion—authorized by the FDA—harms women because they may have underestimated the gestational age of their unborn child. Women who should not be a candidate for chemical abortion because they are past the FDA-approved cutoff of ten weeks gestation may consume chemical abortion drugs, which will increase their chances of complications due to the increased amount of tissue, leading to hemorrhage, infection and/or the need for surgeries or other emergency care.

29. For example, approximately 2% of pregnancies are ectopic pregnancies, implanted outside of the uterine cavity. Chemical abortion drugs will not effectually end an ectopic pregnancy because they exert their effects on the uterus, which leaves women at risk of severe harm from hemorrhage due to tubal rupture, in need of emergent surgery or potentially at risk of death. Failure to perform an ultrasound prior to prescribing abortion drugs will cause some women to remain undiagnosed and at high risk for these adverse outcomes.

30. The FDA's removal of the reporting requirement for adverse events of mifepristone harms women by creating an inaccurate safety profile, and it harms my practice because it makes it more difficult to practice evidence-based medicine. The incidence of abortion-related complications remains unknown if there is no accurate system for data collection.

31. The FDA's actions also harm women because the lack of oversight will likely exacerbate human trafficking, which happens frequently in San Antonio. In

my practice, part of my care of my patients is ensuring that they are making medical decisions free of coercion. Many trafficked women experience unintended pregnancies and alert doctors serve as an important resource to intervene on behalf of women. Removing the in-person medical interaction removes an opportunity to identify and rescue these women. It also leaves them at risk of being coerced into an abortion they may not desire.

32. Deregulated chemical abortion harms my practice because it increases the number of women who come to the emergency department with complications. When I must perform surgery to deal with complications from chemical abortions, this takes attention away from my other patients. As a hospitalist, I am often supervising multiple laboring patients on labor and delivery. When I am called to the operating room to address an emergency resulting from chemical abortion, this necessarily means I may not be immediately available if an emergency should occur with one of my laboring patients.

33. Unsupervised chemical abortion is heartbreaking to me because it causes women to suffer unnecessarily, and my patients deserve quality medical care.

34. The FDA's expansion of chemical abortion also harms my conscience rights because it could force me to have to surgically finish an incomplete elective chemical abortion. I object to abortion because it ends a human life. My moral and ethical obligation to my patients is to promote human life and health.

But the FDA's actions may force me to end the life of a human being in the womb for no medical reason.

Executed this November 11, 2022.

By: Ingrid Skop MD
Ingrid Skop, MD

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EXHIBIT 83

Declaration of Dr. Shaun Jester

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF DR. SHAUN JESTER

I, Shaun Jester, a citizen of the United States and a resident of Dumas, Texas, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I am a board-certified obstetrician and gynecologist and am the Medical Director of Moore County Ob/Gyn in Dumas, Texas. I have been board-certified since 2007.
3. I received my medical degree in 1999 from the Texas College of Osteopathic Medicine at the University of North Texas Health Science Center at Fort Worth.
4. I have a busy medical practice. I am one of three doctors on call. My practice includes cesarean section deliveries, hysterectomies, and other women's health treatments. My practice includes about thirty deliveries each month.
5. A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.
6. I understand that the FDA approved chemical abortion drugs for use in the United States in 2000.

7. I am also familiar with the FDA's regulatory changes regarding chemical abortion drugs, especially the REMS issued in 2016 and associated with the use of mifepristone and misoprostol for chemical abortions.
8. I understand that the FDA approved the use of mifepristone up to 70 days (or 10 weeks) of gestation in 2016, which is longer than the previous standard of 49 days (or 7 weeks).
9. I am familiar with the FDA's suspension and elimination of the in-person dispensing requirements for administering these dangerous drugs in 2021.
10. I am familiar with the removal of the requirement for an in-person, post-abortion office visit, which is when a physician determines whether any fetal parts or other products of conception remain. These visits are essential to ensure that women experience no complications after chemical abortion.
11. I am also familiar with the relaxed reporting requirements for adverse events related to chemical abortions.
12. I believe these FDA actions will harm my patients, women, and women's medicine.
13. I believe that the FDA's approval for using mifepristone at a later gestational age, and the elimination of the in-person dispensing requirement and follow-up visit requirement, are especially dangerous for women.
14. Based on my experience, mothers are often mistaken about how far along they are in pregnancy. According to the Listening to Mothers III survey, 26% of women's due dates are changed.

15. Without an in-person visit to obtain an ultrasound, there is no way to be certain about the gestational age of an unborn child. Women may be further along in pregnancy than is currently acceptable for chemical abortion. Similarly, without an in-person examination, it is impossible to rule out an ectopic pregnancy, which would not be terminated by a chemical abortion and could put women at an increased risk of rupture or even death.

16. Based on my experience treating patients, I believe unsupervised chemical abortions are dangerous and potentially life-threatening especially due to increased risk of hemorrhage and/or infection the further along they are after 6 weeks' gestation.

17. For instance, I treated a woman who traveled from Texas to obtain chemical abortion drugs from Planned Parenthood New Mexico to complete an abortion at 10 weeks' gestation. The woman returned to Texas, suffered from two weeks of moderate to heavy bleeding, and then developed a uterine infection. At the hospital, I provided her with intravenous antibiotics and performed a dilation and curettage procedure. If she had waited a few more days before receiving care, she could have been septic and died. I reported this adverse event to the FDA.

18. The FDA's actions harm my practice by causing unnecessary harm to my patients that could have been avoided by retention and enforcement of the REMS.

19. Doctors like me serve patients as professional health care providers. I provide care to all women and unborn children, and I give them the best professional services possible. Just like other employed obstetrical providers, my hospital will bill for the cost of obstetrical and medical services rendered. When my patients have chemical abortions, I lose the opportunity to provide these obstetrical and medical services to care for the woman and child through pregnancy and bring about a successful delivery of a new life.

20. Additionally, the wider availability of chemical abortion drugs will result in more patients experiencing complications and the number of patients in emergency situations will rise. These situations are naturally higher risk for both the patient and for the physician providing care. In the chemical abortion case that I reported as an adverse event to the FDA, I had no existing patient relationship or prior knowledge of the patient's medical history. Such cases can be a high-pressure, high-risk situation for practitioners like me.

21. The FDA's deregulation of these dangerous drugs increases our exposure to liability.

22. There are many contraindications to prescribing mifepristone, including adrenal failure, steroid use, severe anemia, bleeding disorders, the use of intrauterine devices, undiagnosed ectopic pregnancy, and others. I do not believe telemedicine can rule out all contraindications to prescribing

mifepristone because some of these conditions can only be ascertained with an in-person examination or lab work.

23. Telemedicine does not allow for a critical ultrasound assessment to rule out ectopic pregnancies and verify that the patients are within the 70 days allowed for chemical abortions. In this way, the FDA's loosening of regulations for abortifacient drugs harms women and practitioners by exposing them to increased risk of complications.

24. I believe the relaxed reporting requirements for adverse events related to chemical abortion drugs harm women and physicians because they create an inaccurate and false safety profile for the use of mifepristone and misoprostol. Many women and girls do not fully understand the nature of chemical abortion and the risks that these drugs present to them.

25. The elimination of mandatory follow-up visits after chemical abortion drugs have been administered is also dangerous and harms women and practitioners. Without follow-up visits, physicians cannot identify potential complications like sepsis and hemorrhage, lingering products of conception, and others until the patient is at a critical time or it is too late to help the patient.

26. I care for my patients and give them the best medical care and guidance that I can. I believe that chemical abortions harm women, including my patients, and harm the medical practice. The elimination of REMS critical to ensuring safe use of the chemical abortion drugs prevents doctors from fulfilling their

oath to "do no harm" by permitting the administration of abortifacient drugs to patients without full knowledge or appreciation for the impact those drugs would have on them.

27. As with my patient who suffered an adverse event, it disturbed me that she was not informed that it was not normal to bleed for multiple weeks and that if she had a routine follow-up visit, as required by past REMS, this situation could have been avoided before requiring overnight hospitalization and her being at risk for developing sepsis.

Executed this November 14, 2022.

By: _____, D.O.
Shaun Jester, D.O.

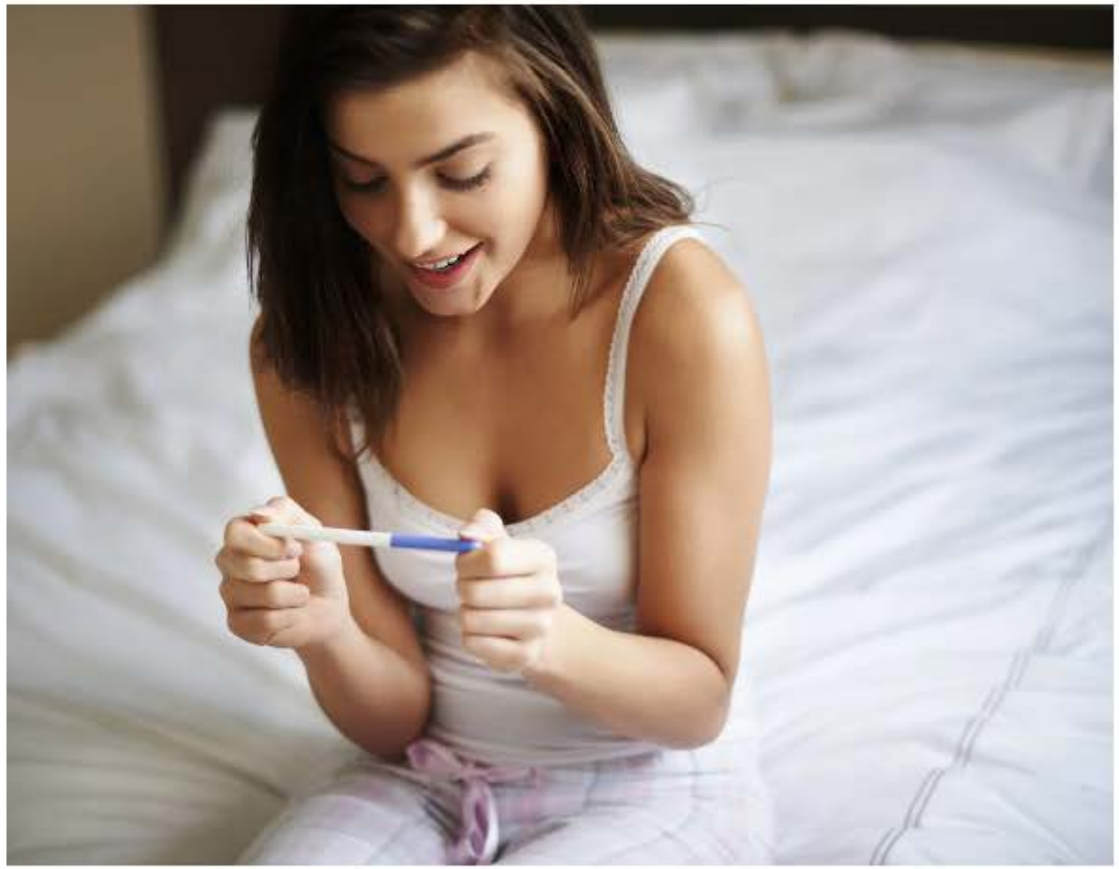
EXHIBIT 84

Her Safe Harbor

Where Can I Get The Abortion Pill?

You can get medication abortion (AKA abortion pills) delivered from from Her Safe Harbor for just $150. Our caring doctors and nurses are experts at providing safe abortion and non-judgmental support throughout the process. You can also get abortion pills from some private doctors or gynecologists, family planning clinics, and abortion.

When you're looking for a place to get an abortion, beware of "crisis pregnancy centers." These are places that seem like normal medical centers, but they don't provide abortion or a full range of health care — they're actually run by people who want to scare or shame people out of getting an abortion. They often give you false or misleading information about pregnancy, abortion, and birth control, and they usually don't have to follow privacy laws.



Getting the abortion pill in the mail

Medication is mailed in plain packaging to protect your privacy and avoid unwanted suspicion.

EXHIBIT 85

Her Safe Harbor - Abortion Pills for Future Use

Buy Abortion Pills For Future Use

You can order abortion pills before you are pregnant, as a precaution for future needs. This service is known as Advance Provision. By providing access to abortion pills before they are needed, individuals can access abortions earlier in their pregnancy.

Ordering abortion pills for future use is similar to the process for ordering pills when you are pregnant. However, it may take longer (usually a few days) to receive a response, as we prioritize those who are currently pregnant.

Begin Consultation



EXHIBIT 86

Declaration of Dr. Regina Frost-Clark

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF DR. REGINA FROST-CLARK

I, Regina R. Frost-Clark, a citizen of the United States and a resident of Michigan, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I am board-certified in obstetrics and gynecology. I practice with St. John OB/Gyn Associates, part of Ascension Medical Group.
3. I received my M.D. from Wayne State University and did my residency at St. John Hospital and Medical Center in Detroit, Michigan.
4. I am in a hospital owned practice and am often called to the emergency department for consultations.
5. I am familiar with the approval and regulatory changes by the United States Food and Drug Administration (FDA) regarding chemical abortion. Specifically, I am familiar with the relaxing of supervision requirements for administering these very serious drugs, and I am familiar with the relaxed reporting requirements for adverse events related to chemical abortions.
6. I believe these FDA actions will harm women, including my patients, and my practice.
7. As an OB/Gyn, I have treated several women who have suffered complications from chemical abortions.

8. The wider availability of chemical abortion drugs will result in an increase in the frequency of complications related to the drugs' use.

9. In at least a dozen cases, I have treated women who were suffering significant bleeding after taking chemical abortion drugs. Occasionally, women have to be admitted to the hospital for observation due to bleeding complications.

10. In my experience, women who have been given chemical abortion drugs often do not know what they were given or how much of a particular drug they took.

11. In most instances where I treat women who have complications from chemical abortion drugs, they have received it from an abortion facility. Recently a woman told me she obtained these drugs by herself—likely online—and took them without any medical supervision.

12. The FDA's suspension of the in-person dispensing requirement of mifepristone and misoprostol harms women and doctors because it has resulted in an increase in complications.

13. Without an in-person dispensing requirement for chemical abortion drugs, there is a greater chance that women with a molar or ectopic pregnancy will be given drugs that will be ineffectual, leaving them exposed to potentially deadly complications like a rupture or hemorrhage.

14. Similarly, without an in-person dispensing requirement, patients may be given chemical abortion drugs without a confirmed pregnancy or for an inappropriate gestational age.

15. In these instances, patients may avoid seeking appropriate medical care because they are unaware of the risks they potentially face, which puts them in greater danger of complications.

16. Women presenting with complications from chemical abortion pose a challenging situation because I may not have access to their medical history—either because I am unable to access any medical records from prescribers of the chemical abortion drugs or because they obtained the chemical abortion drugs without any medical oversight to begin with. Additionally, the patients themselves usually do not understand what they have been given, how much they have taken, or their follow-up instructions.

17. The lack of patient history and knowledge harms my ability to treat patients. For example, with patients experiencing bleeding, the course of treatment will vary if I believe the bleeding is regular or abnormal cyclical bleeding as opposed to bleeding resulting from attempted abortion.

18. I expect to see more and more women with chemical abortion complications as the use of the drugs increases. Because of the increased complications and the limited information available to me due to the FDA's actions, I fear that I will have greater exposure to liability in my practice.

19. The FDA's actions have led to more confusion for patients and providers. The FDA has forced my colleagues and me to make decisions about patient care based on limited information. It also requires me to spend a lot of time trying to reconstruct patient medical histories to best serve my patients.

20. The FDA's actions make it difficult for patients to have informed consent. Doctors cannot confirm the pregnancy, the location of the pregnancy, or the gestational age without an examination. In abortion clinic settings, it is unclear whether patients are seeing the same physician each time. And often there are no patient follow-up visits with the dispensing facility.

21. Under the current practice by those who prescribe chemical abortion drugs like mifepristone and misoprostol, there is no follow-up or additional care provided to patients and therefore no rapport between patients and their physicians. This makes it difficult to assess who is responsible for these patients when they experience complications.

22. The FDA's removal of the adverse event reporting requirement for all adverse events except death harms my ability to perform evidence-based medicine. I am unable to assess the risks present to women because the FDA's removal of reporting requirements undermines the legitimacy of risk data. For example, Ranitidine, commonly known as Zantac, was pulled from the market due to cancer associations after years of use. Without adverse event reporting, I cannot properly assess the risks that my patients face from abortifacient drugs.

23. I have not reported adverse events that I have witnessed as a result of chemical abortions because the process is so cumbersome. In addition to the burdensome paperwork, it is difficult to file an accurate report given that in many cases I am not certain what the patient was given by the chemical abortion prescriber.

Executed this November 13, 2022.

By: _____

Regina Frost-Clark, M.D.

EXHIBIT 87

Declaration of Mario R. Dickerson

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF MARIO R. DICKERSON

I, Mario R. Dickerson, a citizen of the United States and a resident of Willow Grove, Pennsylvania, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I serve as the Executive Director of the Catholic Medical Association ("CMA"). Given my involvement in CMA, I am familiar with the organization's history, the issues confronting it, and the views of the organization and its members concerning various emerging issues, including the deregulated use of mifepristone, or RU-486, to accomplish chemical abortions. I am also familiar with CMA members and their practices.
3. CMA is the largest association of Catholic individuals in healthcare. CMA is a national, physician-led community that includes about 2700 physicians and healthcare professionals nationwide.
4. CMA is a nonprofit organization incorporated in Virginia, and its registered agent is in Virginia.
5. CMA's mission is to inform, organize, and inspire its members, in steadfast fidelity to the teachings of the Catholic Church, to uphold the principles of the Catholic faith in the science and practice of medicine.
6. CMA seeks to pursue its mission in conformity to Christ the Divine Physician. Its members are challenged to be a voice of truth spoken in charity, to show

how Catholic teachings on the human person, human rights and the common good intersect with and improve the science and practice of medicine, and to defend the sacredness and dignity of human life at all stages.

7. CMA is a member of the Alliance for Hippocratic Medicine (AHM).

8. CMA is committed to taking a Catholic and Hippocratic approach to medicine.

9. Consistent with Catholic teaching, CMA and its members are morally and ethically opposed to all forms of abortion—chemical or surgical.

10. I have spoken with CMA members who have treated women harmed by chemical abortion drugs.

11. The FDA's unauthorized approval of mifepristone (also known as "Mifeprex" and "RU-486") and subsequent elimination of certain safeguards for the use of the dangerous chemical abortion drug regimen, including those found in the Risk Evaluation and Mitigation Strategy (REMS) for mifepristone, has led to an increasing risk that women and girls may suffer adverse events from chemical abortion.

12. The FDA has continued to eliminate safeguards such that the chemical abortion drugs can now be administered and dispensed with no in-person examination or oversight by a physician. This leaves physicians, including CMA members, to treat the complications that women and girls suffer due to the actions of the FDA and abortionists.

13. CMA's member physicians include OB/GYNs and emergency department physicians who have treated women suffering complications from chemical abortion.

14. The FDA's actions harm CMA and its member physicians who are called away from other patients to render emergency treatment to women and/or girls who present to emergency departments with symptoms, such as heavy bleeding and severe pain, and more serious complications, including hemorrhage and sepsis caused by chemical abortion drugs. This causes CMA's member physicians much stress and grief, while impeding their ability to perform their practice of medicine in the manner that they desire.

15. Often, emergency department doctors do not have a prior relationship with these patients and lack access to the patient's medical history. Sometimes these patients were underinformed about the effects of the chemical abortion drug regimen, they may not even know what drugs they consumed, or they are told to say they are suffering a miscarriage if there is a need for them to seek emergency help following a chemical abortion. This leaves doctors at increased risk of liability and could impact their ability to render the best care possible to the patient—all because of the FDA's elimination of necessary safeguards.

16. Moreover, the FDA's removal of necessary safeguards could force CMA members to treat women and girls who present to emergency departments following an elective chemical abortion requiring those doctors to complete an

unfinished elective abortion—terminating the life of an unborn child—in violation of their conscience rights.

17. Since 2005, CMA has called upon the FDA to respond to citizens petitions calling for removal of RU-486 from the market in an urgent action. CMA renewed this resolution in 2015.

18. In 2016, CMA enacted a resolution that called for the FDA to require a central registry for all those having a chemical abortion, with mandatory reporting from every state and territory of complications and mortalities from chemical abortions; that the drug be administered only by a physician with surgical privileges at a hospital within 30 minutes of the facility where the drug is dispensed; that the dispensing physician be responsible for follow-up and handling of complications; and that the patient be informed that the process could be stopped without harm to her or the baby.

19. These resolutions are vital to ensure the safety of women and girls, and to protect doctors, including CMA members.

20. CMA has spent considerable time, effort and resources challenging the FDA's actions—at the expense of other CMA priorities. For example, to implement these resolutions, committees have had to review them, it has taken time during General Assembly meetings to discuss them, which takes our members away from their other business, and it has taken time for our Executive Director and Board to review, taking them away from other priorities such as fundraising and membership recruitment and retention.

21. Due to inadequate adverse event reporting, the true rates of risks associated with chemical abortion drugs remain unknown and undercounted. This prevents CMA from providing the public, their members, and their members' patients with accurate statistics and complete information regarding the risks associated with the use of chemical abortion drugs.

22. CMA is a leading national voice on applying the principles of the Catholic faith to medicine. CMA creates and organizes educational resources and events; advocates for members, the Church, and the medical profession in public forums; and provides guidance for bishops and other national leaders on healthcare ethics and policy. The inability to share accurate information on the risks of chemical abortion frustrates and complicates CMA's purpose to educate doctors, their patients, and the public about these dangers.

Executed this November 12, 2022.

By: Mario R. Dickerson
Mario R. Dickerson

EXHIBIT 88

Declaration of Dr. Tyler Johnson

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF DR. TYLER JOHNSON

I, Tyler Johnson, D.O., a citizen of the United States and a resident of Leo, Indiana, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I received my Bachelor of Science in Biology from the University of Saint Francis in Fort Wayne. I attended medical school at the Lake Erie College of Osteopathic Medicine. My residency was at Michigan State University's Kalamazoo Center for Medical Studies.
3. I am an emergency department physician certified by the American Board of Emergency Medicine. I practice in the emergency departments of hospitals in northern Indiana. My practice includes treating patients throughout rural northern Indiana into the inner-city of Fort Wayne. I am also the director of emergency medicine at Parkview Dekalb Hospital.
4. I am a member of the American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG).
5. I am familiar with the U.S. Food and Drug Administration's (FDA) Risk Evaluation and Mitigation Strategy (REMS) drug safety program. I am also familiar with the REMS issued by the FDA for the chemical abortion drugs mifepristone and misoprostol in 2016.

6. The FDA's 2016 REMS for mifepristone and misoprostol expanded the acceptable gestational age for chemical abortion, eliminated the in-person administration requirement for these dangerous drugs, eliminated mandatory post-abortion follow-up visits, and eliminated the requirement for prescribers to report all non-fatal adverse events.
7. The FDA's actions harm both women and practitioners.
8. Mifepristone and misoprostol are dangerous drugs that have serious effects on a woman's body. Without the medical supervision, women taking these drugs are at risk of serious and life-threatening complications and even death.
9. I have seen at least a dozen cases of life-threatening complications from the use of abortifacient drugs over the years. These emergency situations are becoming more common as more women are turning to chemical abortion as the FDA has relaxed its regulations.
10. In one case, for example, I treated a woman in the emergency department who had been given an abortion pill from a clinic in Chicago. She took the pill and began to experience heavy bleeding on the drive back to Fort Wayne. By the time she arrived at the hospital, she was unconscious. I performed emergent treatment and gave her a necessary blood transfusion. The patient required further evaluation and observation in the hospital. I have seen multiple cases similar to this one.

11. About a month ago, I treated an 18-year-old woman in the emergency department who was experiencing severe pain. Although the situation was not life-threatening to her, she was terrified, and it was clear to me that she did not understand what she had been given. It is not uncommon for women who take mifepristone and misoprostol to come to the emergency department because the pain is so terrible.

12. Many of the patients I have treated for complications with chemical abortion experience trauma. They usually have no follow-up with the doctors who prescribed or dispensed the abortifacient drugs, and they are not adequately prepared to understand what the drugs will do to them. In these situations, it is clear to me that these women and girls could not have given informed consent to chemical abortion.

13. In many cases, women are hesitant to tell us that they have taken chemical abortion drugs. On multiple occasions I have treated women in the emergency department who are experiencing extremely heavy bleeding even after they have already passed the unborn child. The women will sometimes eventually explain that they took abortifacient drugs, which helps us understand what is happening to them. I understand that many women are told by staff at the dispensing clinics to tell emergency department doctors that they are experiencing a "miscarriage."

14. Because of the FDA's relaxed regulation of these dangerous drugs, it is extremely easy for women to obtain mifepristone and misoprostol with little

or no supervision. This leaves emergency physicians like me to deal with preventable emergent and life-threatening situations after these women have taken these drugs. The unsupervised administration of chemical abortion drugs simply harms women and physicians.

15. The FDA's actions have created a culture of chaos for emergency room physicians. In my experience, patients who are given abortifacient drugs at clinics do not understand what they have taken and are often reluctant to tell emergency doctors what they have taken. This puts me and my colleagues in a position where we have to treat women in emergency situations without crucial information. This culture puts us in increasingly higher risk situations, which increases our exposure to claims of malpractice and liability.

16. The increase in women presenting in the emergency department for complications with chemical abortions harms other patients too. Because more women are unnecessarily presenting in the emergency department, more of my time and attention is taken away from other patients who need it.

17. I also believe the FDA's elimination of reporting requirements for non-fatal adverse events harms women and practitioners. I believe we are not tracking these medications closely enough to know the extent of the negative side-effects commonly experienced. This also harms physicians' ability to practice evidence-based medicine. Moreover, women and girls cannot give informed

consent to chemical abortion when they do not receive accurate information about the risks associated with mifepristone and misoprostol.

18. Given my experience, I expect to see and treat more patients presenting themselves with complications from chemical abortion.

Executed this November 11, 2022.

By: _____
Tyler Johnson, D.O.

