

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

## MAYDAY HEALTH,

*Plaintiff,*

V.

**MARTY J. JACKLEY**, Attorney General for the State of South Dakota in his official capacity,

*Defendant.*

1:26-cv-00078-KPF

## **REFENDANT'S MEMORANDUM OF LAW RE: YOUNGER ABSTENTION**

Defendant Marty J. Jackley, *pro se* and by and through his counsel Paul S. Swedlund and Amanda J. Miiller, hereby files this response to this court's request for a memorandum of law on *Younger* abstention.

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## INTRODUCTION

Our federal system of government exists to respect the social and cultural differences between states. Thus, citing the “proper respect for state functions” and the core principle of our federal structure that the nation “will fare best if the states and their institutions are left free to perform their separate functions,” the court in *Simopoulos v. Virginia Bd. of Med.*, 644 F.2d 321, 325 (4<sup>th</sup> Cir. 1981), abstained on *Younger* grounds from hearing a Virginia doctor’s 42 U.S.C. § 1983 challenge to his de-licensing for performing an illegal abortion on a minor. In Mayday’s home state of New York, abortion is accepted; in South Dakota it is not. *Dobbs v. Jackson Women’s Health Org.*, 597 U.S. 215, 217 (2022) (“the people of the various states may evaluate [abortion] interests differently”).

Mayday claims simply to “help” those in search of medical information, which may be true as applied to some of its activities in states where abortion is legal, but Mayday’s “help,” particularly the means it employs to “help,” is something altogether different as applied to states where abortion is illegal. In a state like South Dakota, which has laws against abortion and abortion pills, Mayday’s “help” violates the state’s civil and criminal laws. Which is precisely why Mayday targets its activities toward abortion-illegal states – to aid and abet women<sup>1</sup> and abortionists to skirt South Dakota’s laws . . . without telling them that in truth they are being solicited to solicit an illegal act and to engage in medically risky and potentially life-threatening behavior.

Abortion is a divisive issue that unavoidably colors one’s views of laws which permit or prohibit it. Americans strongly disagree about abortion. But almost nobody disagrees that child

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<sup>1</sup> An assumption underlies Mayday’s business model that every woman who makes abortion inquiries wants an abortion. There is abundant data that in a statistically significant number of cases, women are being pressured into abortions by male partners, family members, or economic circumstances. But it does not “help” a woman to facilitate an abortion she does not want. These dynamics in abortion decision making reveal that that Mayday’s premise of “helping” all women who log onto its site is not categorically true.

pornography or sexual intercourse with children is wrong. So, to put the matter in stark perspective, if Mayday's services were directed toward connecting pedophiles with child pornography or children, nobody could seriously contend it had a First Amendment right to do so. *Pittsburgh Press Co. v. Pittsburgh Human Rel. Comm'n*, 413 U.S. 376, 388 (1973) ("no doubt that a newspaper constitutionally could be forbidden to publish a want ad . . . soliciting prostitutes"). Nobody could seriously contend that a state does not have the absolute right to shut down advertising that is a conduit to platforms that supply child pornography or children to pedophiles, or sex-trafficked women to pimps, or contract killers to bitter ex-husbands, or methamphetamine to addicts. Though Mayday obviously does not see it in such terms, to South Dakota and South Dakotans the state has the same interest in keeping unborn children from the hands of abortionists as it does in keeping born children from the hands of pedophiles. It is a core social and cultural value which our federal system recognizes and protects through myriad constitutional and legal mechanisms, the *Younger* doctrine among them. *Simopoulos*, 644 F.2d at 325.

So, it is necessary to scrutinize the means Mayday employs to "help" South Dakota women in order to exercise informed judgment about the laws the state is enforcing here.

## **MAYDAY'S WEBSITE**

In early December 2025, Mayday posted this placard at gas stations throughout South Dakota:



KLEMMAN AFFIDAVIT, Exhibit A at Exhibits 1, 2. At a press conference, Mayday crowed that it was targeting South Dakota for this advertisement campaign “due to the state’s strict abortion laws.” KLEMMAN AFFIDAVIT, Exhibit A at Exhibit 2.