EXHIBIT 89

Declaration of Dr. Steven A. Foley

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF DR. STEVEN A. FOLEY

I, Steven A. Foley, a citizen of the United States and a resident of Carmel, Indiana, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I am board-certified in obstetrics and gynecology. I practice in Angola, Indiana, and Evansville, Indiana.
3. As a hospitalist, I am associated with several hospitals and cover the emergency department for hospitals. As an OB/Gyn in a hospital setting, I have treated numerous women who have suffered complications from abortions.
4. I have practiced obstetrics and gynecology in Indiana and other states for many years.
5. I am a member of Plaintiff Christian Medical and Dental Associations.
6. During my time in Colorado, I was one of the only OB/Gyn doctors available to many patients. For example, during my time working in the plains of Colorado, it was 120 miles to the next OB/Gyn doctor.
7. I believe regulatory actions of the United States Food and Drug Administration (FDA) on chemical abortion will harm my practice and my patients.

8. Women suffer more complications from chemical abortions than surgical abortions.
9. The removal of the supervision requirements before administering chemical abortion drugs harms patients because it does not allow a doctor to establish gestational age, determine whether the woman has an ectopic pregnancy, or to check the Rhesus (Rh) levels of the patients. Giving women abortifacient drugs without these simple screening steps is simply against the standard of care and will cause more complications.
10. The FDA's actions will especially harm my practice in Indiana since the state's ban on abortions after 15 weeks took effect on September 15, 2022. This means more women will turn to chemical abortion drugs that they are able to obtain online and through the mail because they will seek to use these drugs to obtain surreptitious abortions after the gestational age limit. The increase in number of women taking chemical abortion drugs, especially later in gestational age, will lead to an increased demand in the emergency department.
11. Under the current practice by those who prescribe and dispense chemical abortion drugs like mifepristone and misoprostol, there is no follow-up or additional care provided to patients. Instead, with no established relationship with a physician, patients are simply left to report to the emergency room when they experience adverse effects.

12. Many women are underinformed on the severity of the effects associated with chemical abortions, including the duration and severity of bleeding, the pain associated with the process, and the emotional trauma that they experience.

13. When chemical abortion drugs work as intended, a woman will effectively deliver her unborn child and the placental and any other pregnancy tissues.

14. Many women who report to the emergency department do not disclose that they have taken abortifacient drugs. In some instances, women will tell medical providers that they are suffering a miscarriage. The lack of information or misinformation received by doctors by their patients impacts the course of treatment and the care that doctors can provide.

15. Because abortionists do not adequately inform a woman or a girl about what happens during a chemical abortion and give these drugs to her to take outside of the abortion facility, I have needed to treat and care for many women who have presented to the emergency department with intense bleeding and other effects of the chemical abortion drugs—although not considered complications from the regimen.

16. I have also treated several women for abortion-pill reversal, where women seek to stop a chemical abortion from occurring after they have taken mifepristone. I prescribe the drug progesterone for these patients in an attempt to save their pregnancy. These women experience mental anguish

over the experience of having chosen chemical abortion, and some of them do not feel like they were properly advised as to what they were choosing.

17. The FDA's removal of the adverse event reporting requirement for all adverse events except death harms my ability to perform evidence-based medicine. I am unable to assess the risks present to women because the FDA's removal of reporting requirements undermines the legitimacy of risk data.

Executed this November 13, 2022.

By: _____
Steven A. Foley, M.D.

EXHIBIT 90

Declaration of Dr. Nancy Wozniak

IN IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF DR. NANCY WOZNIAK

I, Nancy Wozniak, M.D., a citizen of the United States and a resident of Fishers, Indiana, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I am a board-certified obstetrician and gynecologist practicing in the greater Indianapolis area. My practice includes obstetrics at two Indianapolis-area hospitals.
3. I am a member of the Board of Directors of Plaintiff American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) and serve as AAPLOG's Secretary. I am familiar with AAPLOG, its policy positions, its members, the members' interests and concerns. AAPLOG and its members oppose elective abortions, both surgical and chemical.
4. I am familiar the approval of mifepristone and misoprostol as chemical abortion drugs by the U.S. Food and Drug Administration (FDA) and with the FDA's Risk Evaluation and Mitigation Strategy (REMS) for the use of mifepristone and misoprostol for chemical abortions.
5. A REMS is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

6. Under the REMS established by the FDA in 2016 for mifepristone and misoprostol, the agency eliminated (a) the in-person administration requirement, (b) mandatory post-abortion follow-ups, and (c) the requirement that prescribers report all adverse events except death.
7. In 2016, the FDA also expanded the gestational age for approved mifepristone use to 70 days (or 10 weeks) from 49 days (or 7 weeks).
8. The FDA's actions harm patients and practitioners like me.
9. Mifepristone and misoprostol are dangerous drugs that can harm women. Without the appropriate supervision, women taking these drugs are at risk of serious complications and even death in the worst cases.
10. I believe the FDA's expansion of the approved timeframe for mifepristone and misoprostol use to 10 weeks of gestation harms women. An abortionist should never prescribe these drugs to any woman for an abortion after 8 weeks' gestation because I have seen so many women get into trouble with bleeding past that gestational age.
11. Few people die from chemical abortions because of the excellent care they receive from OBGYN doctors, but the infrequency of deaths conceals the danger that these drugs pose to women and girls—especially when administered without proper supervision.
12. In my experience, most of the complications related to the use of mifepristone and misoprostol for chemical abortions result in "near misses" due to the timely intervention of healthcare providers.

13. Recently many states like Indiana have enacted laws to regulate abortions more carefully. To circumvent those laws, abortion providers are relying on increased access to chemical abortion drugs through mail-order schemes or telemedicine.

14. The increasing number of chemical abortions through mail-order or telemedicine methods means that more women will suffer complications from unsupervised use of mifepristone and misoprostol.

15. The risk of complications from chemical abortions is four to seven times greater than from surgical abortions.

16. Currently, many women are now being prescribed mifepristone and misoprostol without a sonogram to verify the gestational age of the unborn child or to rule out ectopic pregnancies or other potential complications.

17. Women have the potential to present to the emergency department with torrential bleeding due to taking mifepristone and misoprostol for a chemical abortion without accurate dating and appropriate supervision. This places enormous stress and pressure on physicians and OB/Gyns who work in hospitals.

18. In my observation, incidents of women presenting to emergency departments with complaints of bleeding are becoming increasingly more common.

19. Due to the FDA's elimination of the adverse event reporting requirements, however, it is impossible to know how frequently women and doctors are facing these complications.

20. The FDA's elimination of the adverse event reporting requirements for non-fatal complications harms doctors' ability to practice evidence-based medicine and to provide their patients about the risks of chemical abortion and obtain their informed consent. Doctors are only as good as the information that they receive.

21. These physicians must treat women in emergency situations without an existing relationship with the patient, without a known gestational age, and without any known medications that the patient may have been prescribed. This dynamic also increases doctors' exposure to allegations of malpractice and potential liability.

22. The FDA's loosening of regulations related to chemical abortions harms hospitalists by putting them in higher-risk situations with less critical information about patients, which increases their exposure to allegations of malpractice and potential liability.

23. In the last six months, I had an experience treating a woman that illustrates how dangerous and damaging the FDA's actions are to women and practitioners.

24. One of my patients, who was about nine weeks pregnant, had previously been treated by hospital staff for a pulmonary embolism with anti-coagulants. She was advised that she could not seek a chemical abortion because it was contraindicated due to the medications; yet the woman left the hospital and sought an abortion at Planned Parenthood of Indiana. The woman was given

mifepristone by the doctor at Planned Parenthood and took the drug. The woman called an Uber for a ride home from Planned Parenthood. The woman began to experience bleeding and other adverse side effects from the mifepristone. The woman's Uber driver did not take her home because she was so ill and instead brought her to the hospital's emergency department. At the hospital, the woman came under my care. The woman had not yet taken the second abortion drug, misoprostol. I treated the patient for the adverse effects she suffered and told her not to take the misoprostol given to her by Planned Parenthood because of the grave risk that she could bleed out and die. The woman had a subsequent ultrasound, which showed that her unborn child was still alive. I advised the internists treating this patient to avoid administering certain medications that could harm the patient and her unborn child.

25. This experience that I had illustrates one of many "near misses" where women and girls face potentially deadly situations, but they are saved by intervention at a hospital's emergency department.

26. Under the FDA's current reporting requirements, this experience need not be reported as an adverse event. I attempted to report this event to the Indiana Department of Public Health, but my report was rejected because the State said it was not a "true" adverse event because the patient ultimately recovered.

27. In my experience with the patient I just described, I spent a significant amount of time that day working to save her life from unnecessary complications due to the irresponsible administration and use of mifepristone and misoprostol. As a result of the significant time that I devoted to that patient, my time and attention was taken away from my other patients, who also need my care.

28. I also know that many women who are suffering complications from chemical abortions tell their doctors that they are experiencing miscarriages. This phenomenon—regardless of why it occurs—means that doctors cannot be certain of what their patients have taken or are experiencing. The lack of information makes it extremely difficult to provide proper treatment to these patients. This inaccurate information also means that the true number of incidences of complications from chemical abortions are significantly underreported or not fully known.

29. Given my experience, I expect to see and treat more patients presenting themselves with complications from chemical abortion.

Executed this November 11, 2022.

By: _____
Nancy Goodwine-Wozniak, M.D.

EXHIBIT 91

Declaration of Dr. Jeffrey Barrows

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF DR. JEFFREY BARROWS

I, Jeffrey Barrows, D.O. M.A. (Ethics), a citizen of the United States and a resident of Blountville, Tennessee, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I am a board-certified obstetrician and gynecologist and am the Senior Vice President of Bioethics and Public Policy for Plaintiff Christian Medical & Dental Associations (CMDA).
3. I practiced obstetrics and gynecology for approximately 18 years. I practiced gynecology in an office setting for an additional ten years.
4. I am familiar with CMDA, its members, their fields of practice, and CMDA's policies and positions.
5. CMDA is a national nonprofit organization headquartered in Tennessee. Its members are more than 13,000 Christian physicians, dentists, and allied healthcare professionals. CMDA has more than 1,200 members in Texas, including more than 600 physicians and approximately 35 OBGYNs.
6. CMDA is opposed to elective abortions as contrary to sacred scripture, respect for the sanctity of human life, and traditional, historical Judeo-Christian medical ethics.
7. CMDA's mission includes advocating on behalf of its members, including in litigation.

8. CMDA brings this suit on behalf of itself and its members.

9. CMDA has members in Texas and around the country who care for pregnant women in hospitals and clinics. CMDA's members care for women who suffer complications from chemical abortions.

10. A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

11. I am familiar with the FDA's approval of chemical abortion drugs in 2000.

12. I am familiar with the FDA's regulatory changes regarding chemical abortion drugs, especially the REMS issued in 2016 and associated with the use of mifepristone and misoprostol for chemical abortions.

13. I understand that the FDA's 2016 changes expanded the gestational age for approved mifepristone use to 70 days (or 10 weeks) from 49 days (or 7 weeks), that it eliminated the in-person administration requirements for chemical abortion drugs, that it eliminated the requirement for a follow-up appointment after those drugs have been taken, and that it eliminated the prescriber reporting requirement for all adverse events except for death.

14. I also understand that the FDA subsequently eliminated the in-person dispensing requirements in 2021.

15. The FDA's actions harm women, practitioners, CMDA members, CMDA as an organization, and the medical profession generally.

16. Mifepristone and misoprostol are dangerous drugs that can potentially harm women. Relaxing the required medical supervision and oversight for patients taking these drugs puts women's health at risk.

17. By eliminating the in-person dispensing requirement and the requirement for a post-abortion follow-up, the FDA has exposed women to a higher likelihood of undetected serious complications. Specifically, the expanded use of telemedicine for chemical abortions means that some women who are beyond 70 days' gestation because they are mistaken or wrong about the gestational age of their unborn child will take these drugs outside of the appropriate window.

18. Similarly, without in-person visits and sonograms, women with ectopic pregnancies may escape diagnosis, which puts them at a greater risk of serious and life-threatening complications such as rupture of the Fallopian tube and secondary hemorrhage. Undetected ectopic pregnancies are especially dangerous for women because in some cases they can result in extreme bleeding for women.

19. By eliminating the adverse event reporting requirement for all events except death, the FDA has also undermined physicians' ability to practice evidence-based medicine. By failing to collect accurate information about the complications associated with chemical abortion, the FDA leaves doctors without accurate information about the drugs' safety for women.

20. As an organization, CMDA is harmed by the FDA's failure to require reporting of all adverse events, which prevents CMDA from providing the public, our members, and our members' patients with accurate statistics and complete information regarding potential risks associated with the use of chemical abortion drugs.

21. The inability to share accurate information with member physicians, their patients, and the public on the risks of chemical abortion frustrates and complicates CMDA's purpose to provide professional healthcare and to educate doctors, their patients, and the public about the dangers of chemical abortion.

22. By removing the requirements for in-person visits, the FDA has increased the risk of malpractice claims against physicians. The best way to prevent malpractice is for physicians to establish relationships with patients who they can treat over time. By doing away with the necessary medical supervision, the FDA will cause more women to present in life-threatening circumstances into the care of hospitalists and emergency department physicians who have no prior history with these patients.

23. By putting more doctors into riskier, emergent medical situations, the FDA's regulatory actions expose physicians to increased claims of liability.

24. The increased risks of exposure to liability and malpractice claims also impacts physicians because it drives up their insurance costs, especially those who practice in the hospital.

25. The FDA's loosening of chemical abortion regulations impacts the standard of care and the demands and expectations that hospitals will put on their physicians. The FDA has radically altered the standard of care for mifepristone and misoprostol. The agency did this without the requisite evidence to support its actions.

26. I am also concerned that the FDA's actions will force CMDA members to complete an unfinished elective abortion in an emergency situation, causing immediate emotional and moral distress for our members who are opposed to elective abortion and do not want to feel complicit in an immoral, unnecessary procedure.

27. CMDA has been involved with challenging the FDA's approval of chemical abortion drugs for 20 years. In 2002, we submitted a Citizen Petition with other pro-life groups challenging the FDA's actions, diverting valuable time and effort from CMDA's routine functions in order to assist in filing the petition.

Executed this November 12, 2022.

By: BARROWS DO MA
Jeffrey Barrows, D.O. M.A.

EXHIBIT 92

Rachel K. Jones & Amy Friedrich-Karnik, *Medication Abortion Accounted for 63% of All US Abortions in 2023—An Increase from 53% in 2020*, Guttmacher Institute (March 2024)

Medication Abortion Accounted for 63% of All US Abortions in 2023—An Increase from 53% in 2020



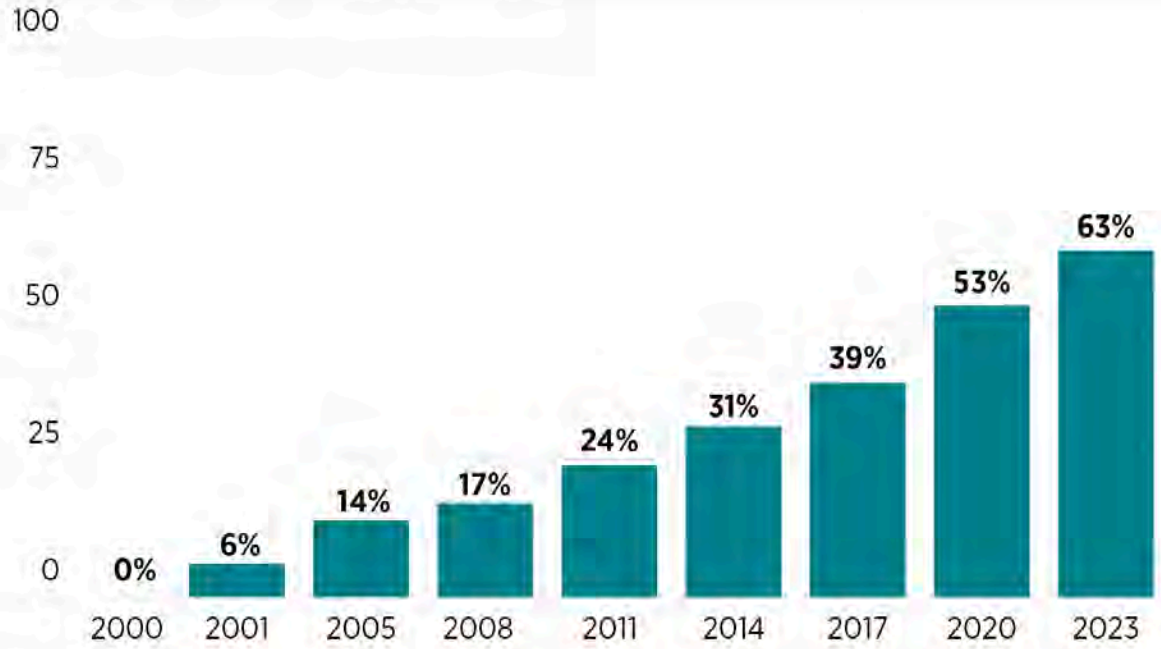
AUTHORS

Rachel K. Jones, Guttmacher Institute

Amy Friedrich-Karnik, Guttmacher Institute

Reproductive rights are under attack. Will you help us fight back with facts? Donate

New Guttmacher Institute research from the **Monthly Abortion Provision Study** shows that there were approximately 642,700 medication abortions in the United States in 2023, accounting for 63% of all abortions in the formal health care system. This is an increase from 2020, when medication abortions accounted for 53% of all abortions.



Sources: Guttmacher Abortion Provider Census and Monthly Abortion Provision Study.
guttmacher.org

Medication abortion using mifepristone was first approved for use in the United States by the U.S. Food and Drug Administration (FDA) in 2000, and reliance on medication abortion has increased steadily as it has become more accessible over time. The two-drug combination of mifepristone and misoprostol is the most common medication abortion regimen offered by US providers, and decades of research have established that medication abortion using mifepristone is **highly safe and effective**. Increased access to and use of medication abortion is likely one reason why the overall number of abortions in the formal health care system **increased 10% nationally** between 2020 and 2023.

The medication abortion counts for 2023 do not include **self-managed medication abortions** that take place outside of the formal health care system or abortion medication mailed to people in states with total abortion bans. While there are no comprehensive data on the number of self-managed medication abortions in the United States, evidence suggests they **have been increasing** in the past several years. Therefore, the total count of medication abortions nationally is higher than our count of those offered within the formal health care system.

Unfortunately, gains in access to and use of medication abortion are at risk. The US Supreme Court will hear a case on March 26—*Alliance for Hippocratic Medicine v. FDA*—

and reinstate the requirement for the drug to be provided in person. If outdated and medically unnecessary restrictions are placed on the provision of mifepristone—in contrast with the FDA's evidence-based protocol—access to abortion across the country would be greatly impacted.

Medication Abortion Has Become More Widely Available

For many people, medication abortion is more accessible than a procedural abortion. In 2021 (the most recent year with available data), 40% of facilities known to provide abortion care **offered only medication abortion**. And, starting in 2021, the FDA lifted medically unnecessary restrictions that had required in-person provision of mifepristone. That **regulation change**, which the FDA finalized in January 2023, meant that health care providers and online pharmacies could mail abortion medication to patients, including those who live far from a provider or are otherwise unable to make an in-person visit. In addition, brick-and-mortar pharmacies can now become certified to **dispense and fill mifepristone prescriptions**, so access is expected to continue growing.

The number of US providers offering a telemedicine consultation—by video, phone call, text or online platform—and **mailing abortion pills increased** from 7% of all providers known to offer medication abortion in 2020 to 31% in 2022. Online-only clinics, after first appearing as a new type of abortion provider in 2021, accounted for **8% of all abortions** provided within the formal health care system in the first six months of 2023.

Medication abortion provided via telemedicine is as **safe and effective** as provision in a health care facility. Offering options besides in-person care can reduce, or even remove, some of the secondary costs related to seeking an abortion, such as transportation, child care and missed wages from taking time off work. Like with other types of health care, having the option to access abortion care via telemedicine allows for more flexibility and can expand **person-centered care** by meeting patients where they want to be served.

Not All People Prefer Medication Abortion Over Procedural Abortion

While broader access to medication abortion has likely contributed to its increased use, it does not necessarily indicate that all people are getting their preferred method.

Since the Supreme Court's *Dobbs v. Jackson Women's Health Organization* decision in ne 2022 ended a right to abortion nationally, there has been an increase in patients at linics in states where abortion continues to be available. Sixteen percent of abortion

banned. At the same time, abortion has also increased among residents in almost all of these bordering states. In some places, these developments have led to **wait times** of two weeks or longer for abortion care.

Some individuals may opt to access care through telehealth options to avoid long wait times for appointments, even if they would have preferred in-clinic care. Even at brick-and-mortar clinics, wait times may be shorter for medication abortion than procedural abortion since the pills can be offered by methods such as "**quick pick-up**." Finally, for some patients, the closest abortion provider may only offer medication abortion, limiting their access to a procedural abortion unless they can travel to a clinic where it is offered.

When procedural abortion is harder to access relative to medication abortion, the impact of those restricted options falls hardest on groups of people historically marginalized within the health care system. For example, research suggests that Black individuals, people who have had a prior abortion and those with incomes below the federal poverty level are less likely than other groups **to prefer**, and **to have**, a medication abortion (vs. a procedural abortion).

State Restrictions on Use of Medication Abortion

Anti-abortion policymakers have been working to restrict access to abortion care on many fronts. Besides the 14 states that are **enforcing a total ban on abortion**, five states where abortion remains legal until at least six weeks' gestation have laws that restrict access to medication abortion via telemedicine. Arizona, Nebraska, North Carolina, South Carolina and Wisconsin require that a patient being prescribed medication abortion have an in-person visit with a physician, and Arizona and North Carolina also ban mailing medication abortion pills to a patient. Furthermore, 15 states require medication abortion to be provided by a physician, despite evidence that advanced practice clinicians can provide it safely, as they do in other states.

It Is Critical to Ensure Full Access to Medication Abortion

Medication abortion has proven to be a game changer in expanding abortion care in the United States. Unfortunately, legal attacks and restrictive policies continue to challenge access. When the Supreme Court rules on the case challenging access to mifepristone this spring, it will have to decide whether to ignore the FDA and reimpose unnecessary

Any return to restrictions on medication abortion provision via telemedicine would be detrimental for people who either prefer or only have access to abortion using telemedicine. While the current court case only affects use of mifepristone—and a misoprostol-only regimen is also a **safe and effective method** of medication abortion—everyone seeking an abortion should have access to the full range of safe, effective options.

Methodology

Data on medication abortion for 2023 are from Guttmacher's **Monthly Abortion Provision Study**, which produces national and state estimates of the number of abortions provided within the formal health care system in the United States based on data collected from samples of abortion providers. Questions about medication abortion were included in versions of the survey distributed to providers in August and September 2023 and in February 2024 (with the latter asking providers for annual medication abortion figures for 2023). Estimates include abortions provided at brick-and-mortar facilities (including those that use telehealth) and online-only providers. These estimates do not include abortions obtained outside of the formal health care sector or any abortions—whether self-managed or provided by out-of-state clinicians—involving medication mailed to states with total abortion bans.

First published online: **March 19, 2024**

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EXHIBIT 93

Society of Family Planning, #*WeCount Report April 2022 to March 2024* (August 7, 2024)

#WeCount report, April 2022 to December 2024
Released: June 23, 2025

#WeCount is a time-limited reporting effort that aims to capture national shifts in abortion volume, by state and month, following the *Dobbs v Jackson Women's Health Organization* Supreme Court decision to overturn *Roe v Wade*. This report includes data from April 2022 to December 2024.

For media inquiries, please contact SFP@ConwayStrategic.com.

For questions about #WeCount and information on how to enroll your practice, please contact WeCount@SocietyFP.org.

Please use the citation below to cite this #WeCount report.

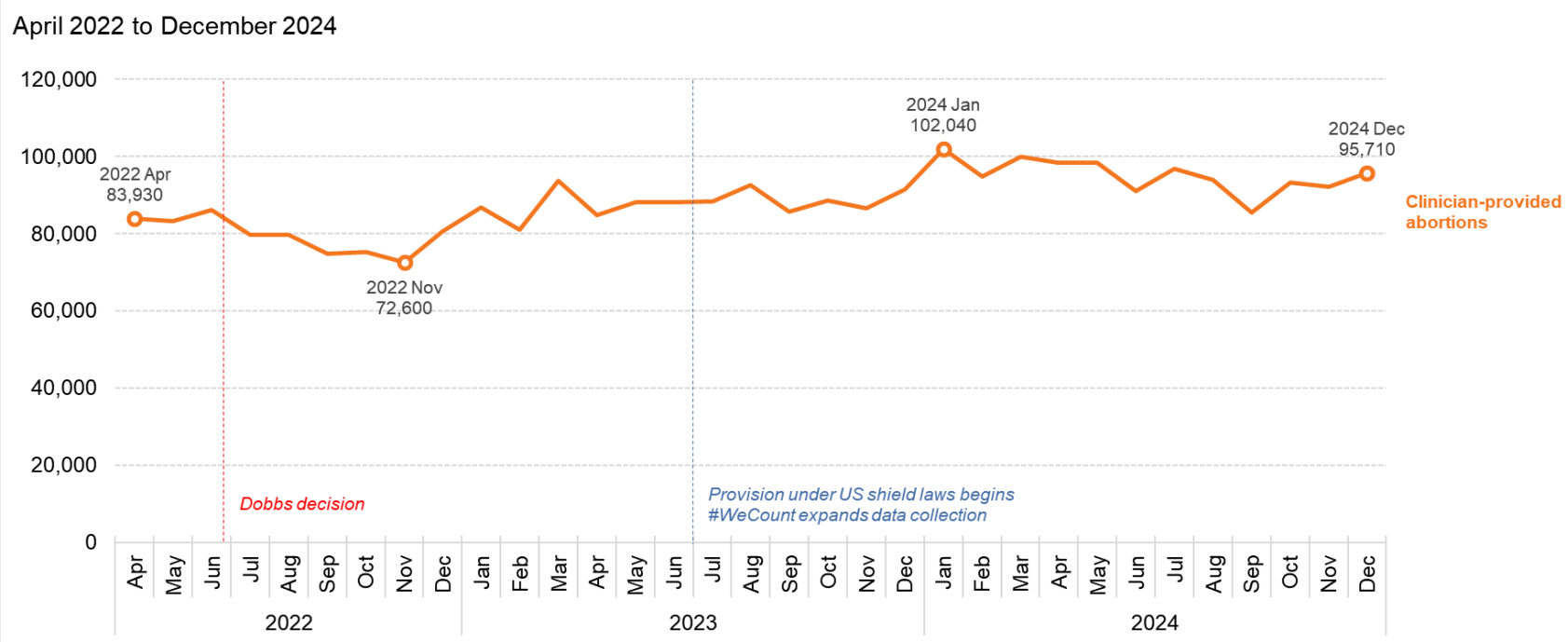
> *Society of Family Planning. #WeCount Report April 2022 through December 2024. 23 Jun. 2025, https://societyfp.org/wecount-report-9-december-2024-data/, https://doi.org/10.46621/725961gzsnai.*

Key findings

- The total number of abortions was **higher in 2024** than it was in 2023 or 2022.
- The majority of abortions occurred **in-person**.
- The number of abortions delivered via **telehealth has continued to increase** since April 2022, when #WeCount became the first national study to track telehealth.
- By the end of 2024, 1 in 4 abortions was provided via telehealth.
- **Shield laws** continue to facilitate the receipt of medication abortion, with an average of 12,330 abortions per month provided under shield laws by the end of 2024.
- Drivers of these trends are unclear, especially in the context of multiple changes in the service delivery environment; new evidence that helps contextualize these findings continues to emerge.

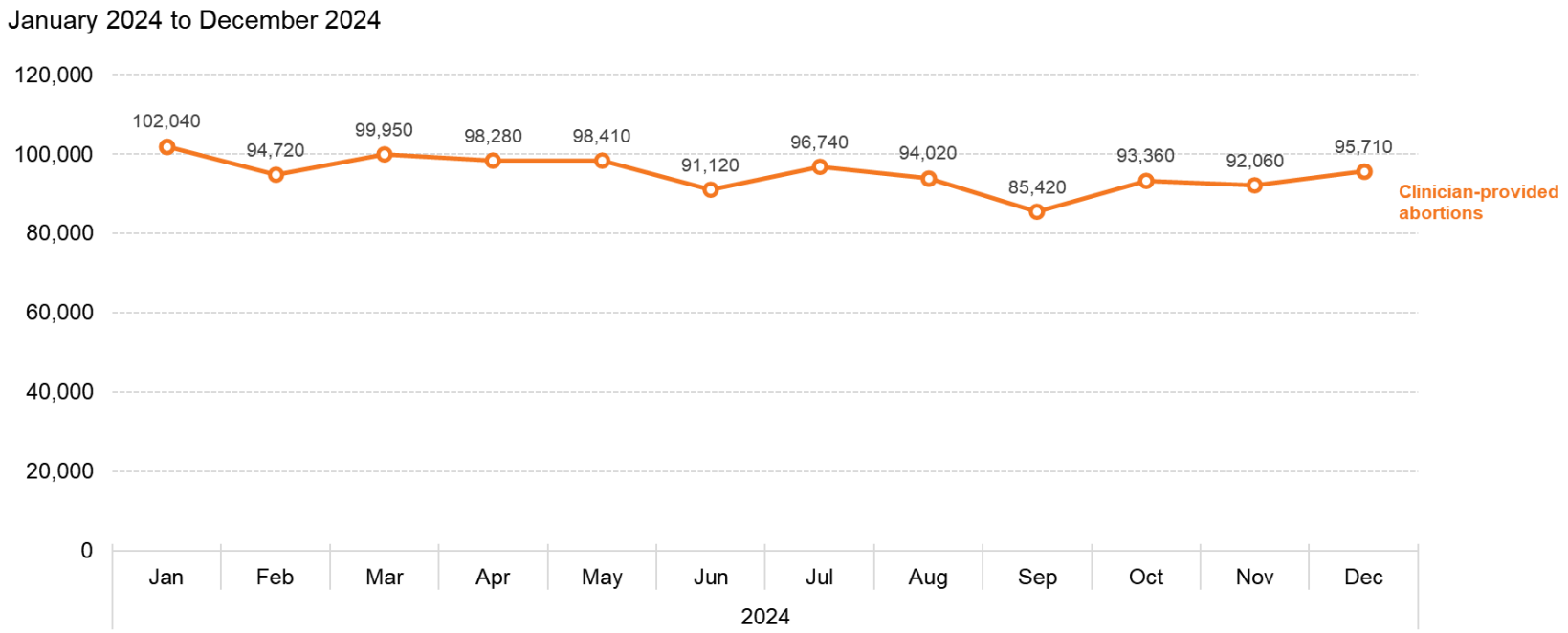
National findings

Total abortions in the US have increased since Dobbs



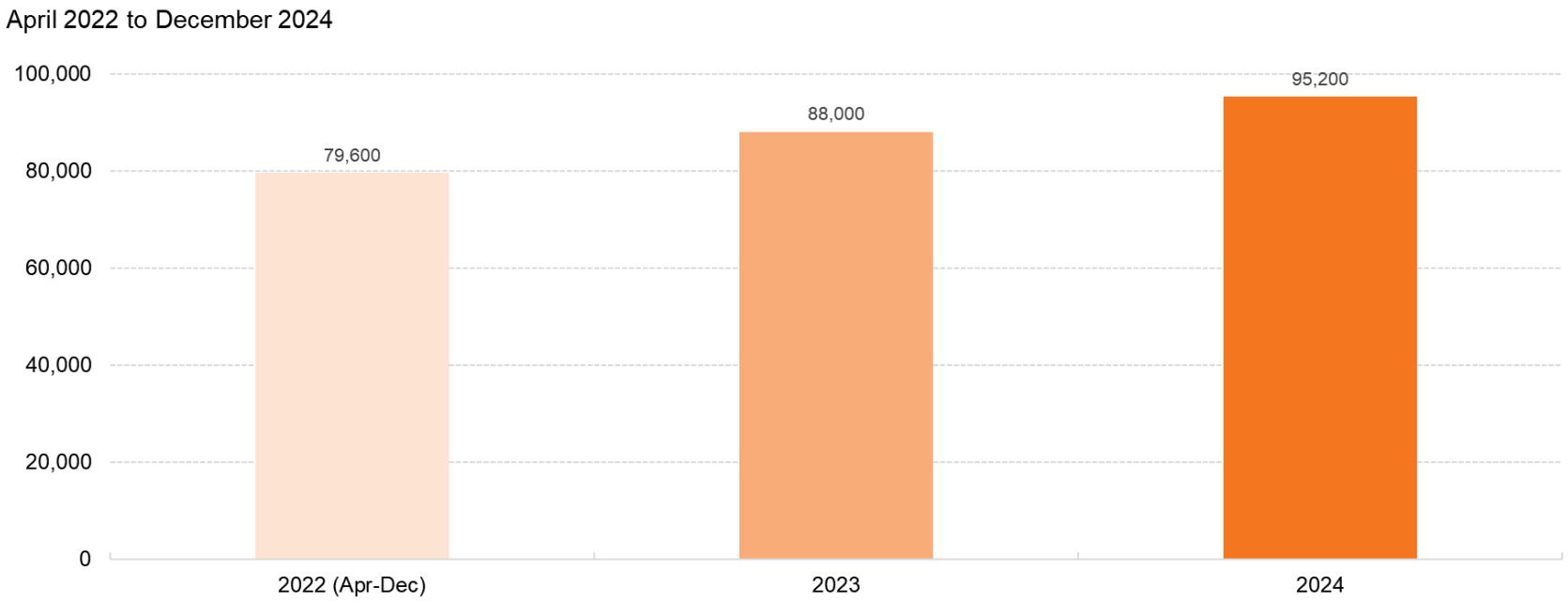
The monthly number of abortions increased gradually over time in the US since 2022.

US abortions totaled 1.14 million in 2024



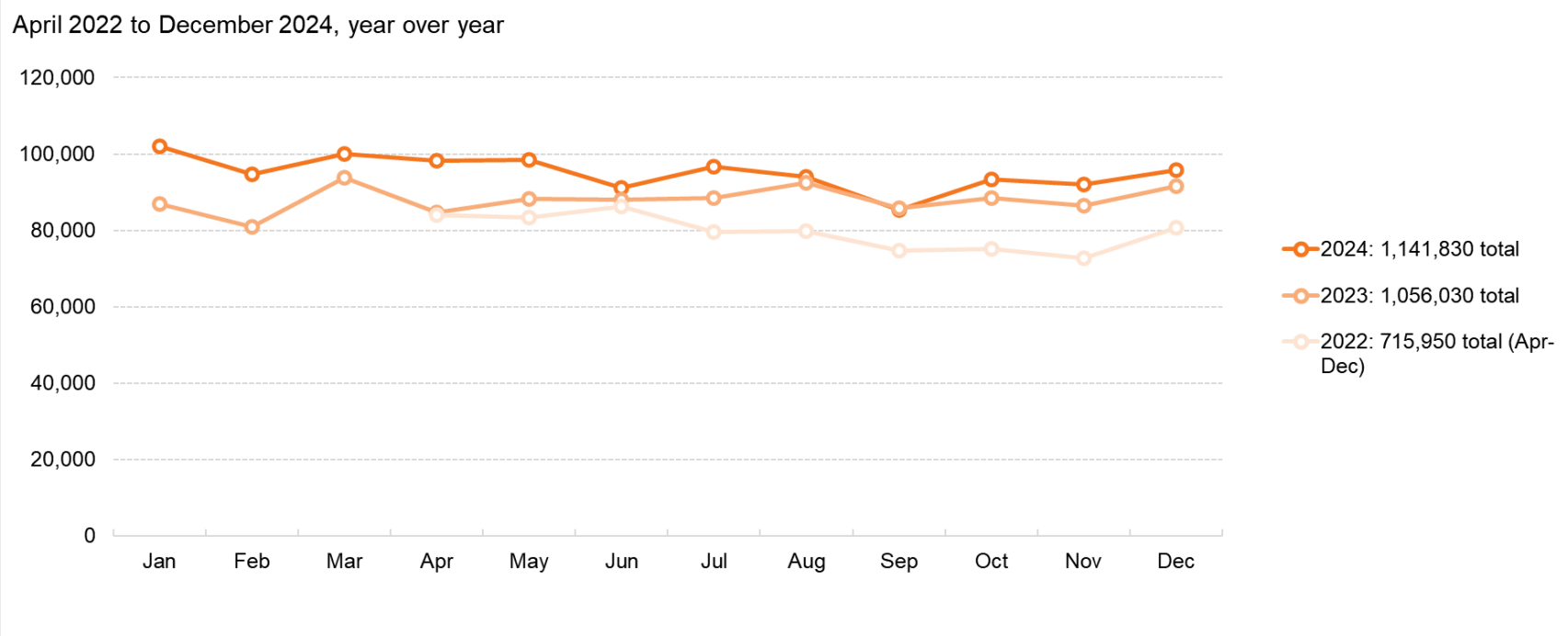
In 2024, 1.14 million abortions occurred in the US, the largest number of abortions in the US in recent years. The monthly total peaked in January 2024, reaching over 102,000 abortions in a single month.

Monthly average number of abortions increased each year



The monthly average number of abortions climbed from around 80,000 in 2022, to 88,000 in 2023, to 95,000 in 2024. Note that the 2022 monthly average is less precise because it reflects only April to December of that year; we did not collect data in January to March, which, in subsequent years, had higher volume of abortions. In addition, these months were pre-*Dobbs*, before abortion bans were enacted.

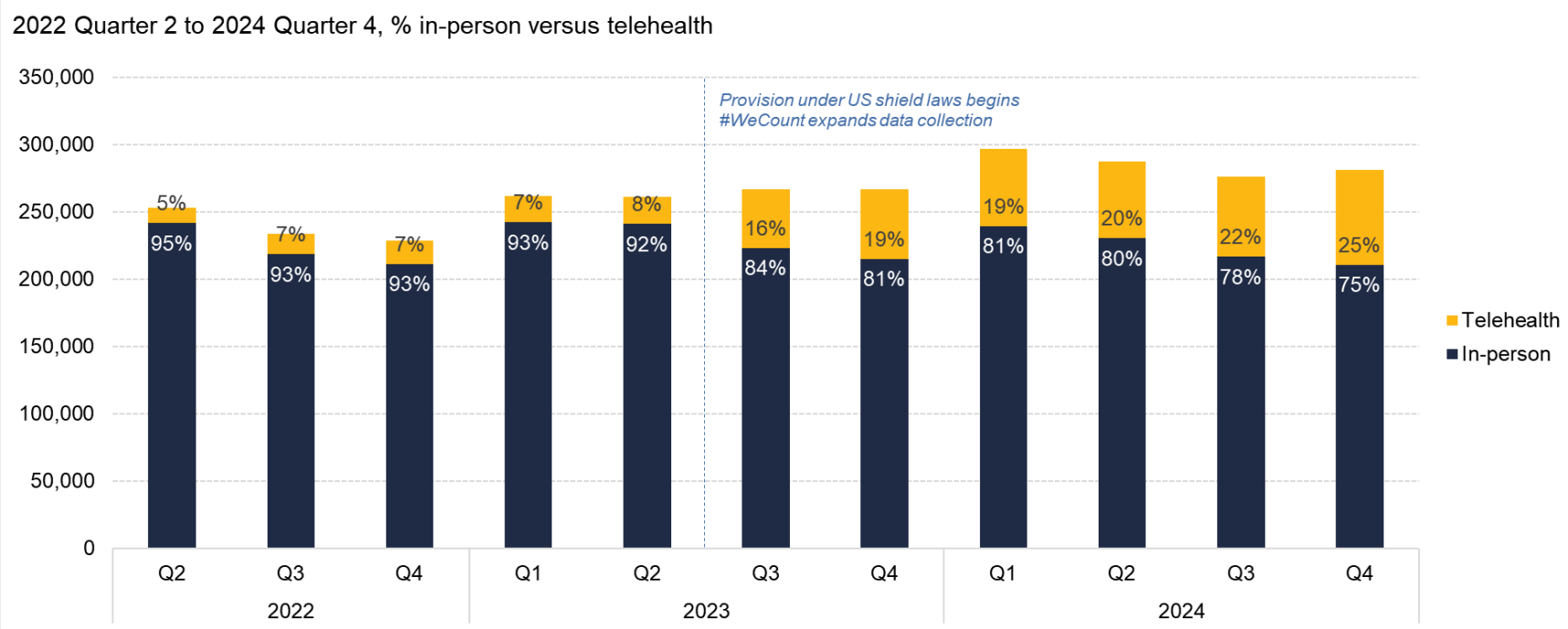
The monthly number of abortions increased each year



Comparisons of year over year show that for most months the number of abortions in 2024 was higher than the number of abortions in the same month of 2023 or 2022.

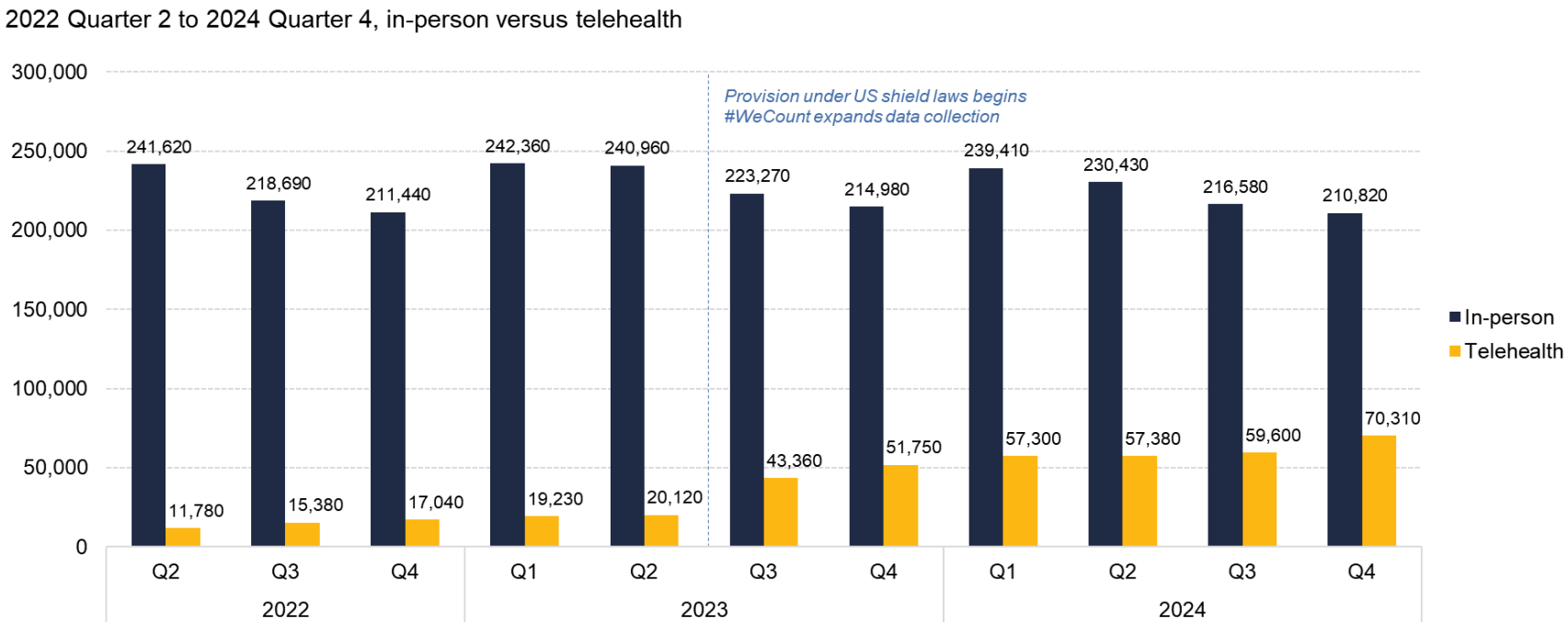
Telehealth findings

By Q4 of 2024, 1 in 4 abortions were provided via telehealth



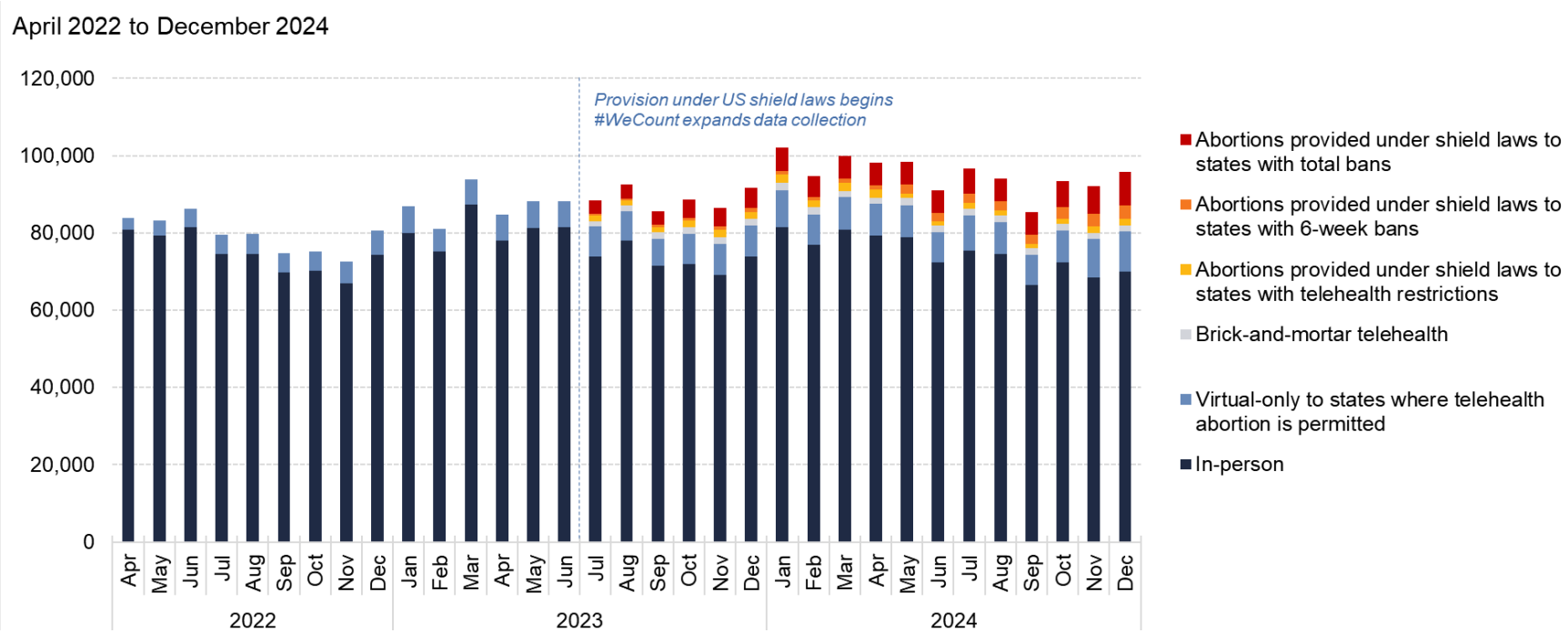
The proportion of abortions that were provided via telehealth increased over time from 5% in April-June of 2022 to 25% by the end of December 2024.

In-person abortion care declined slightly, while telehealth grew



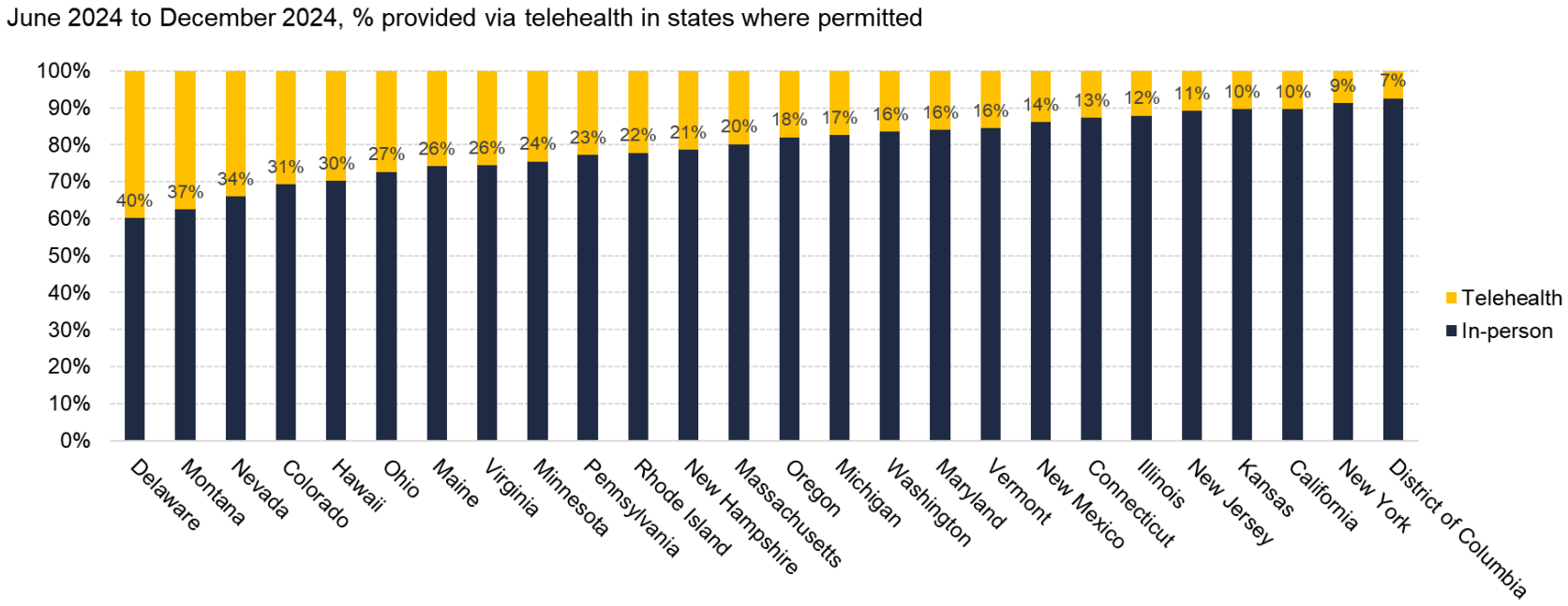
Telehealth abortion care (which involves mailing medication abortion pills) increased both in proportion and in absolute numbers over the study period. In-person abortion care (which includes both procedural abortions and medication abortion pills dispensed in person), was much more common than telehealth abortions. As telehealth has grown, the number of in-person abortions has not declined commensurately. The number of in-person abortions was lower in the second half of each year compared to the first half.

The majority of abortions still take place in-person



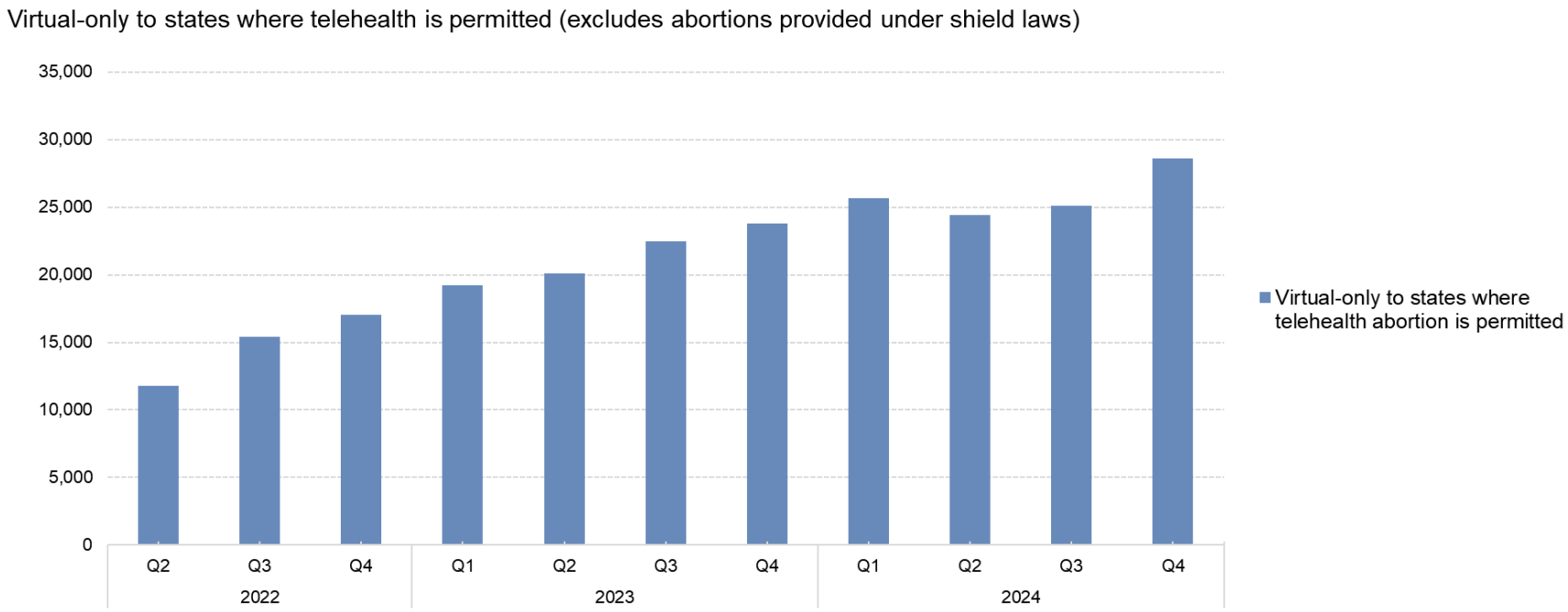
In the US, in-person provision continues to represent the majority of abortion care.