When a consumer accesses the [MAYDAY.HEALTH](#) website posted on the placard, a banner question asks “What do you need?” KLEMMAN AFFIDAVIT, Exhibit A at Exhibit 8. Below this are four clickable links to choose from: abortion, morning after pills, birth control and gender-affirming care. KLEMMAN AFFIDAVIT, Exhibit A at Exhibit 9. If the consumer selects “abortion,” they are asked how long it has been since their last period. KLEMMAN AFFIDAVIT, Exhibit A at Exhibit 9. The answer to this question prompts a series of questions that lead to different abortion options depending on the woman’s length of pregnancy. This is likely because the FDA has only approved abortion-inducing pills (medicinal abortion) for pregnant women “through ten weeks gestation.”<sup>2</sup> Abortions performed after the twelfth week of pregnancy necessitate an in-clinic surgical procedure to abort the baby.

If “more than 12 weeks” is selected, consumers are directed to a linked website, [ineedana.com](#) (as in “I need an abortion”), where they are told that “No matter what state you live in you still have options.” KLEMMAN AFFIDAVIT, Exhibit A at Exhibit 11. A clickable link prompting consumers to “Search your options now” leads to a page where a consumer is asked what city she lives in, the first day of her last period and her age. KLEMMAN AFFIDAVIT, Exhibit A at Exhibit 12. No matter what combination of information is entered into these fields (*i.e.* South Dakota addresses, date of last period, age) the consumer is always given three options:

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<sup>2</sup> U.S. Food and Drug Administration, *Information About Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation> (last visited December 21, 2025). KLEMMAN AFFIDAVIT, Exhibit A at Exhibit 10.

driving directions to the nearest out-of-state abortion clinic that can perform surgical abortion, a link to “order abortion pills online” to self-induce a medicinal abortion at home, and the option to fly to another state that performs surgical abortions. KLEMANN AFFIDAVIT, Exhibit A at Exhibit 13.

The only exception to the options offered is when a consumer identifies as a minor. The minor will see the same options as adult consumers but they are shown a disclaimer that says “You are a minor. If you decide to travel for care, you may face additional barriers as a teen. Learn more in our Guide for Teens.” KLEMANN AFFIDAVIT, Exhibit A at Exhibit 14.

The “Guide for Teens” is deceptive by commission and omission. Children are advised that “[a]bortion is safe, normal and any reason to have one is a good reason.” KLEMANN AFFIDAVIT, Exhibit A at Exhibit 15. The website specifically instructs a child to self-induce an abortion at home by having abortion-inducing pills sent to their home “or to a trusted friend or family member” or to travel to a state that does not have parental consent laws so she can obtain an abortion without parental consent or judicial oversight required by South Dakota law. KLEMANN AFFIDAVIT, Exhibit A at Exhibit 16; SDCL 34-23A-7. But Mayday makes even more deceptive and inaccurate representations to consumers who click on “less than 12 weeks.”

Circling back to the fork of the decision tree on [MAYDAY.HEALTH](#)’s main website, consumers who select “less than 12 weeks” are directed to a screen that asks if the consumer lives in a “red state” which are detailed on a map below the question. KLEMANN AFFIDAVIT, Exhibit A at Exhibit 17. South Dakota is identified as a “red state.” KLEMANN AFFIDAVIT, Exhibit A at Exhibit 18. If the “red state” option is selected, the consumer is directed to a page that lists five separate abortion pill providers, four of whom proclaim in all caps that they are willing to “SHIP TO ALL 50 STATES.” KLEMANN AFFIDAVIT, Exhibit A at Exhibit 17. There is nowhere a

disclaimer, as there is on surgical abortion pages, that medicinal abortions and shipping pills into South Dakota for that purpose are illegal.

SDCL 22-17-5.1 provides that it is illegal to mail abortion-inducing pills into the South Dakota. Per that statute, “any person who administers to any pregnant female or who prescribes or procures for any pregnant female any medicine, drug, or substance . . . to procure an abortion . . . is guilty of a Class 6 felony.” [MAYDAY.HEALTH](#)’s placards and website are the first links in the abortion pill procurement chain. One of [MAYDAY.HEALTH](#)’s platforms (Abuzz) tells a consumer that she may perform her own at-home medicinal abortion if she is less than “13 weeks pregnant,” which is 91 days since the first day of her last period. KLEMANN AFFIDAVIT, Exhibit A at Exhibit 19. However, the FDA has only approved the use of medicinal abortion pills “through ten weeks gestation (70 days or less since the first day of a patient’s last menstrual period). KLEMANN AFFIDAVIT, Exhibit A at Exhibit 10.