The proportion of abortions provided via telehealth varied by state, 2024



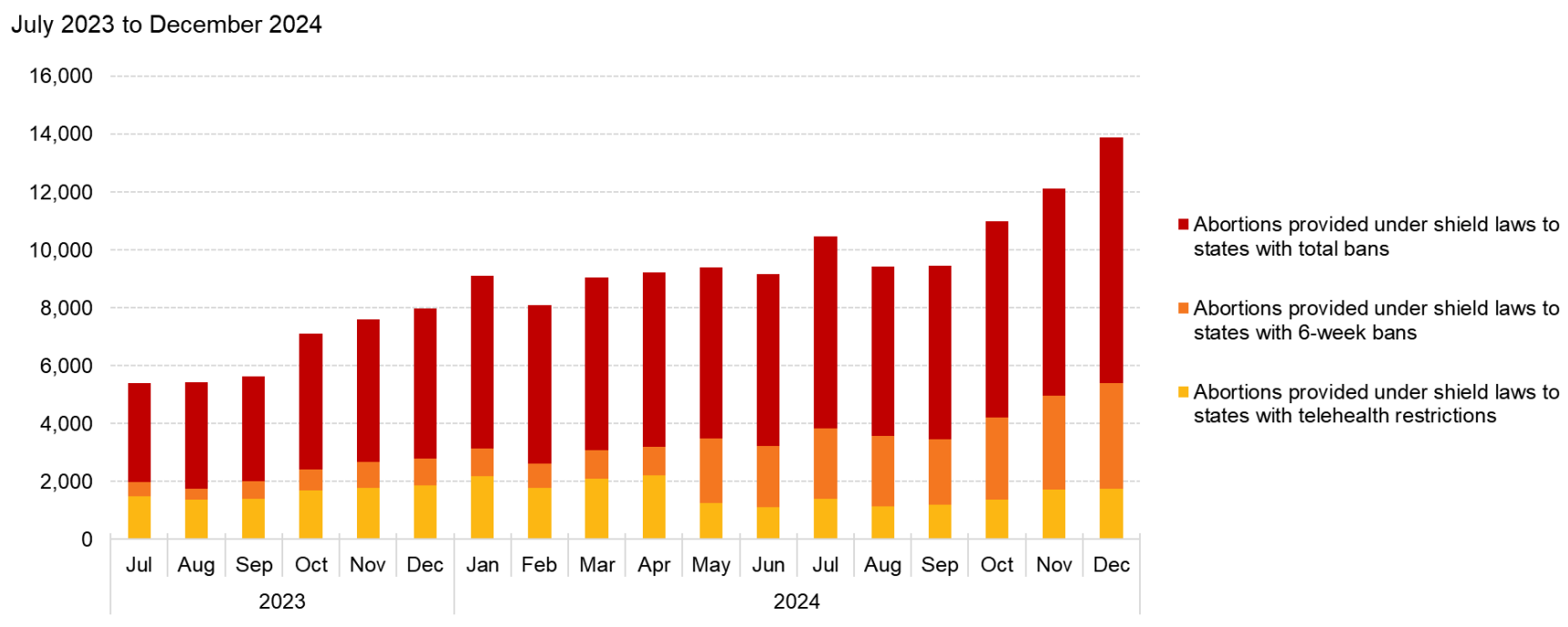
Across the US, in states that permit abortion and telehealth provision of abortion, there is substantial variation in the proportion of abortions provided via telehealth, ranging from 7% to 40%. In several larger states, telehealth is a smaller share of the abortions, at about 9-12% of all abortions.

Abortions provided by virtual-only clinics have increased since *Dobbs*



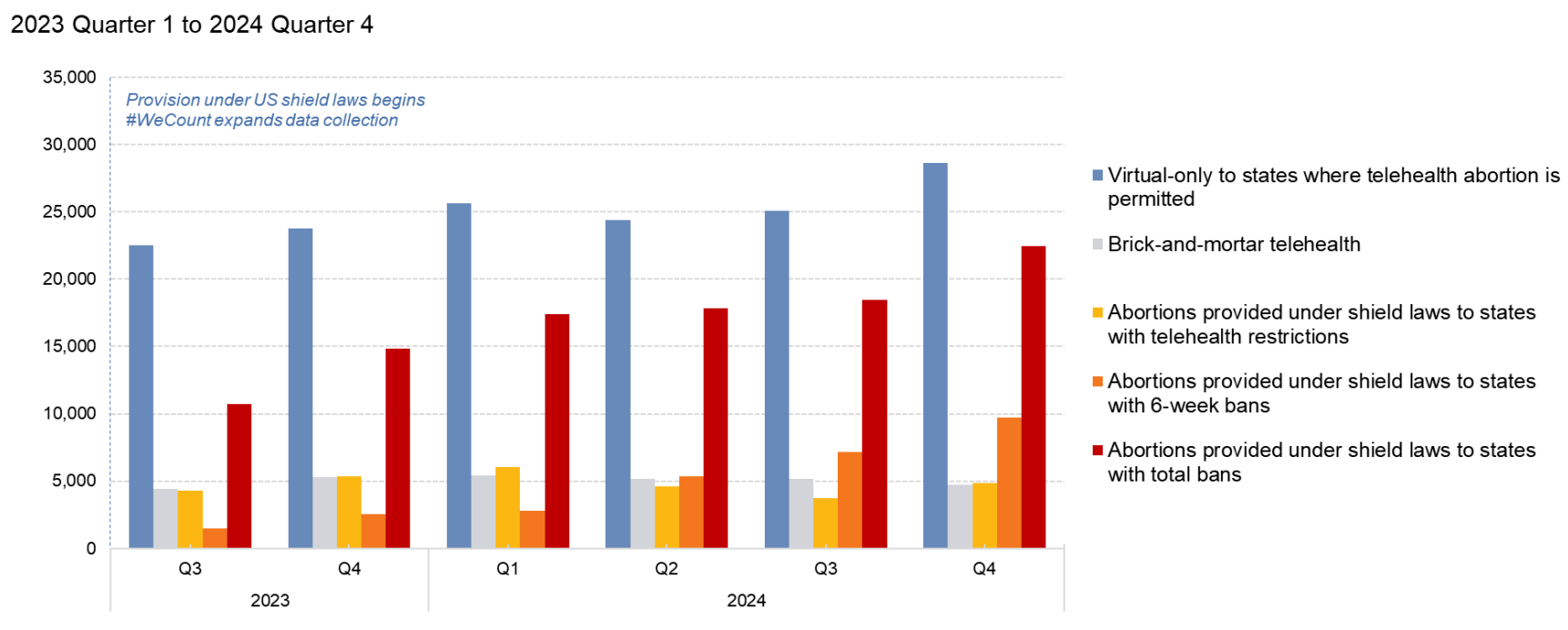
Virtual clinics (those that that are online only and have no brick-and mortar clinic) in states that permit abortion and telehealth abortion have provided an increasing number of abortions since 2022.

Abortions provided under shield laws have increased since this route to care became available



Providing abortions under shield laws involves mailing medication abortion pills to people in states with telehealth restrictions, 6-week bans, or total abortion bans. The number of abortions provided under shield laws has increased since providers began to offer abortion under shield laws in July 2023, with notable increases in provision to states with 6-week bans and total abortion bans. Some of the increase into states with 6-week bans is due to the states switching categories, when the states transitioned from having telehealth restrictions to having 6-week bans during this time period. By December 2024, abortions provided under shield laws totaled nearly 14,000 that month.

Legal climates appear to play an important role in telehealth use



Telehealth abortions provided by virtual clinics (those that that are online only and have no brick-and mortar clinic) to states that permit abortion and telehealth abortion have increased since 2023. Telehealth abortions provided by brick-and-mortar clinics have remained steady. Telehealth abortions provided into states with telehealth restrictions also remained relatively steady. Telehealth abortions provided into states with 6-week bans have increased; some of the increase into states with 6-week bans was due to the states switching from having telehealth restrictions to having 6-week bans during this time period. Telehealth abortions provided into states with total bans increased substantially by the end of 2024.

Half of abortions provided via telehealth in 2024 were facilitated by shield laws

2024 monthly average number of abortions		
	In-person	Telehealth
Abortion and telehealth permitted	60,780	10,360
Abortion permitted, telehealth restricted	8,610	1,610
6-week abortion ban, telehealth restricted	5,350	2,080
Abortion is totally banned	30	6,350

Disaggregating in-person and telehealth and summing up across states by legal climate in 2024, there were stark differences in mode of provision, with a larger proportion of abortions provided by telehealth with each restrictiveness category. In states where abortion and telehealth were permitted, on average, 15% of abortions were provided via telehealth each month. In states where abortion was permitted but telehealth was restricted, on average 16% of abortions were provided via telehealth each month. In states with 6-week bans, on average 28% of abortions were provided via telehealth each month. In states where abortion was totally banned, there was a monthly average of only 30 abortions provided in-person, under so-called exceptions, and over 99% of abortions were provided by telehealth. In 2024, the monthly average number of abortions provided under shield laws was about 10,000 per month. Abortions provided under shield laws accounted for 49% of all abortion provided via telehealth in 2024.

Background

#WeCount is a national effort that aims to report the monthly number of abortions in the US, by state and month starting in April 2022. #WeCount data include clinician-provided abortions, defined in this report as medication or procedural abortions completed by a licensed clinician within the US in a clinic, private medical office, hospital, or virtual-only clinic. This report does not reflect any self-managed abortions, defined as ending a pregnancy outside the formal healthcare system. These data reflect the status of abortion provision in the US and can be used by healthcare systems, public health practitioners, and policymakers so that their decisions can be informed by evidence.

Terminology

Delivery settings

- **Brick and mortar clinic:** A physical clinic where a patient can go to receive care
- **Virtual-only clinic:** An online-only provider

Delivery methods

- **Brick-and-mortar telehealth:** Telehealth abortions offered by a brick-and-mortar clinic
- **In-person care:** Abortions in which a clinician meets with the patient face-to-face; can be procedural or medication abortions
- **Self-managed abortion:** Abortion using medications, herbs, or something else, or obtaining pills from friends or online without clinician assistance
- **Telehealth abortion:** Medication abortion offered by a clinician through remote consultation with the patient, resulting in remote dispensing of medications by mail

Types of care

- **Medication abortion:** Abortion performed with medications, including mifepristone, misoprostol, and misoprostol alone
- **Procedural abortion:** Abortion performed with instrumentation, including uterine aspiration (manual or electric), dilation and curettage, dilation and evacuation, or dilation and extraction

Legal context

- **Shield laws:** Legal protections put in place by some states to reduce legal risk for clinicians who offer abortions to patients in states where abortion is prohibited or severely restricted

Methods

In early 2022, #WeCount developed a database of all clinics, private medical offices, hospitals, and virtual clinic providers in the US known to offer abortion care. We started with the Abortion Facility Database from Advancing New Standards in Reproductive

Health (ANSIRH) at University of California, San Francisco. Throughout the study period, we added new providers to our database as we became aware of them, using AbortionFinder.org and INeedanA.com to conduct regular searches in all 50 states and the District of Columbia. This report also includes abortions provided under shield laws by US-based licensed providers who are following their own state law. The Society provided compensation to participating facilities for each monthly submission.

The data in this report includes the monthly counts reported by providers for April 2022 through December 2024. In total, 83% of the abortions across the study period were based on data obtained from providers or health departments, while the remaining 17% of the data were imputed. The magnitude of imputation in each state is noted with symbols in the data tables. In 18 states, all known providers reported to #WeCount; we imputed any months not reported by these providers. For these imputations, we calculated the average percent change in abortion volume in the state and imputed values for providers with missing months. In the remaining 33 states and Washington, DC, some providers never reported to #WeCount; for these providers we imputed all months of data. To develop our imputations, we used information from news articles, contacts known to the non-reporting clinics, knowledge of the abortion volumes by state, or the median #WeCount number for the clinic or hospital type. To compute medians, we categorized reporters to #WeCount into five types of facilities and calculated the median for April and May 2022 for each category: 1) small abortion clinics, 2) large abortion clinics, 3) primary care clinics, 4) low volume hospitals, and 5) high volume hospitals. In ten states we also used publicly available state administrative data to supplement our estimates. We developed separate imputations for virtual clinics that did not submit data to us, using the median number of abortions that were provided by other virtual clinics in the state.

We reported the number of abortions by state and by restrictiveness level using three categories: states that banned abortion, states that restricted abortion to before detection of embryonic cardiac activity, also referred to as a “6-week bans” because detection of such activity usually occurs around that point, and states that permitted abortion. These categories were based on the abortion policy in each state on the 15th of each month as reported by the New York Times. For a legal analysis of restrictions that prevent explicitly ban telehealth or implicitly preclude telehealth abortion, we rely on the RHITES map. Monthly state totals were rounded to the nearest 10.

#WeCount was deemed exempt by Advarra IRB. All major decisions were guided by a Research Steering Committee listed below. This research was sponsored by the Society of Family Planning.

Limitations

Counts are an underrepresentation of all abortions in the US. #WeCount has a comprehensive count of abortions provided by licensed clinicians, with more than 83% of all abortions reported and about 17% imputed. Abortions provided by individual

hospitals and private practice clinicians may be underreported. These counts also do not include abortions that take place in the US outside of the formal health care system.

We do not have estimates of the proportion of people who did not take the medications sent to them. These data show telehealth abortions as the providers documented mailing them. Some people may not have taken the pills, and we do not have an estimate of that. Use of shield laws to provide abortion via telehealth into states with total or 6-week abortion bans or with telehealth abortion restrictions started in July 2023, and #WeCount began to count abortions provided under shield laws at that time. Because of this transition in abortion provision, #WeCount does not have a comparator for previous months.

#WeCount cannot estimate the unmet needs for abortion. Research has yet to accurately capture the underlying need for abortion. We don't have any counts of the number of people who needed an abortion and didn't get it.
#WeCount is designed to describe changes in abortion access and provision, rather than to explain why these changes are taking place.

Contributors

#WeCount is made possible by the many abortion providers who generously reported their data in support of this effort. This report was prepared by the #WeCount Co-Chairs and Society of Family Planning staff, with guidance from the Research Steering Committee, as well as many members of the Society of Family Planning community.

#WeCount Co-Chairs

- Alison Norris, MD, PhD; Ohio State University
- Ushma Upadhyay, PhD, MPH; University of California, San Francisco

#WeCount Research Steering Committee

- Abigail Aiken, MD, PhD, MPH; University of Texas at Austin
- Danielle Bessett, PhD, MA; University of Cincinnati
- Anitra Beasley, MD, MPH; Baylor College of Medicine
- Angel Foster, DPhil, MD, AM; University of Ottawa
- Jenny Higgins, PhD, MPH; University of Wisconsin
- Rachel Jones, PhD; Guttmacher Institute
- Isaac Maddow-Zimet, MS; Guttmacher Institute
- Caitlin Myers, PhD; Middlebury College
- Whitney Rice, DrPH, MPH; Emory University
- Hannah Simons, DrPH; Planned Parenthood Federation of America
- Mikaela Smith, PhD; Ohio State University
- Terri-Ann Thompson, PhD; Ibis Reproductive Health
- Kari White, PhD, MPH; Resound Research for Reproductive Health

#WeCount Society of Family Planning staff

- Jenny O’Donnell, ScD, MS; Vice President of Research and Evaluation
- Claire Yuan, MPP; #WeCount Data Manager

EXHIBIT 94

Society of Family Planning, *#WeCount Report April 2022 to March 2024* (August 7, 2024)

Data Table

State	Month	Total abortions	In-person	Total telehealth	Virtual-only	Brick-and-morta
_All US states	4/1/2022	83,930	80,790	3,140	3,140	0
_All US states	5/1/2022	83,320	79,380	3,940	3,940	0
_All US states	6/1/2022	86,150	81,450	4,700	4,700	0
_All US states	7/1/2022	79,610	74,480	5,130	5,130	0
_All US states	8/1/2022	79,750	74,510	5,240	5,240	0
_All US states	9/1/2022	74,710	69,700	5,010	5,010	0
_All US states	10/1/2022	75,250	70,110	5,140	5,140	0
_All US states	11/1/2022	72,600	67,020	5,580	5,580	0
_All US states	12/1/2022	80,630	74,310	6,320	6,320	0
_All US states	1/1/2023	86,810	79,890	6,920	6,920	0
_All US states	2/1/2023	80,970	75,220	5,750	5,750	0
_All US states	3/1/2023	93,810	87,250	6,560	6,560	0
_All US states	4/1/2023	84,730	78,090	6,640	6,640	0
_All US states	5/1/2023	88,240	81,310	6,930	6,930	0
_All US states	6/1/2023	88,110	81,560	6,550	6,550	0
_All US states	7/1/2023	88,430	73,910	14,520	13,250	1,270
_All US states	8/1/2023	92,500	77,930	14,570	13,080	1,490
_All US states	9/1/2023	85,700	71,430	14,270	12,630	1,640
_All US states	10/1/2023	88,570	71,930	16,640	14,910	1,730
_All US states	11/1/2023	86,570	69,200	17,370	15,570	1,800
_All US states	12/1/2023	91,590	73,850	17,740	16,000	1,740
_All US states	1/1/2024	102,040	81,480	20,560	18,670	1,890
_All US states	2/1/2024	94,720	77,010	17,710	15,880	1,830
_All US states	3/1/2024	99,950	80,920	19,030	17,330	1,700
_All US states	4/1/2024	98,280	79,290	18,990	17,390	1,600
_All US states	5/1/2024	98,410	78,830	19,580	17,700	1,880
_All US states	6/1/2024	91,120	72,310	18,810	17,100	1,710
_All US states	7/1/2024	96,740	75,490	21,250	19,410	1,840
_All US states	8/1/2024	94,020	74,560	19,460	17,700	1,760
_All US states	9/1/2024	85,420	66,530	18,890	17,330	1,560
_All US states	10/1/2024	93,360	72,410	20,950	19,220	1,730
_All US states	11/1/2024	92,060	68,520	23,540	22,030	1,510
_All US states	12/1/2024	95,710	69,890	25,820	24,340	1,480
_Permitted	4/1/2022	80,800	77,640	3,160	3,160	0
_Permitted	5/1/2022	80,360	76,420	3,940	3,940	0
_Permitted	6/1/2022	83,540	78,850	4,690	4,690	0
_Permitted	7/1/2022	78,520	73,380	5,140	5,140	0
_Permitted	8/1/2022	76,630	71,400	5,230	5,230	0
_Permitted	9/1/2022	71,740	66,740	5,000	5,000	0
_Permitted	10/1/2022	72,840	67,680	5,160	5,160	0
_Permitted	11/1/2022	69,890	64,330	5,560	5,560	0
_Permitted	12/1/2022	78,230	71,880	6,350	6,350	0
_Permitted	1/1/2023	84,160	77,240	6,920	6,920	0

_Permitted	2/1/2023	78,580	72,830	5,750	5,750	0
_Permitted	3/1/2023	90,760	84,230	6,530	6,530	0
_Permitted	4/1/2023	82,140	75,510	6,630	6,630	0
_Permitted	5/1/2023	85,780	78,860	6,920	6,920	0
_Permitted	6/1/2023	85,670	79,120	6,550	6,550	0
_Permitted	7/1/2023	81,890	71,230	10,660	9,370	1,290
_Permitted	8/1/2023	86,040	75,520	10,520	9,020	1,500
_Permitted	9/1/2023	79,080	68,990	10,090	8,440	1,650
_Permitted	10/1/2023	80,750	69,510	11,240	9,510	1,730
_Permitted	11/1/2023	78,290	66,690	11,600	9,780	1,820
_Permitted	12/1/2023	82,850	71,180	11,670	9,920	1,750
_Permitted	1/1/2024	92,430	78,760	13,670	11,770	1,900
_Permitted	2/1/2024	86,020	74,610	11,410	9,560	1,850
_Permitted	3/1/2024	90,160	78,080	12,080	10,370	1,710
_Permitted	4/1/2024	88,780	76,720	12,060	10,450	1,610
_Permitted	5/1/2024	82,730	71,270	11,460	9,560	1,900
_Permitted	6/1/2024	76,300	65,570	10,730	9,010	1,720
_Permitted	7/1/2024	80,880	68,710	12,170	10,340	1,830
_Permitted	8/1/2024	78,940	67,680	11,260	9,480	1,780
_Permitted	9/1/2024	70,890	60,250	10,640	9,070	1,570
_Permitted	10/1/2024	76,880	65,510	11,370	9,610	1,760
_Permitted	11/1/2024	75,130	62,020	13,110	11,590	1,520
_Permitted	12/1/2024	77,210	63,500	13,710	12,210	1,500
_Gestational lin	4/1/2022	3,190	3,190	0	0	0
_Gestational lin	5/1/2022	2,990	2,990	0	0	0
_Gestational lin	6/1/2022	2,600	2,600	0	0	0
Gestational lin	7/1/2022	990	990	0	0	0
_Gestational lin	8/1/2022	3,110	3,110	0	0	0
_Gestational lin	9/1/2022	2,260	2,260	0	0	0
_Gestational lin	10/1/2022	2,380	2,380	0	0	0
_Gestational lin	11/1/2022	2,690	2,690	0	0	0
_Gestational lin	12/1/2022	2,420	2,420	0	0	0
_Gestational lin	1/1/2023	2,640	2,640	0	0	0
_Gestational lin	2/1/2023	2,390	2,390	0	0	0
_Gestational lin	3/1/2023	2,980	2,980	0	0	0
_Gestational lin	4/1/2023	2,590	2,590	0	0	0
_Gestational lin	5/1/2023	2,440	2,440	0	0	0
_Gestational lin	6/1/2023	2,470	2,470	0	0	0
_Gestational lin	7/1/2023	3,080	2,590	490	490	0
_Gestational lin	8/1/2023	2,740	2,370	370	370	0
_Gestational lin	9/1/2023	3,020	2,410	610	610	0
_Gestational lin	10/1/2023	3,130	2,390	740	740	0
_Gestational lin	11/1/2023	3,310	2,420	890	890	0
_Gestational lin	12/1/2023	3,530	2,610	920	920	0

_Gestational lin	1/1/2024	3,640	2,670	970	970	0
_Gestational lin	2/1/2024	3,220	2,370	850	850	0
_Gestational lin	3/1/2024	3,810	2,820	990	990	0
_Gestational lin	4/1/2024	3,480	2,490	990	990	0
_Gestational lin	5/1/2024	9,770	7,520	2,250	2,250	0
_Gestational lin	6/1/2024	8,880	6,770	2,110	2,110	0
_Gestational lin	7/1/2024	9,230	6,790	2,440	2,440	0
_Gestational lin	8/1/2024	9,250	6,820	2,430	2,430	0
_Gestational lin	9/1/2024	8,480	6,210	2,270	2,270	0
_Gestational lin	10/1/2024	9,680	6,830	2,850	2,850	0
_Gestational lin	11/1/2024	9,760	6,530	3,230	3,230	0
_Gestational lin	12/1/2024	9,980	6,350	3,630	3,630	0
_Banned	4/1/2022	0	0	0	0	0
_Banned	5/1/2022	0	0	0	0	0
_Banned	6/1/2022	0	0	0	0	0
_Banned	7/1/2022	120	100	20	20	0
_Banned	8/1/2022	10	0	10	10	0
_Banned	9/1/2022	730	710	20	20	0
_Banned	10/1/2022	20	10	10	10	0
_Banned	11/1/2022	30	10	20	20	0
_Banned	12/1/2022	20	0	20	20	0
_Banned	1/1/2023	30	10	20	20	0
_Banned	2/1/2023	20	0	20	20	0
_Banned	3/1/2023	60	10	50	50	0
_Banned	4/1/2023	20	10	10	10	0
_Banned	5/1/2023	20	10	10	10	0
Banned	6/1/2023	10	0	10	10	0
_Banned	7/1/2023	3,440	20	3,420	3,420	0
_Banned	8/1/2023	3,720	40	3,680	3,680	0
_Banned	9/1/2023	3,650	40	3,610	3,610	0
_Banned	10/1/2023	4,690	10	4,680	4,680	0
_Banned	11/1/2023	4,980	50	4,930	4,930	0
_Banned	12/1/2023	5,220	20	5,200	5,200	0
_Banned	1/1/2024	5,990	30	5,960	5,960	0
_Banned	2/1/2024	5,480	20	5,460	5,460	0
_Banned	3/1/2024	6,000	30	5,970	5,970	0
_Banned	4/1/2024	6,040	40	6,000	6,000	0
_Banned	5/1/2024	5,920	20	5,900	5,900	0
_Banned	6/1/2024	5,970	10	5,960	5,960	0
_Banned	7/1/2024	6,650	20	6,630	6,630	0
_Banned	8/1/2024	5,850	20	5,830	5,830	0
_Banned	9/1/2024	6,050	40	6,010	6,010	0
_Banned	10/1/2024	6,810	30	6,780	6,780	0
_Banned	11/1/2024	7,190	10	7,180	7,180	0

_Banned	12/1/2024	8,550	30	8,520	8,520	0
_Abortions prov	4/1/2022	0		0	0	
_Abortions prov	5/1/2022	0		0	0	
_Abortions prov	6/1/2022	0		0	0	
_Abortions prov	7/1/2022	0		0	0	
_Abortions prov	8/1/2022	0		0	0	
_Abortions prov	9/1/2022	0		0	0	
_Abortions prov	10/1/2022	0		0	0	
_Abortions prov	11/1/2022	0		0	0	
_Abortions prov	12/1/2022	0		0	0	
_Abortions prov	1/1/2023	0		0	0	
_Abortions prov	2/1/2023	0		0	0	
_Abortions prov	3/1/2023	0		0	0	
_Abortions prov	4/1/2023	0		0	0	
_Abortions prov	5/1/2023	0		0	0	
_Abortions prov	6/1/2023	0		0	0	
_Abortions prov	7/1/2023	1,500		1,500	1,500	
_Abortions prov	8/1/2023	1,380		1,380	1,380	
_Abortions prov	9/1/2023	1,410		1,410	1,410	
_Abortions prov	10/1/2023	1,690		1,690	1,690	
_Abortions prov	11/1/2023	1,790		1,790	1,790	
_Abortions prov	12/1/2023	1,870		1,870	1,870	
_Abortions prov	1/1/2024	2,180		2,180	2,180	
_Abortions prov	2/1/2024	1,770		1,770	1,770	
_Abortions prov	3/1/2024	2,090		2,090	2,090	
_Abortions prov	4/1/2024	2,220		2,220	2,220	
_Abortions prov	5/1/2024	1,250		1,250	1,250	
_Abortions prov	6/1/2024	1,110		1,110	1,110	
_Abortions prov	7/1/2024	1,400		1,400	1,400	
_Abortions prov	8/1/2024	1,150		1,150	1,150	
_Abortions prov	9/1/2024	1,200		1,200	1,200	
_Abortions prov	10/1/2024	1,370		1,370	1,370	
_Abortions prov	11/1/2024	1,730		1,730	1,730	
_Abortions prov	12/1/2024	1,760		1,760	1,760	
_Abortions prov	4/1/2022	0		0	0	
_Abortions prov	5/1/2022	0		0	0	
_Abortions prov	6/1/2022	0		0	0	
_Abortions prov	7/1/2022	0		0	0	
_Abortions prov	8/1/2022	0		0	0	
_Abortions prov	9/1/2022	0		0	0	
_Abortions prov	10/1/2022	0		0	0	
_Abortions prov	11/1/2022	0		0	0	
_Abortions prov	12/1/2022	0		0	0	
_Abortions prov	1/1/2023	0		0	0	

_Abortions prov	2/1/2023	0	0	0
_Abortions prov	3/1/2023	0	0	0
_Abortions prov	4/1/2023	0	0	0
_Abortions prov	5/1/2023	0	0	0
_Abortions prov	6/1/2023	0	0	0
_Abortions prov	7/1/2023	490	490	490
_Abortions prov	8/1/2023	370	370	370
_Abortions prov	9/1/2023	610	610	610
_Abortions prov	10/1/2023	740	740	740
_Abortions prov	11/1/2023	890	890	890
_Abortions prov	12/1/2023	920	920	920
_Abortions prov	1/1/2024	970	970	970
_Abortions prov	2/1/2024	850	850	850
_Abortions prov	3/1/2024	990	990	990
_Abortions prov	4/1/2024	990	990	990
_Abortions prov	5/1/2024	2,250	2,250	2,250
_Abortions prov	6/1/2024	2,110	2,110	2,110
_Abortions prov	7/1/2024	2,440	2,440	2,440
_Abortions prov	8/1/2024	2,430	2,430	2,430
_Abortions prov	9/1/2024	2,270	2,270	2,270
_Abortions prov	10/1/2024	2,850	2,850	2,850
_Abortions prov	11/1/2024	3,230	3,230	3,230
_Abortions prov	12/1/2024	3,630	3,630	3,630
_Abortions prov	4/1/2022	0	0	0
_Abortions prov	5/1/2022	0	0	0
_Abortions prov	6/1/2022	0	0	0
_Abortions prov	7/1/2022	0	0	0
_Abortions prov	8/1/2022	0	0	0
_Abortions prov	9/1/2022	0	0	0
_Abortions prov	10/1/2022	0	0	0
_Abortions prov	11/1/2022	0	0	0
_Abortions prov	12/1/2022	0	0	0
_Abortions prov	1/1/2023	0	0	0
_Abortions prov	2/1/2023	0	0	0
_Abortions prov	3/1/2023	0	0	0
_Abortions prov	4/1/2023	0	0	0
_Abortions prov	5/1/2023	0	0	0
_Abortions prov	6/1/2023	0	0	0
_Abortions prov	7/1/2023	3,420	3,420	3,420
_Abortions prov	8/1/2023	3,680	3,680	3,680
_Abortions prov	9/1/2023	3,610	3,610	3,610
_Abortions prov	10/1/2023	4,680	4,680	4,680
_Abortions prov	11/1/2023	4,930	4,930	4,930
_Abortions prov	12/1/2023	5,200	5,200	5,200

_Abortions prov	1/1/2024	5,960		5,960	5,960	
_Abortions prov	2/1/2024	5,460		5,460	5,460	
_Abortions prov	3/1/2024	5,970		5,970	5,970	
_Abortions prov	4/1/2024	6,000		6,000	6,000	
_Abortions prov	5/1/2024	5,900		5,900	5,900	
_Abortions prov	6/1/2024	5,960		5,960	5,960	
_Abortions prov	7/1/2024	6,630		6,630	6,630	
_Abortions prov	8/1/2024	5,840		5,840	5,840	
_Abortions prov	9/1/2024	6,000		6,000	6,000	
_Abortions prov	10/1/2024	6,760		6,760	6,760	
_Abortions prov	11/1/2024	7,160		7,160	7,160	
_Abortions prov	12/1/2024	8,500		8,500	8,500	
Alabama	4/1/2022	650	650	0	0	0
Alabama	5/1/2022	620	620	0	0	0
Alabama	6/1/2022	520	520	0	0	0
Alabama	7/1/2022	0	0	0	0	0
Alabama	8/1/2022	0	0	0	0	0
Alabama	9/1/2022	0	0	0	0	0
Alabama	10/1/2022	0	0	0	0	0
Alabama	11/1/2022	0	0	0	0	0
Alabama	12/1/2022	0	0	0	0	0
Alabama	1/1/2023	0	0	0	0	0
Alabama	2/1/2023	0	0	0	0	0
Alabama	3/1/2023	0	0	0	0	0
Alabama	4/1/2023	0	0	0	0	0
Alabama	5/1/2023	0	0	0	0	0
Alabama	6/1/2023	0	0	0	0	0
Alabama	7/1/2023	220	0	220	220	0
Alabama	8/1/2023	250	0	250	250	0
Alabama	9/1/2023	250	0	250	250	0
Alabama	10/1/2023	300	0	300	300	0
Alabama	11/1/2023	340	0	340	340	0
Alabama	12/1/2023	360	0	360	360	0
Alabama	1/1/2024	390	0	390	390	0
Alabama	2/1/2024	410	0	410	410	0
Alabama	3/1/2024	420	0	420	420	0
Alabama	4/1/2024	420	0	420	420	0
Alabama	5/1/2024	440	0	440	440	0
Alabama	6/1/2024	440	0	440	440	0
Alabama	7/1/2024	530	0	530	530	0
Alabama	8/1/2024	450	0	450	450	0
Alabama	9/1/2024	450	0	450	450	0
Alabama	10/1/2024	470	0	470	470	0
Alabama	11/1/2024	530	0	530	530	0

Alabama	12/1/2024	660	0	660	660	0
Alaska	4/1/2022	120	110	10	10	0
Alaska	5/1/2022	130	120	10	10	0
Alaska	6/1/2022	140	120	20	20	0
Alaska	7/1/2022	110	90	20	20	0
Alaska	8/1/2022	140	110	30	30	0
Alaska	9/1/2022	150	120	30	30	0
Alaska	10/1/2022	130	110	20	20	0
Alaska	11/1/2022	130	110	20	20	0
Alaska	12/1/2022	150	120	30	30	0
Alaska	1/1/2023	130	100	30	30	0
Alaska	2/1/2023	140	120	20	20	0
Alaska	3/1/2023	140	120	20	20	0
Alaska	4/1/2023	110	90	20	20	0
Alaska	5/1/2023	160	130	30	30	0
Alaska	6/1/2023	140	120	20	20	0
Alaska	7/1/2023	170	140	30	30	0
Alaska	8/1/2023	170	140	30	30	0
Alaska	9/1/2023	150	110	40	40	0
Alaska	10/1/2023	180	140	40	40	0
Alaska	11/1/2023	150	120	30	30	0
Alaska	12/1/2023	140	100	40	40	0
Alaska	1/1/2024	130	110	20	20	0
Alaska	2/1/2024	140	120	20	20	0
Alaska	3/1/2024	140	110	30	30	0
Alaska	4/1/2024	160	130	30	30	0
Alaska	5/1/2024	160	130	30	30	0
Alaska	6/1/2024	170	130	40	40	0
Alaska	7/1/2024	150	120	30	30	0
Alaska	8/1/2024	140	110	30	30	0
Alaska	9/1/2024	130	100	30	30	0
Alaska	10/1/2024	130	100	30	30	0
Alaska	11/1/2024	160	120	40	40	0
Alaska	12/1/2024	150	100	50	50	0
Arizona	4/1/2022	1,320	1,320	0	0	0
Arizona	5/1/2022	1,470	1,470	0	0	0
Arizona	6/1/2022	1,170	1,170	0	0	0
Arizona	7/1/2022	210	210	0	0	0
Arizona	8/1/2022	720	720	0	0	0
Arizona	9/1/2022	610	610	0	0	0
Arizona	10/1/2022	420	420	0	0	0
Arizona	11/1/2022	790	790	0	0	0
Arizona	12/1/2022	820	820	0	0	0
Arizona	1/1/2023	1,120	1,120	0	0	0

Arizona	2/1/2023	990	990	0	0	0
Arizona	3/1/2023	1,250	1,250	0	0	0
Arizona	4/1/2023	1,000	1,000	0	0	0
Arizona	5/1/2023	1,150	1,150	0	0	0
Arizona	6/1/2023	1,090	1,090	0	0	0
Arizona	7/1/2023	1,280	1,030	250	250	0
Arizona	8/1/2023	1,350	1,120	230	230	0
Arizona	9/1/2023	1,410	1,120	290	290	0
Arizona	10/1/2023	1,310	1,020	290	290	0
Arizona	11/1/2023	1,230	950	280	280	0
Arizona	12/1/2023	1,260	1,010	250	250	0
Arizona	1/1/2024	1,570	1,250	320	320	0
Arizona	2/1/2024	1,480	1,190	290	290	0
Arizona	3/1/2024	1,580	1,230	350	350	0
Arizona	4/1/2024	1,470	1,110	360	360	0
Arizona	5/1/2024	1,430	1,120	310	310	0
Arizona	6/1/2024	1,310	1,050	260	260	0
Arizona	7/1/2024	1,420	1,080	340	340	0
Arizona	8/1/2024	1,350	1,050	300	300	0
Arizona	9/1/2024	1,280	950	330	330	0
Arizona	10/1/2024	1,290	960	330	330	0
Arizona	11/1/2024	1,350	960	390	390	0
Arizona	12/1/2024	1,480	1,010	470	470	0
Arkansas	4/1/2022	290	290	0	0	0
Arkansas	5/1/2022	340	340	0	0	0
Arkansas	6/1/2022	260	260	0	0	0
Arkansas	7/1/2022	0	0	0	0	0
Arkansas	8/1/2022	0	0	0	0	0
Arkansas	9/1/2022	0	0	0	0	0
Arkansas	10/1/2022	0	0	0	0	0
Arkansas	11/1/2022	0	0	0	0	0
Arkansas	12/1/2022	0	0	0	0	0
Arkansas	1/1/2023	0	0	0	0	0
Arkansas	2/1/2023	0	0	0	0	0
Arkansas	3/1/2023	0	0	0	0	0
Arkansas	4/1/2023	0	0	0	0	0
Arkansas	5/1/2023	0	0	0	0	0
Arkansas	6/1/2023	0	0	0	0	0
Arkansas	7/1/2023	130	0	130	130	0
Arkansas	8/1/2023	140	0	140	140	0
Arkansas	9/1/2023	140	0	140	140	0
Arkansas	10/1/2023	180	0	180	180	0
Arkansas	11/1/2023	200	0	200	200	0
Arkansas	12/1/2023	180	0	180	180	0

Arkansas	1/1/2024	230	0	230	230	0
Arkansas	2/1/2024	230	0	230	230	0
Arkansas	3/1/2024	260	0	260	260	0
Arkansas	4/1/2024	220	0	220	220	0
Arkansas	5/1/2024	240	0	240	240	0
Arkansas	6/1/2024	260	0	260	260	0
Arkansas	7/1/2024	280	0	280	280	0
Arkansas	8/1/2024	220	0	220	220	0
Arkansas	9/1/2024	240	0	240	240	0
Arkansas	10/1/2024	260	0	260	260	0
Arkansas	11/1/2024	300	0	300	300	0
Arkansas	12/1/2024	330	0	330	330	0
California	4/1/2022	13,920	13,210	710	710	0
California	5/1/2022	13,910	13,040	870	870	0
California	6/1/2022	14,530	13,500	1,030	1,030	0
California	7/1/2022	14,180	13,050	1,130	1,130	0
California	8/1/2022	14,370	13,210	1,160	1,160	0
California	9/1/2022	12,640	11,620	1,020	1,020	0
California	10/1/2022	12,690	11,640	1,050	1,050	0
California	11/1/2022	12,830	11,750	1,080	1,080	0
California	12/1/2022	14,900	13,680	1,220	1,220	0
California	1/1/2023	15,900	14,470	1,430	1,430	0
California	2/1/2023	14,210	13,010	1,200	1,200	0
California	3/1/2023	16,300	15,000	1,300	1,300	0
California	4/1/2023	15,040	13,760	1,280	1,280	0
California	5/1/2023	15,750	14,360	1,390	1,390	0
California	6/1/2023	15,400	14,170	1,230	1,230	0
California	7/1/2023	14,290	12,790	1,500	1,310	190
California	8/1/2023	15,560	14,040	1,520	1,260	260
California	9/1/2023	14,130	12,810	1,320	1,110	210
California	10/1/2023	14,380	12,780	1,600	1,270	330
California	11/1/2023	13,720	12,160	1,560	1,200	360
California	12/1/2023	14,960	13,380	1,580	1,260	320
California	1/1/2024	17,260	15,420	1,840	1,500	340
California	2/1/2024	15,350	13,840	1,510	1,120	390
California	3/1/2024	15,990	14,460	1,530	1,190	340
California	4/1/2024	15,450	13,930	1,520	1,260	260
California	5/1/2024	15,840	14,330	1,510	1,240	270
California	6/1/2024	14,590	13,190	1,400	1,170	230
California	7/1/2024	15,830	14,350	1,480	1,230	250
California	8/1/2024	14,990	13,560	1,430	1,140	290
California	9/1/2024	13,820	12,410	1,410	1,130	280
California	10/1/2024	14,940	13,400	1,540	1,190	350
California	11/1/2024	13,930	12,310	1,620	1,370	250

California	12/1/2024	15,550	13,830	1,720	1,460	260
Colorado	4/1/2022	1,620	1,380	240	240	0
Colorado	5/1/2022	1,700	1,380	320	320	0
Colorado	6/1/2022	1,810	1,440	370	370	0
Colorado	7/1/2022	1,980	1,470	510	510	0
Colorado	8/1/2022	2,160	1,610	550	550	0
Colorado	9/1/2022	1,940	1,440	500	500	0
Colorado	10/1/2022	1,900	1,370	530	530	0
Colorado	11/1/2022	1,910	1,400	510	510	0
Colorado	12/1/2022	2,060	1,530	530	530	0
Colorado	1/1/2023	2,340	1,830	510	510	0
Colorado	2/1/2023	2,090	1,620	470	470	0
Colorado	3/1/2023	2,410	1,930	480	480	0
Colorado	4/1/2023	2,200	1,700	500	500	0
Colorado	5/1/2023	2,400	1,920	480	480	0
Colorado	6/1/2023	2,280	1,770	510	510	0
Colorado	7/1/2023	2,230	1,680	550	540	10
Colorado	8/1/2023	2,300	1,740	560	520	40
Colorado	9/1/2023	1,990	1,430	560	530	30
Colorado	10/1/2023	2,140	1,610	530	490	40
Colorado	11/1/2023	2,140	1,580	560	510	50
Colorado	12/1/2023	2,060	1,510	550	510	40
Colorado	1/1/2024	2,320	1,750	570	530	40
Colorado	2/1/2024	2,080	1,570	510	490	20
Colorado	3/1/2024	2,150	1,610	540	510	30
Colorado	4/1/2024	2,110	1,540	570	540	30
Colorado	5/1/2024	2,110	1,550	560	530	30
Colorado	6/1/2024	2,000	1,470	530	510	20
Colorado	7/1/2024	2,080	1,470	610	600	10
Colorado	8/1/2024	2,070	1,480	590	570	20
Colorado	9/1/2024	1,800	1,240	560	530	30
Colorado	10/1/2024	1,990	1,440	550	520	30
Colorado	11/1/2024	1,920	1,290	630	600	30
Colorado	12/1/2024	1,920	1,250	670	650	20
Connecticut	4/1/2022	920	860	60	60	0
Connecticut	5/1/2022	950	890	60	60	0
Connecticut	6/1/2022	970	910	60	60	0
Connecticut	7/1/2022	1,000	940	60	60	0
Connecticut	8/1/2022	930	850	80	80	0
Connecticut	9/1/2022	850	760	90	90	0
Connecticut	10/1/2022	860	780	80	80	0
Connecticut	11/1/2022	880	770	110	110	0
Connecticut	12/1/2022	960	830	130	130	0
Connecticut	1/1/2023	1,120	970	150	150	0

Connecticut	2/1/2023	1,000	890	110	110	0
Connecticut	3/1/2023	1,230	1,100	130	130	0
Connecticut	4/1/2023	1,250	1,100	150	150	0
Connecticut	5/1/2023	1,320	1,180	140	140	0
Connecticut	6/1/2023	1,290	1,140	150	150	0
Connecticut	7/1/2023	1,400	1,250	150	150	0
Connecticut	8/1/2023	1,240	1,100	140	140	0
Connecticut	9/1/2023	1,130	1,000	130	130	0
Connecticut	10/1/2023	1,260	1,110	150	150	0
Connecticut	11/1/2023	1,140	970	170	170	0
Connecticut	12/1/2023	1,260	1,090	170	170	0
Connecticut	1/1/2024	1,310	1,150	160	160	0
Connecticut	2/1/2024	1,110	990	120	120	0
Connecticut	3/1/2024	1,280	1,120	160	150	10
Connecticut	4/1/2024	1,160	1,010	150	140	10
Connecticut	5/1/2024	1,220	1,060	160	150	10
Connecticut	6/1/2024	1,110	990	120	110	10
Connecticut	7/1/2024	1,280	1,120	160	150	10
Connecticut	8/1/2024	1,190	1,030	160	140	20
Connecticut	9/1/2024	1,110	990	120	110	10
Connecticut	10/1/2024	1,180	1,040	140	120	20
Connecticut	11/1/2024	1,160	1,020	140	130	10
Connecticut	12/1/2024	1,160	980	180	170	10
Delaware	4/1/2022	220	190	30	30	0
Delaware	5/1/2022	230	190	40	40	0
Delaware	6/1/2022	270	230	40	40	0
Delaware	7/1/2022	250	210	40	40	0
Delaware	8/1/2022	270	200	70	70	0
Delaware	9/1/2022	300	240	60	60	0
Delaware	10/1/2022	300	240	60	60	0
Delaware	11/1/2022	310	250	60	60	0
Delaware	12/1/2022	350	290	60	60	0
Delaware	1/1/2023	270	200	70	70	0
Delaware	2/1/2023	240	180	60	60	0
Delaware	3/1/2023	300	240	60	60	0
Delaware	4/1/2023	260	180	80	80	0
Delaware	5/1/2023	270	210	60	60	0
Delaware	6/1/2023	310	230	80	80	0
Delaware	7/1/2023	310	220	90	90	0
Delaware	8/1/2023	280	190	90	80	10
Delaware	9/1/2023	270	190	80	70	10
Delaware	10/1/2023	300	200	100	90	10
Delaware	11/1/2023	320	220	100	90	10
Delaware	12/1/2023	300	190	110	100	10

Delaware	1/1/2024	360	230	130	110	20
Delaware	2/1/2024	320	210	110	100	10
Delaware	3/1/2024	310	190	120	110	10
Delaware	4/1/2024	340	240	100	90	10
Delaware	5/1/2024	350	240	110	100	10
Delaware	6/1/2024	290	200	90	80	10
Delaware	7/1/2024	330	180	150	140	10
Delaware	8/1/2024	310	180	130	120	10
Delaware	9/1/2024	310	190	120	110	10
Delaware	10/1/2024	310	210	100	90	10
Delaware	11/1/2024	330	200	130	120	10
Delaware	12/1/2024	340	200	140	130	10
District of Colur	4/1/2022	920	890	30	30	0
District of Colur	5/1/2022	880	850	30	30	0
District of Colur	6/1/2022	870	830	40	40	0
District of Colur	7/1/2022	870	810	60	60	0
District of Colur	8/1/2022	930	870	60	60	0
District of Colur	9/1/2022	820	780	40	40	0
District of Colur	10/1/2022	890	860	30	30	0
District of Colur	11/1/2022	810	780	30	30	0
District of Colur	12/1/2022	830	790	40	40	0
District of Colur	1/1/2023	900	860	40	40	0
District of Colur	2/1/2023	870	840	30	30	0
District of Colur	3/1/2023	1,080	1,030	50	50	0
District of Colur	4/1/2023	920	870	50	50	0
District of Colur	5/1/2023	1,000	940	60	60	0
District of Colur	6/1/2023	730	680	50	50	0
District of Colur	7/1/2023	770	720	50	50	0
District of Colur	8/1/2023	760	690	70	70	0
District of Colur	9/1/2023	610	570	40	40	0
District of Colur	10/1/2023	630	560	70	70	0
District of Colur	11/1/2023	610	530	80	80	0
District of Colur	12/1/2023	590	520	70	70	0
District of Colur	1/1/2024	710	610	100	100	0
District of Colur	2/1/2024	740	670	70	70	0
District of Colur	3/1/2024	800	710	90	90	0
District of Colur	4/1/2024	750	670	80	80	0
District of Colur	5/1/2024	830	750	80	80	0
District of Colur	6/1/2024	770	700	70	70	0
District of Colur	7/1/2024	910	830	80	80	0
District of Colur	8/1/2024	1,000	930	70	70	0
District of Colur	9/1/2024	890	830	60	60	0
District of Colur	10/1/2024	980	920	60	60	0
District of Colur	11/1/2024	870	810	60	60	0

District of Colur	12/1/2024	880	800	80	80	0
Florida	4/1/2022	5,400	5,400	0	0	0
Florida	5/1/2022	5,430	5,430	0	0	0
Florida	6/1/2022	5,980	5,980	0	0	0
Florida	7/1/2022	5,950	5,950	0	0	0
Florida	8/1/2022	6,410	6,410	0	0	0
Florida	9/1/2022	6,050	6,050	0	0	0
Florida	10/1/2022	6,530	6,530	0	0	0
Florida	11/1/2022	5,990	5,990	0	0	0
Florida	12/1/2022	7,000	7,000	0	0	0
Florida	1/1/2023	6,940	6,940	0	0	0
Florida	2/1/2023	6,760	6,760	0	0	0
Florida	3/1/2023	7,790	7,790	0	0	0
Florida	4/1/2023	6,930	6,930	0	0	0
Florida	5/1/2023	6,900	6,900	0	0	0
Florida	6/1/2023	6,850	6,850	0	0	0
Florida	7/1/2023	7,320	6,830	490	490	0
Florida	8/1/2023	7,170	6,720	450	450	0
Florida	9/1/2023	7,190	6,670	520	520	0
Florida	10/1/2023	7,130	6,510	620	620	0
Florida	11/1/2023	6,680	6,030	650	650	0
Florida	12/1/2023	7,040	6,330	710	710	0
Florida	1/1/2024	8,030	7,260	770	770	0
Florida	2/1/2024	7,550	6,900	650	650	0
Florida	3/1/2024	7,920	7,140	780	780	0
Florida	4/1/2024	9,680	8,790	890	890	0
Florida	5/1/2024	5,890	4,700	1,190	1,190	0
Florida	6/1/2024	5,320	4,230	1,090	1,090	0
Florida	7/1/2024	5,830	4,570	1,260	1,260	0
Florida	8/1/2024	5,630	4,530	1,100	1,100	0
Florida	9/1/2024	5,320	4,230	1,090	1,090	0
Florida	10/1/2024	5,550	4,190	1,360	1,360	0
Florida	11/1/2024	5,850	4,300	1,550	1,550	0
Florida	12/1/2024	5,840	4,190	1,650	1,650	0
Georgia	4/1/2022	4,540	4,390	150	150	0
Georgia	5/1/2022	4,230	4,080	150	150	0
Georgia	6/1/2022	4,450	4,290	160	160	0
Georgia	7/1/2022	4,430	4,370	60	60	0
Georgia	8/1/2022	1,970	1,970	0	0	0
Georgia	9/1/2022	2,260	2,260	0	0	0
Georgia	10/1/2022	2,380	2,380	0	0	0
Georgia	11/1/2022	2,690	2,690	0	0	0
Georgia	12/1/2022	2,420	2,420	0	0	0
Georgia	1/1/2023	2,640	2,640	0	0	0