If a South Dakota consumer seeks to obtain abortion-inducing pills from Abuzz, a disclaimer purports to provide “information about the potential legal risks of getting abortion pills by mail.” KLEMANN AFFIDAVIT, Exhibit A at Exhibit 20. But Abuzz does not require a consumer to click on and review the “legal risks” screen so a consumer can order medicinal abortion drugs without ever laying eyes on Abuzz’s “disclaimer” or affirming that they have read it. But if a consumer does click on the “legal risks” link, they are directed to another [MAYDAY.HEALTH](#) platform, [plancpills.org](#), which under the heading “Is this legal? Can someone get in trouble for using abortion pills?” deceptively informs consumers that “[r]esearch shows that hundreds of thousands of people have received pills by mail over the past few years with no legal problems.” This, of course, is no answer at all. KLEMANN AFFIDAVIT, Exhibit A at Exhibit 22. It does not inform a South Dakota consumer that, yes, mailing abortion-inducing pills into South Dakota by mail is illegal. It does not inform a South Dakota consumer what proportion of

those “hundreds of thousands of people” are from abortion-legal states where mailing abortion pills creates “no legal problems.” It does not inform a South Dakota consumer of any knowledge [plancpills.org](#) has of “legal problems” some women have experienced. Nor does it inform a consumer that, while she herself would not be prosecuted under South Dakota law, “someone” – the pill provider – could be, in which case she could become a witness in criminal proceedings against the pill provider. Worse, under a link to “How do people get in trouble,” [plancpills.org](#) confides that it is because:

- They told someone about their abortion and that person reported them.
- They got follow-up medical care and the provider reported them (many people say they are having a miscarriage to avoid this risk, which is medically what is happening to the body).
- They were later in pregnancy than they thought and didn’t know what to do with the fetal tissue.

KLEMAN AFFIDAVIT, Exhibit A at Exhibit 23. The second bullet point reflects that Mayday is aware of risks that could require life-saving follow-up care that it is not telling consumers about. Instead of forthrightly informing a South Dakota consumer that “people get in trouble” when they do something that is illegal in their state or of the risks that make medicinal abortion not entirely “safe,” [plancpills.org](#) provides a primer on how to conceal their participation in the crime of mailing abortion-inducing pills into the state, even to the point of encouraging inaccurate medical reporting that may misdirect medical treatment at the expense of the woman’s health.

Another [MAYDAY.HEALTH](#) pill platform, Aid Access, informs consumers that they are eligible to self-induce an at home using medicinal abortion pills in the fourteenth week of their pregnancy, and that this is “very safe.” KLEMAN AFFIDAVIT, Exhibit A at Exhibit 24. However, the FDA has only approved the use of medicinal abortion pills “through ten weeks gestation,” meaning that use at up to 12-14 weeks as Mayday suggests is inherently unsafe. KLEMAN AFFIDAVIT, Exhibit A at Exhibit 10. [MAYDAY.HEALTH](#) does not inform

consumers that the FDA has issued warning letters to Aid Access for selling unapproved and misbranded abortion-inducing pills over the internet, nor does Aid Access disclose this information on its website. KLEMANN AFFIDAVIT, Exhibit A at Exhibit 25, 26. Aid Access does not inform South Dakota consumers that it is illegal to mail medicinal abortion pills into South Dakota. Instead, it cites to consumer testimonials collected by the World Health Organization which have no relevance to the legality of shipping medicinal abortion pills into South Dakota. KLEMANN AFFIDAVIT, Exhibit A at Exhibit 27.

Despite a disclaimer on its website that it “do[es] not give legal or medical advice” (even as it doles out heaping helpings of both), [MAYDAY.HEALTH](#) represents to consumers that its “information comes from top clinicians, lawyers and health experts” and “trusted organizations” it consults for legal and medical advice. KLEMANN AFFIDAVIT, Exhibit A at Exhibit 28, 29. This is repeated on [MAYDAY.HEALTH](#)’s FAQ page where it vouches that the links and platforms on its website “have the best content for a certain aspect of abortion care” and that they “only link to other trusted websites and partners.” KLEMANN AFFIDAVIT, Exhibit A at Exhibit 30.