Georgia	2/1/2023	2,390	2,390	0	0	0
Georgia	3/1/2023	2,980	2,980	0	0	0
Georgia	4/1/2023	2,590	2,590	0	0	0
Georgia	5/1/2023	2,440	2,440	0	0	0
Georgia	6/1/2023	2,470	2,470	0	0	0
Georgia	7/1/2023	2,770	2,400	370	370	0
Georgia	8/1/2023	2,740	2,370	370	370	0
Georgia	9/1/2023	2,670	2,250	420	420	0
Georgia	10/1/2023	2,690	2,190	500	500	0
Georgia	11/1/2023	2,870	2,250	620	620	0
Georgia	12/1/2023	3,050	2,410	640	640	0
Georgia	1/1/2024	3,060	2,370	690	690	0
Georgia	2/1/2024	2,700	2,090	610	610	0
Georgia	3/1/2024	3,220	2,510	710	710	0
Georgia	4/1/2024	2,970	2,240	730	730	0
Georgia	5/1/2024	3,310	2,520	790	790	0
Georgia	6/1/2024	3,050	2,310	740	740	0
Georgia	7/1/2024	2,840	1,980	860	860	0
Georgia	8/1/2024	2,870	1,980	890	890	0
Georgia	9/1/2024	2,440	1,690	750	750	0
Georgia	10/1/2024	3,280	2,290	990	990	0
Georgia	11/1/2024	3,000	1,890	1,110	1,110	0
Georgia	12/1/2024	3,210	1,910	1,300	1,300	0
Hawaii	4/1/2022	260	250	10	10	0
Hawaii	5/1/2022	220	210	10	10	0
Hawaii	6/1/2022	280	260	20	20	0
Hawaii	7/1/2022	230	210	20	20	0
Hawaii	8/1/2022	300	260	40	40	0
Hawaii	9/1/2022	280	260	20	20	0
Hawaii	10/1/2022	260	240	20	20	0
Hawaii	11/1/2022	280	270	10	10	0
Hawaii	12/1/2022	270	240	30	30	0
Hawaii	1/1/2023	320	280	40	40	0
Hawaii	2/1/2023	280	250	30	30	0
Hawaii	3/1/2023	300	260	40	40	0
Hawaii	4/1/2023	330	290	40	40	0
Hawaii	5/1/2023	330	280	50	50	0
Hawaii	6/1/2023	280	250	30	30	0
Hawaii	7/1/2023	300	230	70	40	30
Hawaii	8/1/2023	340	270	70	50	20
Hawaii	9/1/2023	290	220	70	50	20
Hawaii	10/1/2023	300	230	70	50	20
Hawaii	11/1/2023	300	210	90	70	20
Hawaii	12/1/2023	280	200	80	60	20

Hawaii	1/1/2024	340	250	90	70	20
Hawaii	2/1/2024	290	200	90	60	30
Hawaii	3/1/2024	330	240	90	60	30
Hawaii	4/1/2024	330	230	100	70	30
Hawaii	5/1/2024	280	200	80	60	20
Hawaii	6/1/2024	280	200	80	60	20
Hawaii	7/1/2024	320	240	80	70	10
Hawaii	8/1/2024	290	210	80	50	30
Hawaii	9/1/2024	280	200	80	50	30
Hawaii	10/1/2024	310	220	90	50	40
Hawaii	11/1/2024	270	190	80	60	20
Hawaii	12/1/2024	310	190	120	90	30
Idaho	4/1/2022	220	200	20	20	0
Idaho	5/1/2022	220	190	30	30	0
Idaho	6/1/2022	230	190	40	40	0
Idaho	7/1/2022	190	140	50	50	0
Idaho	8/1/2022	130	100	30	30	0
Idaho	9/1/2022	0	0	0	0	0
Idaho	10/1/2022	10	10	0	0	0
Idaho	11/1/2022	0	0	0	0	0
Idaho	12/1/2022	0	0	0	0	0
Idaho	1/1/2023	0	0	0	0	0
Idaho	2/1/2023	0	0	0	0	0
Idaho	3/1/2023	0	0	0	0	0
Idaho	4/1/2023	0	0	0	0	0
Idaho	5/1/2023	0	0	0	0	0
Idaho	6/1/2023	0	0	0	0	0
Idaho	7/1/2023	30	0	30	30	0
Idaho	8/1/2023	30	0	30	30	0
Idaho	9/1/2023	40	0	40	40	0
Idaho	10/1/2023	60	0	60	60	0
Idaho	11/1/2023	50	0	50	50	0
Idaho	12/1/2023	50	0	50	50	0
Idaho	1/1/2024	70	0	70	70	0
Idaho	2/1/2024	50	0	50	50	0
Idaho	3/1/2024	40	0	40	40	0
Idaho	4/1/2024	60	0	60	60	0
Idaho	5/1/2024	60	0	60	60	0
Idaho	6/1/2024	50	0	50	50	0
Idaho	7/1/2024	80	0	80	80	0
Idaho	8/1/2024	60	0	60	60	0
Idaho	9/1/2024	70	0	70	70	0
Idaho	10/1/2024	60	0	60	60	0
Idaho	11/1/2024	70	0	70	70	0

Idaho	12/1/2024	80	0	80	80	0
Illinois	4/1/2022	5,590	5,270	320	320	0
Illinois	5/1/2022	5,550	5,140	410	410	0
Illinois	6/1/2022	6,170	5,660	510	510	0
Illinois	7/1/2022	6,780	6,290	490	490	0
Illinois	8/1/2022	7,090	6,650	440	440	0
Illinois	9/1/2022	6,530	6,090	440	440	0
Illinois	10/1/2022	6,510	6,080	430	430	0
Illinois	11/1/2022	6,200	5,720	480	480	0
Illinois	12/1/2022	7,040	6,490	550	550	0
Illinois	1/1/2023	7,840	7,210	630	630	0
Illinois	2/1/2023	7,310	6,880	430	430	0
Illinois	3/1/2023	8,470	7,970	500	500	0
Illinois	4/1/2023	7,650	7,190	460	460	0
Illinois	5/1/2023	7,850	7,350	500	500	0
Illinois	6/1/2023	7,930	7,470	460	460	0
Illinois	7/1/2023	7,650	6,680	970	540	430
Illinois	8/1/2023	8,320	7,320	1,000	530	470
Illinois	9/1/2023	7,520	6,630	890	470	420
Illinois	10/1/2023	7,520	6,590	930	560	370
Illinois	11/1/2023	7,650	6,690	960	520	440
Illinois	12/1/2023	7,810	6,840	970	490	480
Illinois	1/1/2024	8,120	7,150	970	490	480
Illinois	2/1/2024	8,100	7,210	890	430	460
Illinois	3/1/2024	8,350	7,410	940	470	470
Illinois	4/1/2024	8,090	7,200	890	460	430
Illinois	5/1/2024	8,530	7,570	960	480	480
Illinois	6/1/2024	8,110	7,220	890	420	470
Illinois	7/1/2024	8,330	7,310	1,020	480	540
Illinois	8/1/2024	8,480	7,450	1,030	450	580
Illinois	9/1/2024	7,020	6,140	880	390	490
Illinois	10/1/2024	7,660	6,770	890	460	430
Illinois	11/1/2024	7,590	6,670	920	520	400
Illinois	12/1/2024	7,560	6,640	920	550	370
Indiana	4/1/2022	920	920	0	0	0
Indiana	5/1/2022	850	850	0	0	0
Indiana	6/1/2022	860	860	0	0	0
Indiana	7/1/2022	1,100	1,100	0	0	0
Indiana	8/1/2022	1,060	1,060	0	0	0
Indiana	9/1/2022	710	710	0	0	0
Indiana	10/1/2022	480	480	0	0	0
Indiana	11/1/2022	670	670	0	0	0
Indiana	12/1/2022	550	550	0	0	0
Indiana	1/1/2023	510	510	0	0	0

Indiana	2/1/2023	690	690	0	0	0
Indiana	3/1/2023	730	730	0	0	0
Indiana	4/1/2023	610	610	0	0	0
Indiana	5/1/2023	640	640	0	0	0
Indiana	6/1/2023	700	700	0	0	0
Indiana	7/1/2023	880	720	160	160	0
Indiana	8/1/2023	180	20	160	160	0
Indiana	9/1/2023	170	20	150	150	0
Indiana	10/1/2023	220	10	210	210	0
Indiana	11/1/2023	220	20	200	200	0
Indiana	12/1/2023	240	20	220	220	0
Indiana	1/1/2024	290	20	270	270	0
Indiana	2/1/2024	240	20	220	220	0
Indiana	3/1/2024	290	20	270	270	0
Indiana	4/1/2024	240	10	230	230	0
Indiana	5/1/2024	250	10	240	240	0
Indiana	6/1/2024	230	10	220	220	0
Indiana	7/1/2024	290	10	280	280	0
Indiana	8/1/2024	280	10	270	270	0
Indiana	9/1/2024	270	20	250	250	0
Indiana	10/1/2024	340	20	320	320	0
Indiana	11/1/2024	360	10	350	350	0
Indiana	12/1/2024	380	10	370	370	0
Iowa	4/1/2022	380	360	20	20	0
Iowa	5/1/2022	370	360	10	10	0
Iowa	6/1/2022	390	380	10	10	0
Iowa	7/1/2022	360	340	20	20	0
Iowa	8/1/2022	280	260	20	20	0
Iowa	9/1/2022	320	300	20	20	0
Iowa	10/1/2022	310	280	30	30	0
Iowa	11/1/2022	350	310	40	40	0
Iowa	12/1/2022	370	330	40	40	0
Iowa	1/1/2023	370	340	30	30	0
Iowa	2/1/2023	300	270	30	30	0
Iowa	3/1/2023	390	330	60	60	0
Iowa	4/1/2023	250	160	90	90	0
Iowa	5/1/2023	270	170	100	100	0
Iowa	6/1/2023	290	230	60	60	0
Iowa	7/1/2023	310	190	120	120	0
Iowa	8/1/2023	370	260	110	110	0
Iowa	9/1/2023	330	240	90	90	0
Iowa	10/1/2023	390	270	120	120	0
Iowa	11/1/2023	350	190	160	160	0
Iowa	12/1/2023	360	190	170	170	0

Iowa	1/1/2024	360	160	200	200	0
Iowa	2/1/2024	350	210	140	140	0
Iowa	3/1/2024	410	230	180	180	0
Iowa	4/1/2024	380	240	140	140	0
Iowa	5/1/2024	420	280	140	140	0
Iowa	6/1/2024	370	250	120	120	0
Iowa	7/1/2024	320	180	140	140	0
Iowa	8/1/2024	200	100	100	100	0
Iowa	9/1/2024	190	80	110	110	0
Iowa	10/1/2024	240	110	130	130	0
Iowa	11/1/2024	250	100	150	150	0
Iowa	12/1/2024	220	50	170	170	0
Kansas	4/1/2022	970	970	0	0	0
Kansas	5/1/2022	950	950	0	0	0
Kansas	6/1/2022	930	930	0	0	0
Kansas	7/1/2022	930	930	0	0	0
Kansas	8/1/2022	1,280	1,280	0	0	0
Kansas	9/1/2022	1,150	1,150	0	0	0
Kansas	10/1/2022	1,260	1,260	0	0	0
Kansas	11/1/2022	1,130	1,130	0	0	0
Kansas	12/1/2022	1,310	1,300	10	10	0
Kansas	1/1/2023	1,660	1,580	80	80	0
Kansas	2/1/2023	1,560	1,450	110	110	0
Kansas	3/1/2023	1,700	1,550	150	150	0
Kansas	4/1/2023	1,740	1,600	140	140	0
Kansas	5/1/2023	1,820	1,690	130	130	0
Kansas	6/1/2023	2,020	1,890	130	130	0
Kansas	7/1/2023	1,710	1,530	180	180	0
Kansas	8/1/2023	1,810	1,680	130	130	0
Kansas	9/1/2023	1,620	1,510	110	110	0
Kansas	10/1/2023	1,720	1,570	150	150	0
Kansas	11/1/2023	1,820	1,660	160	160	0
Kansas	12/1/2023	1,830	1,670	160	160	0
Kansas	1/1/2024	2,060	1,860	200	200	0
Kansas	2/1/2024	2,020	1,870	150	150	0
Kansas	3/1/2024	2,220	2,060	160	160	0
Kansas	4/1/2024	1,960	1,790	170	170	0
Kansas	5/1/2024	2,010	1,850	160	160	0
Kansas	6/1/2024	1,710	1,540	170	170	0
Kansas	7/1/2024	1,650	1,440	210	210	0
Kansas	8/1/2024	2,110	1,950	160	160	0
Kansas	9/1/2024	1,660	1,510	150	150	0
Kansas	10/1/2024	1,900	1,710	190	190	0
Kansas	11/1/2024	1,820	1,640	180	180	0

Kansas	12/1/2024	1,660	1,430	230	230	0
Kentucky	4/1/2022	310	310	0	0	0
Kentucky	5/1/2022	380	380	0	0	0
Kentucky	6/1/2022	300	300	0	0	0
Kentucky	7/1/2022	280	280	0	0	0
Kentucky	8/1/2022	0	0	0	0	0
Kentucky	9/1/2022	0	0	0	0	0
Kentucky	10/1/2022	0	0	0	0	0
Kentucky	11/1/2022	0	0	0	0	0
Kentucky	12/1/2022	0	0	0	0	0
Kentucky	1/1/2023	0	0	0	0	0
Kentucky	2/1/2023	0	0	0	0	0
Kentucky	3/1/2023	0	0	0	0	0
Kentucky	4/1/2023	0	0	0	0	0
Kentucky	5/1/2023	0	0	0	0	0
Kentucky	6/1/2023	0	0	0	0	0
Kentucky	7/1/2023	140	0	140	140	0
Kentucky	8/1/2023	130	10	120	120	0
Kentucky	9/1/2023	150	0	150	150	0
Kentucky	10/1/2023	180	0	180	180	0
Kentucky	11/1/2023	190	10	180	180	0
Kentucky	12/1/2023	180	0	180	180	0
Kentucky	1/1/2024	230	0	230	230	0
Kentucky	2/1/2024	180	0	180	180	0
Kentucky	3/1/2024	220	0	220	220	0
Kentucky	4/1/2024	220	10	210	210	0
Kentucky	5/1/2024	220	10	210	210	0
Kentucky	6/1/2024	210	0	210	210	0
Kentucky	7/1/2024	240	0	240	240	0
Kentucky	8/1/2024	210	0	210	210	0
Kentucky	9/1/2024	230	10	220	220	0
Kentucky	10/1/2024	260	0	260	260	0
Kentucky	11/1/2024	290	0	290	290	0
Kentucky	12/1/2024	300	0	300	300	0
Louisiana	4/1/2022	760	760	0	0	0
Louisiana	5/1/2022	810	810	0	0	0
Louisiana	6/1/2022	540	540	0	0	0
Louisiana	7/1/2022	310	310	0	0	0
Louisiana	8/1/2022	0	0	0	0	0
Louisiana	9/1/2022	0	0	0	0	0
Louisiana	10/1/2022	0	0	0	0	0
Louisiana	11/1/2022	0	0	0	0	0
Louisiana	12/1/2022	0	0	0	0	0
Louisiana	1/1/2023	0	0	0	0	0

Louisiana	2/1/2023	0	0	0	0	0
Louisiana	3/1/2023	0	0	0	0	0
Louisiana	4/1/2023	0	0	0	0	0
Louisiana	5/1/2023	0	0	0	0	0
Louisiana	6/1/2023	0	0	0	0	0
Louisiana	7/1/2023	310	0	310	310	0
Louisiana	8/1/2023	380	0	380	380	0
Louisiana	9/1/2023	320	0	320	320	0
Louisiana	10/1/2023	480	0	480	480	0
Louisiana	11/1/2023	470	0	470	470	0
Louisiana	12/1/2023	520	0	520	520	0
Louisiana	1/1/2024	560	0	560	560	0
Louisiana	2/1/2024	540	0	540	540	0
Louisiana	3/1/2024	600	0	600	600	0
Louisiana	4/1/2024	610	0	610	610	0
Louisiana	5/1/2024	620	0	620	620	0
Louisiana	6/1/2024	620	0	620	620	0
Louisiana	7/1/2024	630	0	630	630	0
Louisiana	8/1/2024	560	0	560	560	0
Louisiana	9/1/2024	530	0	530	530	0
Louisiana	10/1/2024	670	0	670	670	0
Louisiana	11/1/2024	740	0	740	740	0
Louisiana	12/1/2024	830	0	830	830	0
Maine	4/1/2022	200	190	10	10	0
Maine	5/1/2022	230	220	10	10	0
Maine	6/1/2022	240	220	20	20	0
Maine	7/1/2022	240	220	20	20	0
Maine	8/1/2022	230	210	20	20	0
Maine	9/1/2022	220	190	30	30	0
Maine	10/1/2022	190	170	20	20	0
Maine	11/1/2022	180	140	40	40	0
Maine	12/1/2022	200	160	40	40	0
Maine	1/1/2023	240	190	50	50	0
Maine	2/1/2023	220	190	30	30	0
Maine	3/1/2023	260	230	30	30	0
Maine	4/1/2023	220	180	40	40	0
Maine	5/1/2023	230	200	30	30	0
Maine	6/1/2023	250	210	40	40	0
Maine	7/1/2023	230	170	60	50	10
Maine	8/1/2023	220	150	70	40	30
Maine	9/1/2023	230	130	100	70	30
Maine	10/1/2023	220	140	80	60	20
Maine	11/1/2023	220	140	80	50	30
Maine	12/1/2023	220	140	80	60	20

Maine	1/1/2024	280	210	70	50	20
Maine	2/1/2024	250	190	60	40	20
Maine	3/1/2024	250	190	60	50	10
Maine	4/1/2024	250	170	80	60	20
Maine	5/1/2024	270	210	60	40	20
Maine	6/1/2024	230	180	50	40	10
Maine	7/1/2024	260	190	70	60	10
Maine	8/1/2024	260	190	70	50	20
Maine	9/1/2024	250	190	60	50	10
Maine	10/1/2024	260	190	70	50	20
Maine	11/1/2024	210	160	50	40	10
Maine	12/1/2024	230	170	60	50	10
Maryland	4/1/2022	2,880	2,840	40	40	0
Maryland	5/1/2022	2,860	2,810	50	50	0
Maryland	6/1/2022	2,890	2,820	70	70	0
Maryland	7/1/2022	2,770	2,680	90	90	0
Maryland	8/1/2022	2,860	2,790	70	70	0
Maryland	9/1/2022	2,940	2,850	90	90	0
Maryland	10/1/2022	3,000	2,920	80	80	0
Maryland	11/1/2022	2,980	2,880	100	100	0
Maryland	12/1/2022	3,460	3,330	130	130	0
Maryland	1/1/2023	3,580	3,450	130	130	0
Maryland	2/1/2023	3,590	3,500	90	90	0
Maryland	3/1/2023	3,570	3,440	130	130	0
Maryland	4/1/2023	3,480	3,370	110	110	0
Maryland	5/1/2023	3,810	3,630	180	180	0
Maryland	6/1/2023	3,820	3,680	140	140	0
Maryland	7/1/2023	3,780	3,270	510	180	330
Maryland	8/1/2023	3,660	3,140	520	180	340
Maryland	9/1/2023	3,190	2,660	530	200	330
Maryland	10/1/2023	3,320	2,780	540	200	340
Maryland	11/1/2023	3,580	3,030	550	200	350
Maryland	12/1/2023	3,410	2,870	540	170	370
Maryland	1/1/2024	3,860	3,210	650	230	420
Maryland	2/1/2024	3,450	2,900	550	160	390
Maryland	3/1/2024	3,550	2,990	560	200	360
Maryland	4/1/2024	3,470	2,940	530	180	350
Maryland	5/1/2024	3,610	3,030	580	190	390
Maryland	6/1/2024	3,240	2,730	510	170	340
Maryland	7/1/2024	3,650	3,040	610	210	400
Maryland	8/1/2024	3,370	2,850	520	180	340
Maryland	9/1/2024	3,000	2,560	440	170	270
Maryland	10/1/2024	3,430	2,910	520	220	300
Maryland	11/1/2024	3,230	2,690	540	250	290

Maryland	12/1/2024	3,470	2,880	590	290	300
Massachusetts	4/1/2022	1,670	1,590	80	80	0
Massachusetts	5/1/2022	1,550	1,450	100	100	0
Massachusetts	6/1/2022	1,650	1,530	120	120	0
Massachusetts	7/1/2022	1,670	1,530	140	140	0
Massachusetts	8/1/2022	1,640	1,510	130	130	0
Massachusetts	9/1/2022	1,600	1,480	120	120	0
Massachusetts	10/1/2022	1,560	1,400	160	160	0
Massachusetts	11/1/2022	1,520	1,320	200	200	0
Massachusetts	12/1/2022	1,730	1,510	220	220	0
Massachusetts	1/1/2023	1,880	1,670	210	210	0
Massachusetts	2/1/2023	1,640	1,480	160	160	0
Massachusetts	3/1/2023	2,080	1,840	240	240	0
Massachusetts	4/1/2023	1,720	1,550	170	170	0
Massachusetts	5/1/2023	1,860	1,660	200	200	0
Massachusetts	6/1/2023	1,910	1,690	220	220	0
Massachusetts	7/1/2023	1,800	1,520	280	270	10
Massachusetts	8/1/2023	1,990	1,700	290	270	20
Massachusetts	9/1/2023	1,760	1,490	270	240	30
Massachusetts	10/1/2023	1,830	1,540	290	250	40
Massachusetts	11/1/2023	1,920	1,580	340	290	50
Massachusetts	12/1/2023	2,150	1,830	320	280	40
Massachusetts	1/1/2024	2,130	1,770	360	310	50
Massachusetts	2/1/2024	2,030	1,710	320	270	50
Massachusetts	3/1/2024	2,090	1,750	340	280	60
Massachusetts	4/1/2024	1,860	1,520	340	290	50
Massachusetts	5/1/2024	2,050	1,680	370	310	60
Massachusetts	6/1/2024	1,760	1,420	340	290	50
Massachusetts	7/1/2024	1,910	1,540	370	320	50
Massachusetts	8/1/2024	1,840	1,510	330	290	40
Massachusetts	9/1/2024	1,760	1,460	300	250	50
Massachusetts	10/1/2024	1,810	1,470	340	270	70
Massachusetts	11/1/2024	1,910	1,490	420	360	60
Massachusetts	12/1/2024	1,710	1,300	410	310	100
Michigan	4/1/2022	2,610	2,610	0	0	0
Michigan	5/1/2022	2,570	2,450	120	120	0
Michigan	6/1/2022	2,910	2,720	190	190	0
Michigan	7/1/2022	3,030	2,830	200	200	0
Michigan	8/1/2022	2,930	2,720	210	210	0
Michigan	9/1/2022	2,770	2,540	230	230	0
Michigan	10/1/2022	2,750	2,530	220	220	0
Michigan	11/1/2022	2,630	2,390	240	240	0
Michigan	12/1/2022	2,720	2,430	290	290	0
Michigan	1/1/2023	2,990	2,700	290	290	0

Michigan	2/1/2023	2,920	2,670	250	250	0
Michigan	3/1/2023	3,380	3,120	260	260	0
Michigan	4/1/2023	3,080	2,820	260	260	0
Michigan	5/1/2023	3,000	2,760	240	240	0
Michigan	6/1/2023	2,950	2,780	170	170	0
Michigan	7/1/2023	2,990	2,680	310	310	0
Michigan	8/1/2023	3,200	2,840	360	360	0
Michigan	9/1/2023	2,970	2,640	330	330	0
Michigan	10/1/2023	2,980	2,650	330	330	0
Michigan	11/1/2023	2,920	2,560	360	360	0
Michigan	12/1/2023	3,030	2,730	300	300	0
Michigan	1/1/2024	3,490	3,030	460	460	0
Michigan	2/1/2024	3,230	2,880	350	350	0
Michigan	3/1/2024	3,340	2,990	350	350	0
Michigan	4/1/2024	3,090	2,740	350	350	0
Michigan	5/1/2024	3,190	2,840	350	350	0
Michigan	6/1/2024	2,990	2,630	360	360	0
Michigan	7/1/2024	3,140	2,710	430	430	0
Michigan	8/1/2024	3,200	2,790	410	400	10
Michigan	9/1/2024	2,740	2,260	480	460	20
Michigan	10/1/2024	3,140	2,670	470	450	20
Michigan	11/1/2024	2,970	2,310	660	620	40
Michigan	12/1/2024	3,260	2,500	760	710	50
Minnesota	4/1/2022	940	760	180	180	0
Minnesota	5/1/2022	930	730	200	200	0
Minnesota	6/1/2022	1,040	840	200	200	0
Minnesota	7/1/2022	1,180	940	240	240	0
Minnesota	8/1/2022	1,200	1,000	200	200	0
Minnesota	9/1/2022	1,210	990	220	220	0
Minnesota	10/1/2022	1,240	1,000	240	240	0
Minnesota	11/1/2022	1,270	1,050	220	220	0
Minnesota	12/1/2022	1,200	980	220	220	0
Minnesota	1/1/2023	1,240	990	250	250	0
Minnesota	2/1/2023	1,110	870	240	240	0
Minnesota	3/1/2023	1,430	1,110	320	320	0
Minnesota	4/1/2023	1,220	1,000	220	220	0
Minnesota	5/1/2023	1,400	1,100	300	300	0
Minnesota	6/1/2023	1,360	1,100	260	260	0
Minnesota	7/1/2023	1,320	970	350	320	30
Minnesota	8/1/2023	1,410	1,080	330	290	40
Minnesota	9/1/2023	1,280	1,010	270	250	20
Minnesota	10/1/2023	1,250	960	290	260	30
Minnesota	11/1/2023	1,240	940	300	270	30
Minnesota	12/1/2023	1,180	840	340	320	20

Minnesota	1/1/2024	1,380	1,020	360	330	30
Minnesota	2/1/2024	1,300	930	370	350	20
Minnesota	3/1/2024	1,320	970	350	320	30
Minnesota	4/1/2024	1,350	990	360	330	30
Minnesota	5/1/2024	1,370	1,030	340	310	30
Minnesota	6/1/2024	1,340	980	360	330	30
Minnesota	7/1/2024	1,390	1,070	320	290	30
Minnesota	8/1/2024	1,450	1,110	340	320	20
Minnesota	9/1/2024	1,250	980	270	250	20
Minnesota	10/1/2024	1,430	1,090	340	320	20
Minnesota	11/1/2024	1,380	1,010	370	360	10
Minnesota	12/1/2024	1,430	1,030	400	380	20
Mississippi	4/1/2022	350	350	0	0	0
Mississippi	5/1/2022	350	350	0	0	0
Mississippi	6/1/2022	470	470	0	0	0
Mississippi	7/1/2022	0	0	0	0	0
Mississippi	8/1/2022	0	0	0	0	0
Mississippi	9/1/2022	0	0	0	0	0
Mississippi	10/1/2022	0	0	0	0	0
Mississippi	11/1/2022	0	0	0	0	0
Mississippi	12/1/2022	0	0	0	0	0
Mississippi	1/1/2023	0	0	0	0	0
Mississippi	2/1/2023	0	0	0	0	0
Mississippi	3/1/2023	0	0	0	0	0
Mississippi	4/1/2023	0	0	0	0	0
Mississippi	5/1/2023	0	0	0	0	0
Mississippi	6/1/2023	0	0	0	0	0
Mississippi	7/1/2023	200	0	200	200	0
Mississippi	8/1/2023	210	0	210	210	0
Mississippi	9/1/2023	220	0	220	220	0
Mississippi	10/1/2023	280	0	280	280	0
Mississippi	11/1/2023	300	0	300	300	0
Mississippi	12/1/2023	360	0	360	360	0
Mississippi	1/1/2024	390	0	390	390	0
Mississippi	2/1/2024	380	0	380	380	0
Mississippi	3/1/2024	420	0	420	420	0
Mississippi	4/1/2024	390	0	390	390	0
Mississippi	5/1/2024	400	0	400	400	0
Mississippi	6/1/2024	380	0	380	380	0
Mississippi	7/1/2024	400	0	400	400	0
Mississippi	8/1/2024	370	0	370	370	0
Mississippi	9/1/2024	360	0	360	360	0
Mississippi	10/1/2024	450	0	450	450	0
Mississippi	11/1/2024	450	0	450	450	0

Mississippi	12/1/2024	560	0	560	560	0
Missouri	4/1/2022	10	10	0	0	0
Missouri	5/1/2022	10	10	0	0	0
Missouri	6/1/2022	10	10	0	0	0
Missouri	7/1/2022	0	0	0	0	0
Missouri	8/1/2022	0	0	0	0	0
Missouri	9/1/2022	0	0	0	0	0
Missouri	10/1/2022	0	0	0	0	0
Missouri	11/1/2022	0	0	0	0	0
Missouri	12/1/2022	0	0	0	0	0
Missouri	1/1/2023	0	0	0	0	0
Missouri	2/1/2023	0	0	0	0	0
Missouri	3/1/2023	0	0	0	0	0
Missouri	4/1/2023	10	10	0	0	0
Missouri	5/1/2023	0	0	0	0	0
Missouri	6/1/2023	0	0	0	0	0
Missouri	7/1/2023	110	0	110	110	0
Missouri	8/1/2023	120	0	120	120	0
Missouri	9/1/2023	110	10	100	100	0
Missouri	10/1/2023	150	0	150	150	0
Missouri	11/1/2023	150	10	140	140	0
Missouri	12/1/2023	160	0	160	160	0
Missouri	1/1/2024	160	0	160	160	0
Missouri	2/1/2024	140	0	140	140	0
Missouri	3/1/2024	160	0	160	160	0
Missouri	4/1/2024	180	0	180	180	0
Missouri	5/1/2024	160	0	160	160	0
Missouri	6/1/2024	160	0	160	160	0
Missouri	7/1/2024	220	0	220	220	0
Missouri	8/1/2024	160	0	160	160	0
Missouri	9/1/2024	210	10	200	200	0
Missouri	10/1/2024	190	0	190	190	0
Missouri	11/1/2024	230	0	230	230	0
Missouri	12/1/2024	280	10	270	270	0
Montana	4/1/2022	170	130	40	40	0
Montana	5/1/2022	180	150	30	30	0
Montana	6/1/2022	170	130	40	40	0
Montana	7/1/2022	160	120	40	40	0
Montana	8/1/2022	220	180	40	40	0
Montana	9/1/2022	170	130	40	40	0
Montana	10/1/2022	200	160	40	40	0
Montana	11/1/2022	190	160	30	30	0
Montana	12/1/2022	170	140	30	30	0
Montana	1/1/2023	210	170	40	40	0

Montana	2/1/2023	170	140	30	30	0
Montana	3/1/2023	190	150	40	40	0
Montana	4/1/2023	190	160	30	30	0
Montana	5/1/2023	190	150	40	40	0
Montana	6/1/2023	200	170	30	30	0
Montana	7/1/2023	210	140	70	40	30
Montana	8/1/2023	240	170	70	30	40
Montana	9/1/2023	210	130	80	30	50
Montana	10/1/2023	220	140	80	40	40
Montana	11/1/2023	230	140	90	50	40
Montana	12/1/2023	220	140	80	30	50
Montana	1/1/2024	230	140	90	40	50
Montana	2/1/2024	200	130	70	30	40
Montana	3/1/2024	210	130	80	30	50
Montana	4/1/2024	200	130	70	30	40
Montana	5/1/2024	220	140	80	20	60
Montana	6/1/2024	200	120	80	30	50
Montana	7/1/2024	250	140	110	50	60
Montana	8/1/2024	260	180	80	60	20
Montana	9/1/2024	140	60	80	50	30
Montana	10/1/2024	270	180	90	60	30
Montana	11/1/2024	220	150	70	60	10
Montana	12/1/2024	250	160	90	60	30
Nebraska	4/1/2022	200	200	0	0	0
Nebraska	5/1/2022	190	190	0	0	0
Nebraska	6/1/2022	210	210	0	0	0
Nebraska	7/1/2022	210	210	0	0	0
Nebraska	8/1/2022	260	260	0	0	0
Nebraska	9/1/2022	230	230	0	0	0
Nebraska	10/1/2022	240	240	0	0	0
Nebraska	11/1/2022	200	200	0	0	0
Nebraska	12/1/2022	170	170	0	0	0
Nebraska	1/1/2023	320	320	0	0	0
Nebraska	2/1/2023	280	280	0	0	0
Nebraska	3/1/2023	250	250	0	0	0
Nebraska	4/1/2023	280	280	0	0	0
Nebraska	5/1/2023	180	180	0	0	0
Nebraska	6/1/2023	240	240	0	0	0
Nebraska	7/1/2023	180	130	50	50	0
Nebraska	8/1/2023	270	230	40	40	0
Nebraska	9/1/2023	210	170	40	40	0
Nebraska	10/1/2023	190	140	50	50	0
Nebraska	11/1/2023	210	150	60	60	0
Nebraska	12/1/2023	290	220	70	70	0

Nebraska	1/1/2024	270	200	70	70	0
Nebraska	2/1/2024	260	200	60	60	0
Nebraska	3/1/2024	270	190	80	80	0
Nebraska	4/1/2024	280	210	70	70	0
Nebraska	5/1/2024	300	220	80	80	0
Nebraska	6/1/2024	310	240	70	70	0
Nebraska	7/1/2024	300	230	70	70	0
Nebraska	8/1/2024	310	240	70	70	0
Nebraska	9/1/2024	300	220	80	80	0
Nebraska	10/1/2024	340	250	90	90	0
Nebraska	11/1/2024	340	240	100	100	0
Nebraska	12/1/2024	350	250	100	100	0
Nevada	4/1/2022	1,140	1,020	120	120	0
Nevada	5/1/2022	1,090	940	150	150	0
Nevada	6/1/2022	1,320	1,140	180	180	0
Nevada	7/1/2022	1,220	1,030	190	190	0
Nevada	8/1/2022	1,430	1,210	220	220	0
Nevada	9/1/2022	1,290	1,040	250	250	0
Nevada	10/1/2022	1,340	1,110	230	230	0
Nevada	11/1/2022	1,290	1,050	240	240	0
Nevada	12/1/2022	1,440	1,150	290	290	0
Nevada	1/1/2023	1,540	1,230	310	310	0
Nevada	2/1/2023	1,440	1,140	300	300	0
Nevada	3/1/2023	1,580	1,270	310	310	0
Nevada	4/1/2023	1,370	1,080	290	290	0
Nevada	5/1/2023	1,360	1,050	310	310	0
Nevada	6/1/2023	1,390	1,150	240	240	0
Nevada	7/1/2023	1,260	970	290	290	0
Nevada	8/1/2023	1,420	1,100	320	320	0
Nevada	9/1/2023	1,300	900	400	310	90
Nevada	10/1/2023	1,360	960	400	340	60
Nevada	11/1/2023	1,320	940	380	360	20
Nevada	12/1/2023	1,410	990	420	390	30
Nevada	1/1/2024	1,680	1,160	520	500	20
Nevada	2/1/2024	1,520	1,070	450	440	10
Nevada	3/1/2024	1,660	1,160	500	490	10
Nevada	4/1/2024	1,410	970	440	430	10
Nevada	5/1/2024	1,500	1,070	430	410	20
Nevada	6/1/2024	1,460	990	470	440	30
Nevada	7/1/2024	1,450	940	510	490	20
Nevada	8/1/2024	1,410	950	460	450	10
Nevada	9/1/2024	1,310	880	430	400	30
Nevada	10/1/2024	1,460	1,000	460	450	10
Nevada	11/1/2024	1,280	800	480	470	10

Nevada	12/1/2024	1,410	920	490	470	20
New Hampshire	4/1/2022	230	230	0	0	0
New Hampshire	5/1/2022	200	200	0	0	0
New Hampshire	6/1/2022	220	220	0	0	0
New Hampshire	7/1/2022	210	200	10	10	0
New Hampshire	8/1/2022	220	200	20	20	0
New Hampshire	9/1/2022	210	200	10	10	0
New Hampshire	10/1/2022	180	160	20	20	0
New Hampshire	11/1/2022	190	160	30	30	0
New Hampshire	12/1/2022	230	200	30	30	0
New Hampshire	1/1/2023	210	190	20	20	0
New Hampshire	2/1/2023	230	210	20	20	0
New Hampshire	3/1/2023	270	240	30	30	0
New Hampshire	4/1/2023	250	220	30	30	0
New Hampshire	5/1/2023	250	220	30	30	0
New Hampshire	6/1/2023	240	220	20	20	0
New Hampshire	7/1/2023	240	180	60	50	10
New Hampshire	8/1/2023	270	220	50	40	10
New Hampshire	9/1/2023	250	210	40	30	10
New Hampshire	10/1/2023	230	190	40	30	10
New Hampshire	11/1/2023	280	230	50	50	0
New Hampshire	12/1/2023	280	230	50	40	10
New Hampshire	1/1/2024	290	240	50	40	10
New Hampshire	2/1/2024	290	210	80	70	10
New Hampshire	3/1/2024	310	240	70	60	10
New Hampshire	4/1/2024	310	260	50	40	10
New Hampshire	5/1/2024	320	240	80	60	20
New Hampshire	6/1/2024	260	210	50	50	0
New Hampshire	7/1/2024	270	220	50	50	0
New Hampshire	8/1/2024	250	210	40	40	0
New Hampshire	9/1/2024	250	200	50	50	0
New Hampshire	10/1/2024	250	200	50	50	0
New Hampshire	11/1/2024	300	230	70	70	0
New Hampshire	12/1/2024	270	190	80	80	0
New Jersey	4/1/2022	4,020	3,860	160	160	0
New Jersey	5/1/2022	3,980	3,790	190	190	0
New Jersey	6/1/2022	4,070	3,890	180	180	0
New Jersey	7/1/2022	4,100	3,850	250	250	0
New Jersey	8/1/2022	4,300	4,000	300	300	0
New Jersey	9/1/2022	3,730	3,450	280	280	0
New Jersey	10/1/2022	3,850	3,540	310	310	0
New Jersey	11/1/2022	4,020	3,650	370	370	0
New Jersey	12/1/2022	4,190	3,750	440	440	0
New Jersey	1/1/2023	4,370	3,840	530	530	0

New Jersey	2/1/2023	4,140	3,700	440	440	0
New Jersey	3/1/2023	4,780	4,310	470	470	0
New Jersey	4/1/2023	4,400	3,910	490	490	0
New Jersey	5/1/2023	4,920	4,400	520	520	0
New Jersey	6/1/2023	4,710	4,200	510	510	0
New Jersey	7/1/2023	4,480	3,960	520	520	0
New Jersey	8/1/2023	4,690	4,190	500	500	0
New Jersey	9/1/2023	4,130	3,690	440	440	0
New Jersey	10/1/2023	4,070	3,510	560	560	0
New Jersey	11/1/2023	3,900	3,380	520	520	0
New Jersey	12/1/2023	4,560	4,000	560	560	0
New Jersey	1/1/2024	4,780	4,040	740	740	0
New Jersey	2/1/2024	4,120	3,550	570	570	0
New Jersey	3/1/2024	4,630	4,000	630	630	0
New Jersey	4/1/2024	4,380	3,850	530	530	0
New Jersey	5/1/2024	4,830	4,290	540	540	0
New Jersey	6/1/2024	4,790	4,220	570	570	0
New Jersey	7/1/2024	5,190	4,650	540	540	0
New Jersey	8/1/2024	4,990	4,480	510	510	0
New Jersey	9/1/2024	4,760	4,300	460	460	0
New Jersey	10/1/2024	5,060	4,520	540	540	0
New Jersey	11/1/2024	4,950	4,350	600	600	0
New Jersey	12/1/2024	4,830	4,270	560	560	0
New Mexico	4/1/2022	1,230	1,150	80	80	0
New Mexico	5/1/2022	1,200	1,110	90	90	0
New Mexico	6/1/2022	1,430	1,290	140	140	0
New Mexico	7/1/2022	1,460	1,290	170	170	0
New Mexico	8/1/2022	1,510	1,360	150	150	0
New Mexico	9/1/2022	1,650	1,510	140	140	0
New Mexico	10/1/2022	1,700	1,540	160	160	0
New Mexico	11/1/2022	1,790	1,610	180	180	0
New Mexico	12/1/2022	1,890	1,720	170	170	0
New Mexico	1/1/2023	2,070	1,890	180	180	0
New Mexico	2/1/2023	1,850	1,700	150	150	0
New Mexico	3/1/2023	2,150	2,000	150	150	0
New Mexico	4/1/2023	1,890	1,730	160	160	0
New Mexico	5/1/2023	1,870	1,690	180	180	0
New Mexico	6/1/2023	1,980	1,810	170	170	0
New Mexico	7/1/2023	1,770	1,600	170	140	30
New Mexico	8/1/2023	1,650	1,510	140	120	20
New Mexico	9/1/2023	1,650	1,490	160	140	20
New Mexico	10/1/2023	1,520	1,360	160	140	20
New Mexico	11/1/2023	1,520	1,380	140	120	20
New Mexico	12/1/2023	1,630	1,470	160	140	20

New Mexico	1/1/2024	1,890	1,680	210	190	20
New Mexico	2/1/2024	1,650	1,510	140	120	20
New Mexico	3/1/2024	1,790	1,610	180	150	30
New Mexico	4/1/2024	1,560	1,370	190	150	40
New Mexico	5/1/2024	1,650	1,470	180	140	40
New Mexico	6/1/2024	1,560	1,350	210	130	80
New Mexico	7/1/2024	1,480	1,290	190	130	60
New Mexico	8/1/2024	1,500	1,300	200	140	60
New Mexico	9/1/2024	1,270	1,090	180	130	50
New Mexico	10/1/2024	1,260	1,090	170	120	50
New Mexico	11/1/2024	1,350	1,130	220	140	80
New Mexico	12/1/2024	1,270	1,100	170	140	30
New York	4/1/2022	8,770	8,370	400	400	0
New York	5/1/2022	9,190	8,690	500	500	0
New York	6/1/2022	9,790	9,240	550	550	0
New York	7/1/2022	9,410	8,860	550	550	0
New York	8/1/2022	9,920	9,300	620	620	0
New York	9/1/2022	9,080	8,540	540	540	0
New York	10/1/2022	9,120	8,540	580	580	0
New York	11/1/2022	7,300	6,680	620	620	0
New York	12/1/2022	8,620	7,850	770	770	0
New York	1/1/2023	8,610	7,760	850	850	0
New York	2/1/2023	8,030	7,350	680	680	0
New York	3/1/2023	9,980	9,160	820	820	0
New York	4/1/2023	9,010	8,110	900	900	0
New York	5/1/2023	9,380	8,560	820	820	0
New York	6/1/2023	9,530	8,740	790	790	0
New York	7/1/2023	9,160	8,280	880	880	0
New York	8/1/2023	10,060	9,230	830	830	0
New York	9/1/2023	9,110	8,380	730	730	0
New York	10/1/2023	9,630	8,840	790	790	0
New York	11/1/2023	8,930	8,140	790	790	0
New York	12/1/2023	9,720	8,900	820	820	0
New York	1/1/2024	10,790	9,890	900	900	0
New York	2/1/2024	9,940	9,250	690	690	0
New York	3/1/2024	10,210	9,460	750	750	0
New York	4/1/2024	10,320	9,530	790	790	0
New York	5/1/2024	11,020	10,130	890	890	0
New York	6/1/2024	9,780	9,010	770	770	0
New York	7/1/2024	10,510	9,540	970	970	0
New York	8/1/2024	9,980	9,170	810	810	0
New York	9/1/2024	9,200	8,440	760	760	0
New York	10/1/2024	9,840	9,090	750	750	0
New York	11/1/2024	9,440	8,520	920	920	0

New York	12/1/2024	9,800	8,900	900	900	0
North Carolina	4/1/2022	3,280	3,280	0	0	0
North Carolina	5/1/2022	3,270	3,270	0	0	0
North Carolina	6/1/2022	3,230	3,230	0	0	0
North Carolina	7/1/2022	3,930	3,930	0	0	0
North Carolina	8/1/2022	4,390	4,390	0	0	0
North Carolina	9/1/2022	4,090	4,090	0	0	0
North Carolina	10/1/2022	3,870	3,870	0	0	0
North Carolina	11/1/2022	3,770	3,770	0	0	0
North Carolina	12/1/2022	4,070	4,070	0	0	0
North Carolina	1/1/2023	4,510	4,510	0	0	0
North Carolina	2/1/2023	4,120	4,120	0	0	0
North Carolina	3/1/2023	4,730	4,730	0	0	0
North Carolina	4/1/2023	4,210	4,210	0	0	0
North Carolina	5/1/2023	4,560	4,560	0	0	0
North Carolina	6/1/2023	4,730	4,730	0	0	0
North Carolina	7/1/2023	3,390	3,140	250	250	0
North Carolina	8/1/2023	3,570	3,340	230	230	0
North Carolina	9/1/2023	4,190	3,950	240	240	0
North Carolina	10/1/2023	4,130	3,790	340	340	0
North Carolina	11/1/2023	3,540	3,190	350	350	0
North Carolina	12/1/2023	3,960	3,600	360	360	0
North Carolina	1/1/2024	4,310	3,800	510	510	0
North Carolina	2/1/2024	4,250	3,890	360	360	0
North Carolina	3/1/2024	4,410	3,990	420	420	0
North Carolina	4/1/2024	4,730	4,310	420	420	0
North Carolina	5/1/2024	4,530	4,130	400	400	0
North Carolina	6/1/2024	4,390	4,020	370	370	0
North Carolina	7/1/2024	4,250	3,760	490	490	0
North Carolina	8/1/2024	4,340	3,880	460	460	0
North Carolina	9/1/2024	3,730	3,260	470	470	0
North Carolina	10/1/2024	3,970	3,440	530	530	0
North Carolina	11/1/2024	4,520	3,790	730	730	0
North Carolina	12/1/2024	3,950	3,240	710	710	0
North Dakota	4/1/2022	90	90	0	0	0
North Dakota	5/1/2022	110	110	0	0	0
North Dakota	6/1/2022	130	130	0	0	0
North Dakota	7/1/2022	100	100	0	0	0
North Dakota	8/1/2022	20	20	0	0	0
North Dakota	9/1/2022	0	0	0	0	0
North Dakota	10/1/2022	0	0	0	0	0
North Dakota	11/1/2022	0	0	0	0	0
North Dakota	12/1/2022	0	0	0	0	0
North Dakota	1/1/2023	0	0	0	0	0

North Dakota	2/1/2023	0	0	0	0	0
North Dakota	3/1/2023	0	0	0	0	0
North Dakota	4/1/2023	0	0	0	0	0
North Dakota	5/1/2023	0	0	0	0	0
North Dakota	6/1/2023	0	0	0	0	0
North Dakota	7/1/2023	10	0	10	10	0
North Dakota	8/1/2023	10	0	10	10	0
North Dakota	9/1/2023	30	0	30	30	0
North Dakota	10/1/2023	20	0	20	20	0
North Dakota	11/1/2023	20	0	20	20	0
North Dakota	12/1/2023	10	0	10	10	0
North Dakota	1/1/2024	20	0	20	20	0
North Dakota	2/1/2024	20	0	20	20	0
North Dakota	3/1/2024	10	0	10	10	0
North Dakota	4/1/2024	20	0	20	20	0
North Dakota	5/1/2024	20	0	20	20	0
North Dakota	6/1/2024	20	0	20	20	0
North Dakota	7/1/2024	30	0	30	30	0
North Dakota	8/1/2024	30	0	30	30	0
North Dakota	9/1/2024	20	0	20	20	0
North Dakota	10/1/2024	20	0	20	20	0
North Dakota	11/1/2024	40	0	40	40	0
North Dakota	12/1/2024	30	0	30	30	0
Ohio	4/1/2022	2,040	2,040	0	0	0
Ohio	5/1/2022	1,990	1,990	0	0	0
Ohio	6/1/2022	1,830	1,830	0	0	0
Ohio	7/1/2022	810	810	0	0	0
Ohio	8/1/2022	780	780	0	0	0
Ohio	9/1/2022	1,070	1,070	0	0	0
Ohio	10/1/2022	1,500	1,500	0	0	0
Ohio	11/1/2022	1,510	1,510	0	0	0
Ohio	12/1/2022	1,860	1,860	0	0	0
Ohio	1/1/2023	1,950	1,950	0	0	0
Ohio	2/1/2023	1,920	1,920	0	0	0
Ohio	3/1/2023	2,110	2,110	0	0	0
Ohio	4/1/2023	1,860	1,860	0	0	0
Ohio	5/1/2023	1,970	1,970	0	0	0
Ohio	6/1/2023	1,970	1,970	0	0	0
Ohio	7/1/2023	1,970	1,720	250	250	0
Ohio	8/1/2023	2,220	1,920	300	300	0
Ohio	9/1/2023	1,970	1,680	290	290	0
Ohio	10/1/2023	2,290	1,940	350	350	0
Ohio	11/1/2023	2,180	1,750	430	430	0
Ohio	12/1/2023	2,280	1,880	400	400	0

Ohio	1/1/2024	2,340	1,760	580	580	0
Ohio	2/1/2024	2,300	1,810	490	490	0
Ohio	3/1/2024	2,590	2,090	500	500	0
Ohio	4/1/2024	2,470	1,940	530	530	0
Ohio	5/1/2024	2,620	2,100	520	520	0
Ohio	6/1/2024	2,410	1,900	510	510	0
Ohio	7/1/2024	2,430	1,810	620	620	0
Ohio	8/1/2024	2,480	1,900	580	580	0
Ohio	9/1/2024	2,440	1,810	630	630	0
Ohio	10/1/2024	2,610	1,980	630	630	0
Ohio	11/1/2024	2,580	1,790	790	790	0
Ohio	12/1/2024	2,700	1,790	910	910	0
Oklahoma	4/1/2022	480	480	0	0	0
Oklahoma	5/1/2022	140	140	0	0	0
Oklahoma	6/1/2022	0	0	0	0	0
Oklahoma	7/1/2022	0	0	0	0	0
Oklahoma	8/1/2022	0	0	0	0	0
Oklahoma	9/1/2022	0	0	0	0	0
Oklahoma	10/1/2022	0	0	0	0	0
Oklahoma	11/1/2022	0	0	0	0	0
Oklahoma	12/1/2022	0	0	0	0	0
Oklahoma	1/1/2023	0	0	0	0	0
Oklahoma	2/1/2023	0	0	0	0	0
Oklahoma	3/1/2023	0	0	0	0	0
Oklahoma	4/1/2023	0	0	0	0	0
Oklahoma	5/1/2023	0	0	0	0	0
Oklahoma	6/1/2023	0	0	0	0	0
Oklahoma	7/1/2023	120	0	120	120	0
Oklahoma	8/1/2023	150	0	150	150	0
Oklahoma	9/1/2023	140	0	140	140	0
Oklahoma	10/1/2023	190	0	190	190	0
Oklahoma	11/1/2023	180	0	180	180	0
Oklahoma	12/1/2023	200	0	200	200	0
Oklahoma	1/1/2024	220	0	220	220	0
Oklahoma	2/1/2024	190	0	190	190	0
Oklahoma	3/1/2024	220	0	220	220	0
Oklahoma	4/1/2024	260	0	260	260	0
Oklahoma	5/1/2024	240	0	240	240	0
Oklahoma	6/1/2024	250	0	250	250	0
Oklahoma	7/1/2024	240	0	240	240	0
Oklahoma	8/1/2024	250	0	250	250	0
Oklahoma	9/1/2024	250	0	250	250	0
Oklahoma	10/1/2024	300	0	300	300	0
Oklahoma	11/1/2024	310	0	310	310	0