As for [MAYDAY.HEALTH](#)’s own website, it claims without qualification that “abortion pills are safe and effective during the first 12 weeks” of pregnancy and that “[i]t is safe to do your own abortion at home with abortion pills.” KLEMANN AFFIDAVIT, Exhibit A at Exhibit 30. However, the FDA advises that “[i]n about 1 out of 100 women, bleeding can be so heavy that it requires a surgical procedure” to stop.<sup>3</sup> The FDA’s warnings concerning the use of abortion-inducing drugs caution that they carry risks of bacterial infection, rare cases of fatal septic shock, uterine bleeding potentially requiring surgical intervention and that medicinal abortion pills are

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<sup>3</sup> U.S. Food and Drug Administration, Labeling Information for Mifepristone, [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2023/0206870rig1s025Lbl.pdf#page=16](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/0206870rig1s025Lbl.pdf#page=16) (last visited December 21, 2025). KLEMANN AFFIDAVIT, Exhibit A at Exhibit 31.

“available only through a restricted program . . . because of the risks of serious complications.” KLEMANN AFFIDAVIT, Exhibit A at Exhibit 31. Medicinal abortion pills also entail adverse side effects such as infection and infestation (endometritis, endomyometritis, parametritis, pelvic inflammation or infection, salpingitis) and reproductive system and breast disorders (uterine rupture, ruptured ectopic pregnancy, hemotometra, leukorrhea), as well as risks of birth defects and abnormalities for unborn children should the pills fail to induce abortion. A recent study of “real-world insurance claims data for 865,727 prescribed mifepristone abortions” revealed a “serious adverse event rate of 10.93 percent.”<sup>4</sup> But neither the FDA’s warnings nor the adverse effects of these drugs on women or unborn children are mentioned on [MAYDAY.HEALTH](#)’s website.

These facts reveal that [MAYDAY.HEALTH](#), with the active assistance of its platform affiliates, engages in deceptive trade practices and acts in violation of SDCL 37-24-6(1), including but not limited to:

- Claiming that medicinal abortion is safe yet linking to websites that provide abortion-inducing pills well beyond the FDA-recommended gestational period.
- Instructing women and teenaged girls in how to obtain abortion-inducing pills without warning them that the pills are illegal in this state.
- Instructing teenaged girls how to leave the state for an abortion and obtain abortion pills without their parent’s knowledge or consent.
- Informing teenaged girls that abortions are “safe” and “normal” for “any reason” without warning that there is a 1 in 10 risk of severe complications associated with medicinal abortions.
- Counseling women and teenaged girls to conceal their abortions and not seek follow-up medical care relating to abortion complications so that they or “someone,” such as Mayday and its affiliates, does not “get in trouble,” thereby putting females at risk of adverse reactions, side effects, hemorrhaging, infections, septic shock or even death.

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<sup>4</sup> Hall & Anderson, *The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event*, Ethics and Public Policy Center (April 28, 2025) <https://tinyurl.com/wxhfsfdf>.

- Omitting any of the FDA's warnings while claiming that "abortion pills are safe [and] effective" and that "[i]t is safe to do your own abortion at home" with abortion pills.

## ARGUMENT

Per *Younger v. Harris*, 401 U.S. 37 (1971), a federal court must abstain from enjoining a state civil or criminal judicial proceeding if (1) there is an ongoing state judicial proceeding to (2) enforce an important state interest and (3) the pending state proceeding provides an adequate opportunity to litigate a federal plaintiff's constitutional rights. *Middlesex Cnty. Ethics Comm. v. Garden State Bar Ass'n*, 457 U.S. 423, 432-36 (1982).