Oklahoma	12/1/2024	340	0	340	340	0
Oregon	4/1/2022	850	820	30	30	0
Oregon	5/1/2022	800	740	60	60	0
Oregon	6/1/2022	920	840	80	80	0
Oregon	7/1/2022	880	800	80	80	0
Oregon	8/1/2022	1,030	950	80	80	0
Oregon	9/1/2022	920	840	80	80	0
Oregon	10/1/2022	930	850	80	80	0
Oregon	11/1/2022	910	810	100	100	0
Oregon	12/1/2022	960	850	110	110	0
Oregon	1/1/2023	1,050	950	100	100	0
Oregon	2/1/2023	890	800	90	90	0
Oregon	3/1/2023	1,140	1,070	70	70	0
Oregon	4/1/2023	940	840	100	100	0
Oregon	5/1/2023	1,060	960	100	100	0
Oregon	6/1/2023	1,080	990	90	90	0
Oregon	7/1/2023	1,020	880	140	140	0
Oregon	8/1/2023	1,110	990	120	90	30
Oregon	9/1/2023	970	850	120	100	20
Oregon	10/1/2023	1,030	880	150	120	30
Oregon	11/1/2023	980	830	150	130	20
Oregon	12/1/2023	1,000	860	140	130	10
Oregon	1/1/2024	1,070	890	180	160	20
Oregon	2/1/2024	1,100	940	160	140	20
Oregon	3/1/2024	1,040	890	150	130	20
Oregon	4/1/2024	1,060	890	170	150	20
Oregon	5/1/2024	1,020	860	160	140	20
Oregon	6/1/2024	970	790	180	150	30
Oregon	7/1/2024	1,090	920	170	150	20
Oregon	8/1/2024	1,090	920	170	130	40
Oregon	9/1/2024	960	800	160	130	30
Oregon	10/1/2024	1,050	890	160	130	30
Oregon	11/1/2024	1,090	820	270	220	50
Oregon	12/1/2024	1,130	910	220	200	20
Pennsylvania	4/1/2022	2,950	2,950	0	0	0
Pennsylvania	5/1/2022	2,690	2,690	0	0	0
Pennsylvania	6/1/2022	2,970	2,960	10	10	0
Pennsylvania	7/1/2022	3,350	3,310	40	40	0
Pennsylvania	8/1/2022	3,140	3,090	50	50	0
Pennsylvania	9/1/2022	3,080	3,030	50	50	0
Pennsylvania	10/1/2022	2,760	2,700	60	60	0
Pennsylvania	11/1/2022	2,570	2,520	50	50	0
Pennsylvania	12/1/2022	3,170	3,100	70	70	0
Pennsylvania	1/1/2023	2,940	2,940	0	0	0

Pennsylvania	2/1/2023	3,050	3,050	0	0	0
Pennsylvania	3/1/2023	3,530	3,530	0	0	0
Pennsylvania	4/1/2023	3,110	2,980	130	130	0
Pennsylvania	5/1/2023	3,140	3,020	120	120	0
Pennsylvania	6/1/2023	3,300	3,130	170	170	0
Pennsylvania	7/1/2023	3,270	2,810	460	370	90
Pennsylvania	8/1/2023	3,450	3,050	400	380	20
Pennsylvania	9/1/2023	3,210	2,640	570	360	210
Pennsylvania	10/1/2023	3,110	2,500	610	410	200
Pennsylvania	11/1/2023	3,090	2,420	670	440	230
Pennsylvania	12/1/2023	3,340	2,760	580	450	130
Pennsylvania	1/1/2024	3,550	2,810	740	570	170
Pennsylvania	2/1/2024	3,640	3,000	640	460	180
Pennsylvania	3/1/2024	3,640	3,030	610	480	130
Pennsylvania	4/1/2024	3,180	2,570	610	460	150
Pennsylvania	5/1/2024	3,450	2,730	720	500	220
Pennsylvania	6/1/2024	3,050	2,450	600	440	160
Pennsylvania	7/1/2024	3,240	2,530	710	550	160
Pennsylvania	8/1/2024	3,240	2,590	650	510	140
Pennsylvania	9/1/2024	2,770	2,160	610	490	120
Pennsylvania	10/1/2024	3,200	2,490	710	530	180
Pennsylvania	11/1/2024	3,140	2,350	790	670	120
Pennsylvania	12/1/2024	3,170	2,380	790	690	100
Rhode Island	4/1/2022	330	310	20	20	0
Rhode Island	5/1/2022	300	270	30	30	0
Rhode Island	6/1/2022	280	250	30	30	0
Rhode Island	7/1/2022	290	260	30	30	0
Rhode Island	8/1/2022	300	280	20	20	0
Rhode Island	9/1/2022	290	270	20	20	0
Rhode Island	10/1/2022	320	290	30	30	0
Rhode Island	11/1/2022	210	170	40	40	0
Rhode Island	12/1/2022	240	210	30	30	0
Rhode Island	1/1/2023	280	240	40	40	0
Rhode Island	2/1/2023	250	210	40	40	0
Rhode Island	3/1/2023	330	270	60	60	0
Rhode Island	4/1/2023	220	190	30	30	0
Rhode Island	5/1/2023	240	190	50	50	0
Rhode Island	6/1/2023	250	200	50	50	0
Rhode Island	7/1/2023	220	150	70	70	0
Rhode Island	8/1/2023	240	180	60	60	0
Rhode Island	9/1/2023	250	200	50	50	0
Rhode Island	10/1/2023	260	210	50	50	0
Rhode Island	11/1/2023	300	240	60	60	0
Rhode Island	12/1/2023	270	210	60	60	0

Rhode Island	1/1/2024	310	240	70	60	10
Rhode Island	2/1/2024	280	200	80	70	10
Rhode Island	3/1/2024	290	240	50	40	10
Rhode Island	4/1/2024	300	250	50	50	0
Rhode Island	5/1/2024	300	220	80	70	10
Rhode Island	6/1/2024	310	240	70	60	10
Rhode Island	7/1/2024	320	240	80	70	10
Rhode Island	8/1/2024	340	280	60	50	10
Rhode Island	9/1/2024	290	230	60	50	10
Rhode Island	10/1/2024	310	260	50	40	10
Rhode Island	11/1/2024	340	260	80	70	10
Rhode Island	12/1/2024	340	240	100	80	20
South Carolina	4/1/2022	690	690	0	0	0
South Carolina	5/1/2022	630	630	0	0	0
South Carolina	6/1/2022	490	490	0	0	0
South Carolina	7/1/2022	180	180	0	0	0
South Carolina	8/1/2022	360	360	0	0	0
South Carolina	9/1/2022	790	790	0	0	0
South Carolina	10/1/2022	830	830	0	0	0
South Carolina	11/1/2022	830	830	0	0	0
South Carolina	12/1/2022	850	850	0	0	0
South Carolina	1/1/2023	990	990	0	0	0
South Carolina	2/1/2023	1,000	1,000	0	0	0
South Carolina	3/1/2023	1,090	1,090	0	0	0
South Carolina	4/1/2023	950	950	0	0	0
South Carolina	5/1/2023	890	890	0	0	0
South Carolina	6/1/2023	930	930	0	0	0
South Carolina	7/1/2023	1,060	870	190	190	0
South Carolina	8/1/2023	960	760	200	200	0
South Carolina	9/1/2023	350	160	190	190	0
South Carolina	10/1/2023	440	200	240	240	0
South Carolina	11/1/2023	440	170	270	270	0
South Carolina	12/1/2023	480	200	280	280	0
South Carolina	1/1/2024	580	300	280	280	0
South Carolina	2/1/2024	520	280	240	240	0
South Carolina	3/1/2024	590	310	280	280	0
South Carolina	4/1/2024	510	250	260	260	0
South Carolina	5/1/2024	570	300	270	270	0
South Carolina	6/1/2024	510	230	280	280	0
South Carolina	7/1/2024	560	240	320	320	0
South Carolina	8/1/2024	550	210	340	340	0
South Carolina	9/1/2024	530	210	320	320	0
South Carolina	10/1/2024	610	240	370	370	0
South Carolina	11/1/2024	660	240	420	420	0

South Carolina	12/1/2024	710	200	510	510	0
South Dakota	4/1/2022	20	20	0	0	0
South Dakota	5/1/2022	40	40	0	0	0
South Dakota	6/1/2022	30	30	0	0	0
South Dakota	7/1/2022	0	0	0	0	0
South Dakota	8/1/2022	0	0	0	0	0
South Dakota	9/1/2022	0	0	0	0	0
South Dakota	10/1/2022	0	0	0	0	0
South Dakota	11/1/2022	0	0	0	0	0
South Dakota	12/1/2022	0	0	0	0	0
South Dakota	1/1/2023	0	0	0	0	0
South Dakota	2/1/2023	0	0	0	0	0
South Dakota	3/1/2023	0	0	0	0	0
South Dakota	4/1/2023	0	0	0	0	0
South Dakota	5/1/2023	0	0	0	0	0
South Dakota	6/1/2023	0	0	0	0	0
South Dakota	7/1/2023	10	0	10	10	0
South Dakota	8/1/2023	10	0	10	10	0
South Dakota	9/1/2023	10	0	10	10	0
South Dakota	10/1/2023	20	0	20	20	0
South Dakota	11/1/2023	20	0	20	20	0
South Dakota	12/1/2023	20	0	20	20	0
South Dakota	1/1/2024	30	0	30	30	0
South Dakota	2/1/2024	20	0	20	20	0
South Dakota	3/1/2024	20	0	20	20	0
South Dakota	4/1/2024	20	0	20	20	0
South Dakota	5/1/2024	30	0	30	30	0
South Dakota	6/1/2024	30	0	30	30	0
South Dakota	7/1/2024	30	0	30	30	0
South Dakota	8/1/2024	30	0	30	30	0
South Dakota	9/1/2024	20	0	20	20	0
South Dakota	10/1/2024	40	0	40	40	0
South Dakota	11/1/2024	40	0	40	40	0
South Dakota	12/1/2024	40	0	40	40	0
Tennessee	4/1/2022	1,190	1,190	0	0	0
Tennessee	5/1/2022	1,220	1,220	0	0	0
Tennessee	6/1/2022	1,040	1,040	0	0	0
Tennessee	7/1/2022	280	280	0	0	0
Tennessee	8/1/2022	250	250	0	0	0
Tennessee	9/1/2022	0	0	0	0	0
Tennessee	10/1/2022	0	0	0	0	0
Tennessee	11/1/2022	0	0	0	0	0
Tennessee	12/1/2022	0	0	0	0	0
Tennessee	1/1/2023	0	0	0	0	0

Tennessee	2/1/2023	0	0	0	0	0
Tennessee	3/1/2023	0	0	0	0	0
Tennessee	4/1/2023	0	0	0	0	0
Tennessee	5/1/2023	0	0	0	0	0
Tennessee	6/1/2023	0	0	0	0	0
Tennessee	7/1/2023	230	0	230	230	0
Tennessee	8/1/2023	270	0	270	270	0
Tennessee	9/1/2023	260	0	260	260	0
Tennessee	10/1/2023	310	0	310	310	0
Tennessee	11/1/2023	390	0	390	390	0
Tennessee	12/1/2023	360	0	360	360	0
Tennessee	1/1/2024	420	0	420	420	0
Tennessee	2/1/2024	380	0	380	380	0
Tennessee	3/1/2024	440	0	440	440	0
Tennessee	4/1/2024	460	0	460	460	0
Tennessee	5/1/2024	470	0	470	470	0
Tennessee	6/1/2024	450	0	450	450	0
Tennessee	7/1/2024	530	0	530	530	0
Tennessee	8/1/2024	400	0	400	400	0
Tennessee	9/1/2024	460	0	460	460	0
Tennessee	10/1/2024	550	0	550	550	0
Tennessee	11/1/2024	640	0	640	640	0
Tennessee	12/1/2024	670	0	670	670	0
Texas	4/1/2022	3,190	3,190	0	0	0
Texas	5/1/2022	2,990	2,990	0	0	0
Texas	6/1/2022	2,600	2,600	0	0	0
Texas	7/1/2022	70	70	0	0	0
Texas	8/1/2022	0	0	0	0	0
Texas	9/1/2022	0	0	0	0	0
Texas	10/1/2022	0	0	0	0	0
Texas	11/1/2022	10	10	0	0	0
Texas	12/1/2022	0	0	0	0	0
Texas	1/1/2023	10	10	0	0	0
Texas	2/1/2023	0	0	0	0	0
Texas	3/1/2023	10	10	0	0	0
Texas	4/1/2023	0	0	0	0	0
Texas	5/1/2023	10	10	0	0	0
Texas	6/1/2023	0	0	0	0	0
Texas	7/1/2023	1,780	10	1,770	1,770	0
Texas	8/1/2023	1,690	10	1,680	1,680	0
Texas	9/1/2023	1,780	10	1,770	1,770	0
Texas	10/1/2023	2,260	0	2,260	2,260	0
Texas	11/1/2023	2,410	10	2,400	2,400	0
Texas	12/1/2023	2,540	0	2,540	2,540	0

Texas	1/1/2024	2,920	10	2,910	2,910	0
Texas	2/1/2024	2,650	0	2,650	2,650	0
Texas	3/1/2024	2,850	10	2,840	2,840	0
Texas	4/1/2024	2,880	20	2,860	2,860	0
Texas	5/1/2024	2,720	0	2,720	2,720	0
Texas	6/1/2024	2,820	0	2,820	2,820	0
Texas	7/1/2024	3,100	10	3,090	3,090	0
Texas	8/1/2024	2,780	10	2,770	2,770	0
Texas	9/1/2024	2,870	0	2,870	2,870	0
Texas	10/1/2024	3,150	10	3,140	3,140	0
Texas	11/1/2024	3,150	0	3,150	3,150	0
Texas	12/1/2024	4,000	10	3,990	3,990	0
Utah	4/1/2022	320	320	0	0	0
Utah	5/1/2022	400	400	0	0	0
Utah	6/1/2022	360	360	0	0	0
Utah	7/1/2022	270	270	0	0	0
Utah	8/1/2022	310	310	0	0	0
Utah	9/1/2022	320	320	0	0	0
Utah	10/1/2022	280	280	0	0	0
Utah	11/1/2022	320	320	0	0	0
Utah	12/1/2022	340	340	0	0	0
Utah	1/1/2023	360	360	0	0	0
Utah	2/1/2023	340	340	0	0	0
Utah	3/1/2023	400	400	0	0	0
Utah	4/1/2023	340	340	0	0	0
Utah	5/1/2023	310	310	0	0	0
Utah	6/1/2023	330	330	0	0	0
Utah	7/1/2023	410	360	50	50	0
Utah	8/1/2023	390	330	60	60	0
Utah	9/1/2023	400	350	50	50	0
Utah	10/1/2023	380	310	70	70	0
Utah	11/1/2023	440	350	90	90	0
Utah	12/1/2023	380	300	80	80	0
Utah	1/1/2024	450	360	90	90	0
Utah	2/1/2024	420	340	80	80	0
Utah	3/1/2024	420	350	70	70	0
Utah	4/1/2024	440	330	110	110	0
Utah	5/1/2024	460	370	90	90	0
Utah	6/1/2024	400	320	80	80	0
Utah	7/1/2024	510	420	90	90	0
Utah	8/1/2024	420	340	80	80	0
Utah	9/1/2024	430	350	80	80	0
Utah	10/1/2024	470	360	110	110	0
Utah	11/1/2024	490	350	140	140	0

Utah	12/1/2024	470	360	110	110	0
Vermont	4/1/2022	120	100	20	20	0
Vermont	5/1/2022	140	120	20	20	0
Vermont	6/1/2022	130	110	20	20	0
Vermont	7/1/2022	130	110	20	20	0
Vermont	8/1/2022	150	130	20	20	0
Vermont	9/1/2022	130	110	20	20	0
Vermont	10/1/2022	120	100	20	20	0
Vermont	11/1/2022	130	110	20	20	0
Vermont	12/1/2022	120	90	30	30	0
Vermont	1/1/2023	150	130	20	20	0
Vermont	2/1/2023	120	100	20	20	0
Vermont	3/1/2023	150	120	30	30	0
Vermont	4/1/2023	140	120	20	20	0
Vermont	5/1/2023	200	180	20	20	0
Vermont	6/1/2023	140	130	10	10	0
Vermont	7/1/2023	120	90	30	20	10
Vermont	8/1/2023	160	130	30	20	10
Vermont	9/1/2023	130	100	30	20	10
Vermont	10/1/2023	140	120	20	10	10
Vermont	11/1/2023	140	110	30	20	10
Vermont	12/1/2023	150	120	30	20	10
Vermont	1/1/2024	150	120	30	20	10
Vermont	2/1/2024	160	130	30	20	10
Vermont	3/1/2024	160	120	40	30	10
Vermont	4/1/2024	160	120	40	30	10
Vermont	5/1/2024	160	130	30	20	10
Vermont	6/1/2024	140	120	20	20	0
Vermont	7/1/2024	170	150	20	20	0
Vermont	8/1/2024	130	110	20	20	0
Vermont	9/1/2024	150	130	20	20	0
Vermont	10/1/2024	170	140	30	30	0
Vermont	11/1/2024	140	110	30	30	0
Vermont	12/1/2024	140	120	20	20	0
Virginia	4/1/2022	2,180	1,990	190	190	0
Virginia	5/1/2022	2,230	2,030	200	200	0
Virginia	6/1/2022	2,430	2,200	230	230	0
Virginia	7/1/2022	2,650	2,330	320	320	0
Virginia	8/1/2022	2,210	1,900	310	310	0
Virginia	9/1/2022	2,260	1,880	380	380	0
Virginia	10/1/2022	2,320	1,940	380	380	0
Virginia	11/1/2022	1,980	1,530	450	450	0
Virginia	12/1/2022	2,050	1,570	480	480	0
Virginia	1/1/2023	3,130	2,610	520	520	0

Virginia	2/1/2023	2,860	2,420	440	440	0
Virginia	3/1/2023	3,110	2,630	480	480	0
Virginia	4/1/2023	3,030	2,540	490	490	0
Virginia	5/1/2023	3,000	2,510	490	490	0
Virginia	6/1/2023	2,960	2,370	590	590	0
Virginia	7/1/2023	2,720	1,970	750	670	80
Virginia	8/1/2023	3,050	2,270	780	660	120
Virginia	9/1/2023	2,950	2,200	750	620	130
Virginia	10/1/2023	2,840	2,010	830	700	130
Virginia	11/1/2023	2,750	1,920	830	710	120
Virginia	12/1/2023	3,030	2,140	890	740	150
Virginia	1/1/2024	3,720	2,690	1,030	880	150
Virginia	2/1/2024	3,460	2,650	810	680	130
Virginia	3/1/2024	3,730	2,940	790	710	80
Virginia	4/1/2024	3,390	2,580	810	730	80
Virginia	5/1/2024	3,900	3,040	860	710	150
Virginia	6/1/2024	3,580	2,740	840	700	140
Virginia	7/1/2024	3,630	2,710	920	750	170
Virginia	8/1/2024	3,620	2,740	880	790	90
Virginia	9/1/2024	3,210	2,390	820	740	80
Virginia	10/1/2024	3,380	2,640	740	630	110
Virginia	11/1/2024	3,230	2,340	890	800	90
Virginia	12/1/2024	3,260	2,320	940	860	80
Washington	4/1/2022	1,790	1,640	150	150	0
Washington	5/1/2022	1,740	1,550	190	190	0
Washington	6/1/2022	1,960	1,680	280	280	0
Washington	7/1/2022	1,760	1,510	250	250	0
Washington	8/1/2022	1,910	1,650	260	260	0
Washington	9/1/2022	1,960	1,730	230	230	0
Washington	10/1/2022	1,950	1,710	240	240	0
Washington	11/1/2022	1,770	1,510	260	260	0
Washington	12/1/2022	1,880	1,560	320	320	0
Washington	1/1/2023	2,060	1,730	330	330	0
Washington	2/1/2023	1,920	1,670	250	250	0
Washington	3/1/2023	2,100	1,840	260	260	0
Washington	4/1/2023	1,880	1,570	310	310	0
Washington	5/1/2023	2,020	1,710	310	310	0
Washington	6/1/2023	2,010	1,720	290	290	0
Washington	7/1/2023	1,920	1,520	400	400	0
Washington	8/1/2023	2,060	1,670	390	370	20
Washington	9/1/2023	1,840	1,520	320	310	10
Washington	10/1/2023	2,030	1,650	380	350	30
Washington	11/1/2023	1,940	1,580	360	340	20
Washington	12/1/2023	1,950	1,610	340	320	20

Washington	1/1/2024	2,250	1,860	390	370	20
Washington	2/1/2024	2,080	1,760	320	300	20
Washington	3/1/2024	2,070	1,720	350	340	10
Washington	4/1/2024	2,040	1,720	320	290	30
Washington	5/1/2024	2,120	1,810	310	290	20
Washington	6/1/2024	1,880	1,610	270	250	20
Washington	7/1/2024	2,090	1,800	290	280	10
Washington	8/1/2024	1,970	1,650	320	300	20
Washington	9/1/2024	1,840	1,590	250	250	0
Washington	10/1/2024	1,840	1,540	300	280	20
Washington	11/1/2024	1,910	1,550	360	350	10
Washington	12/1/2024	2,020	1,620	400	390	10
West Virginia	4/1/2022	90	90	0	0	0
West Virginia	5/1/2022	120	120	0	0	0
West Virginia	6/1/2022	110	110	0	0	0
West Virginia	7/1/2022	30	30	0	0	0
West Virginia	8/1/2022	80	80	0	0	0
West Virginia	9/1/2022	20	20	0	0	0
West Virginia	10/1/2022	0	0	0	0	0
West Virginia	11/1/2022	0	0	0	0	0
West Virginia	12/1/2022	0	0	0	0	0
West Virginia	1/1/2023	0	0	0	0	0
West Virginia	2/1/2023	0	0	0	0	0
West Virginia	3/1/2023	0	0	0	0	0
West Virginia	4/1/2023	0	0	0	0	0
West Virginia	5/1/2023	0	0	0	0	0
West Virginia	6/1/2023	0	0	0	0	0
West Virginia	7/1/2023	40	10	30	30	0
West Virginia	8/1/2023	30	0	30	30	0
West Virginia	9/1/2023	30	0	30	30	0
West Virginia	10/1/2023	40	0	40	40	0
West Virginia	11/1/2023	40	0	40	40	0
West Virginia	12/1/2023	40	0	40	40	0
West Virginia	1/1/2024	60	0	60	60	0
West Virginia	2/1/2024	50	0	50	50	0
West Virginia	3/1/2024	50	0	50	50	0
West Virginia	4/1/2024	60	0	60	60	0
West Virginia	5/1/2024	50	0	50	50	0
West Virginia	6/1/2024	50	0	50	50	0
West Virginia	7/1/2024	50	0	50	50	0
West Virginia	8/1/2024	50	0	50	50	0
West Virginia	9/1/2024	70	0	70	70	0
West Virginia	10/1/2024	70	0	70	70	0
West Virginia	11/1/2024	80	0	80	80	0

West Virginia	12/1/2024	80	0	80	80	0
Wisconsin	4/1/2022	580	580	0	0	0
Wisconsin	5/1/2022	720	700	20	20	0
Wisconsin	6/1/2022	480	470	10	10	0
Wisconsin	7/1/2022	20	0	20	20	0
Wisconsin	8/1/2022	10	0	10	10	0
Wisconsin	9/1/2022	20	0	20	20	0
Wisconsin	10/1/2022	10	0	10	10	0
Wisconsin	11/1/2022	20	0	20	20	0
Wisconsin	12/1/2022	20	0	20	20	0
Wisconsin	1/1/2023	20	0	20	20	0
Wisconsin	2/1/2023	20	0	20	20	0
Wisconsin	3/1/2023	50	0	50	50	0
Wisconsin	4/1/2023	10	0	10	10	0
Wisconsin	5/1/2023	10	0	10	10	0
Wisconsin	6/1/2023	10	0	10	10	0
Wisconsin	7/1/2023	110	0	110	110	0
Wisconsin	8/1/2023	120	0	120	120	0
Wisconsin	9/1/2023	170	60	110	110	0
Wisconsin	10/1/2023	380	250	130	130	0
Wisconsin	11/1/2023	470	340	130	130	0
Wisconsin	12/1/2023	420	260	160	160	0
Wisconsin	1/1/2024	550	400	150	150	0
Wisconsin	2/1/2024	490	350	140	140	0
Wisconsin	3/1/2024	600	460	140	140	0
Wisconsin	4/1/2024	570	410	160	160	0
Wisconsin	5/1/2024	590	420	170	170	0
Wisconsin	6/1/2024	470	330	140	140	0
Wisconsin	7/1/2024	670	460	210	210	0
Wisconsin	8/1/2024	480	290	190	190	0
Wisconsin	9/1/2024	460	280	180	180	0
Wisconsin	10/1/2024	530	300	230	230	0
Wisconsin	11/1/2024	600	340	260	260	0
Wisconsin	12/1/2024	630	390	240	240	0
Wyoming	4/1/2022	50	10	40	40	0
Wyoming	5/1/2022	50	10	40	40	0
Wyoming	6/1/2022	60	20	40	40	0
Wyoming	7/1/2022	60	20	40	40	0
Wyoming	8/1/2022	50	20	30	30	0
Wyoming	9/1/2022	70	20	50	50	0
Wyoming	10/1/2022	50	10	40	40	0
Wyoming	11/1/2022	50	20	30	30	0
Wyoming	12/1/2022	60	20	40	40	0
Wyoming	1/1/2023	60	20	40	40	0

Wyoming	2/1/2023	50	20	30	30	0
Wyoming	3/1/2023	60	20	40	40	0
Wyoming	4/1/2023	60	20	40	40	0
Wyoming	5/1/2023	80	40	40	40	0
Wyoming	6/1/2023	80	40	40	40	0
Wyoming	7/1/2023	60	30	30	30	0
Wyoming	8/1/2023	80	50	30	30	0
Wyoming	9/1/2023	70	40	30	30	0
Wyoming	10/1/2023	80	50	30	30	0
Wyoming	11/1/2023	80	40	40	40	0
Wyoming	12/1/2023	80	50	30	30	0
Wyoming	1/1/2024	90	40	50	50	0
Wyoming	2/1/2024	70	30	40	30	10
Wyoming	3/1/2024	100	60	40	40	0
Wyoming	4/1/2024	80	40	40	40	0
Wyoming	5/1/2024	70	30	40	30	10
Wyoming	6/1/2024	70	30	40	30	10
Wyoming	7/1/2024	60	30	30	30	0
Wyoming	8/1/2024	80	50	30	20	10
Wyoming	9/1/2024	80	50	30	30	0
Wyoming	10/1/2024	90	40	50	40	10
Wyoming	11/1/2024	70	30	40	30	10
Wyoming	12/1/2024	80	30	50	40	10