### 1. *Younger* Elements Are Satisfied

The record supports this court's finding that the three *Younger* abstention elements are met here. First, under the authority to enjoin deceptive advertising and solicitations for charitable contributions granted to him per SDCL 37-24-6(1),<sup>5</sup> on December 22, 2025, the South Dakota Attorney General instituted a civil enforcement action in South Dakota state court under SDCL § 37-24-23.<sup>6</sup> But before resorting to legal action, in response to complaints from gas station owners objecting to Mayday's placards, 657 complaints to the office's Consumer Protection Division, and a request from Governor Larry Rhoden to investigate, the Attorney General sent Mayday a letter demanding that it cease and desist from the deceptive advertising on its placards. KLEMANN

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<sup>5</sup> SDCL 37-24-6(1) provides that "it is a deceptive act or practice for any person to . . . [k]nowingly act, use, or employ any deceptive act or practice, fraud, false pretense, false promises, or misrepresentation or to conceal, suppress, or omit any material fact in connection with the sale or advertisement of any merchandise or the solicitation of contributions for charitable purposes, regardless of whether any person has in fact been misled, deceived, or damaged thereby."

<sup>6</sup> SDCL 37-24-23 provides that "[i]f the attorney general has reason to believe that any person is using, has used, or is about to use any act or practice declared to be unlawful by § 37-24-6 and that proceedings would be in the public interest, the attorney general may bring an action in the name of the state against the person to restrain by temporary or permanent injunction the use of the act or practice, upon the giving of appropriate notice to that person. The notice shall state generally the relief sought and be served in accordance with § 37-24-16 and at least three days before any hearing in the action. The attorney general, if the prevailing plaintiff, may also recover reasonable attorney's fees and costs."

AFFIDAVIT, Exhibit A at Exhibit G. The letter did not demand that Mayday change the content of its website, only that it take its advertisements down. Mayday refused to take the advertisements down on the ground that it allegedly does “not sell, handle, provide, offer for sale, or benefit from the sale of abortion medication, and it has no customers.” KLEMANN AFFIDAVIT, Exhibit A at Exhibit 4. The South Dakota Attorney General served proper notice to Mayday for the civil enforcement action on January 10, 2026, under service rules outlined in SDCL 37-24-16. Mayday’s South Dakota counsel, Jim Leach, has also accepted service of the Attorney General’s pleadings and has entered his appearance in the case. That action is currently set for a hearing in South Dakota state court on February 20, 2026.

Second, the ongoing state proceeding undeniably implicates the state’s important interests in the health and safety of pregnant women, the life or potential life of the unborn, and promoting respect for human life at all stages of a pregnancy. *Planned Parenthood v. Casey*, 112 S.Ct. 2791, 2817 (1992); *Gonzales v. Carhart*, 127 S.Ct. 1610, 1626, 1643 (2007). In furtherance of these interests a “state may take measures to ensure that the woman’s choice is informed” and adopt policies to encourage women “to choose childbirth over abortion.” *Casey*, 112 S.Ct. at 2821, 2825. The ongoing state proceeding implicates the state’s interest in enforcing duly enacted measures to achieve the ends of its pro-life statutes. *Abott v. Perez*, 138 S.Ct. 2305, 2324 n. 17 (2018).

Third, the pending state proceeding affords Mayday an adequate opportunity to litigate arguments concerning its First Amendment rights. Basic “respect for the state processes, of course, precludes any presumption that the state courts will not safeguard federal constitutional rights.” *Middlesex Ethics Comm.*, 457 U.S. at 431. And “the burden on this point rests on the federal plaintiff to show ‘that state procedural law barred presentation of [its] claims.’” *Pennzoil Co. v. Texaco, Inc.*, 481 U.S. 1, 14 (1987), quoting *Moore v. Sims*, 442 U.S. 415, 432 (1979). Mayday has not and cannot show any barrier to adjudication of its First Amendment arguments in the state

court. Abstention is appropriate when, as here, “every substantial constitutional issue raised or which can be raised by [federal] plaintiffs . . . can be adjudicated by the” state court. *Ryan v. Specter*, 332 F.Supp. 26 (E.D.Pa. 1971)(abstaining from action to enjoin enforcement of state abortion statutes when constitutional challenges to those statutes were pending in state court). Thus, this court correctly ruled that the *Younger* abstention elements are met here. *Middlesex Ethics Comm.*, 457 U.S. at 432-36.

## **2. Exceptional Circumstances Do Not Exist**

Even though this court found the *Younger* abstention elements met, the court entered a temporary restraining order and requested briefing from the state regarding whether extraordinary circumstances existed to refrain from abstention. Extraordinary circumstances are not present here because (1) the Attorney General’s enforcement action does not actually implicate or infringe on protected First Amendment interests and (2) the Attorney General is properly seeking to enforce state consumer laws protecting residents from deceptive advertising and solicitations and in aid of state criminal prohibitions on the importation of illegal and dangerous drugs. Accordingly, abstention is appropriate – indeed mandated – by binding principles of federalism and comity.

A federal court must not “casually enjoin the conduct of pending state court proceedings of either (criminal or civil) type.” *Simopoulos*, 544 F.2d at 325, quoting *Cousins v. Wigoda*, 409 U.S. 1201, 1206 (1972). *Younger* exists to “allow the state an opportunity to ‘set its own house in order’ when the federal issue is already before a state tribunal.” *Simopoulos*, 544 F.2d at 326. “Only if ‘extraordinary circumstance’ render the state court incapable of fairly and fully adjudicating the federal issues before it can there be any relaxation of the deference to be accorded to the state (civil, quasi-criminal or) criminal process.” *Simopoulos*, 544 F.2d at 327-328, quoting *Kugler v. Helfant*, 421 U.S. 117, 124 (1975). Allegations of circumstances of “bad faith,” “harassment” or “official lawlessness” are extraordinary only if a “federal plaintiff’s claim for

federal relief was not such as could be resolved in a pending state proceeding.” *Simopoulos*, 544 F.2d at 328. Thus, “the centerpiece of a test for the application of *Younger* is always the adequacy of the state forum in providing the federal plaintiff an opportunity to raise his constitutional claim and, if there is, comity commands abstention by the federal court.” *Simopoulos*, 544 F.2d at 329. Thus, the bad faith exception is limited and should not be readily invoked. *Hicks v. Miranda*, 422 U.S. 332, 350 (1975).

In the free speech context, federal injunctive relief against valid, pending state enforcement actions is appropriate only when they are brought without reasonable hope of success. *Perez v. Ledsma*, 401 U.S. 82, 84 (1971). The “chilling effect” of state enforcement actions does “not by itself justify federal intervention” in state proceedings. *Younger*, 401 U.S. at 50. “[T]he existence of a ‘chilling effect,’ even in the area of First Amendment rights, has never been considered a sufficient basis, in and of itself, for prohibiting state action.” *Younger*, 401 U.S. at 51. Interference in state proceedings is not justified when “a statute does not directly abridge free speech, but – while regulating a subject within the State’s power – tends to have the incidental effect of inhibiting First Amendment rights.” *Younger*, 401 U.S. at 51. Just as “the chilling effect that admittedly can result from the very existence of certain laws on the statute books does not in itself justify prohibiting the state from carrying out the important and necessary task of enforcing these laws,” the incidental “chilling effect” of [a state enforcement action] does not automatically render [it] unconstitutional.” *Younger*, 401 U.S. at 52. If it did, any First Amendment impact would *ipso facto* be bad faith and *Younger* would be “swallowed up by its exception.” *Hicks*, 422 U.S. at 352. So, even if South Dakota’s enforcement action infringes core, non-commercial speech, a federal court must abstain because the pending state action provides an adequate forum to Mayday to assert its First Amendment rights. But Mayday’s advertisements are not core, non-commercial speech.

### **a. No Protected First Amendment Right Is At Stake**

The constitution affords commercial speech less protection than other forms of expression.

*Central Hudson Gas & Elec. Corp. v. Public Service Comm'n of New York*, 447 U.S. 557, 563 (1980). While commercial speech in general is not entirely denied protection, “commercial speech related to illegal activity,” commercial speech regarding lawful activity that “do[es] not accurately inform the public,” or commercial speech that is “more likely to deceive the public than to inform it” are entitled to no protection. *Central Hudson*, 447 U.S. at 563-564. To receive constitutional protection, commercial speech “must concern lawful activity and not be misleading.” *Central Hudson*, 447 U.S. at 564. [MAYDAY.HEALTH](#)’s website and subsidiary platforms facially flunk this test.

The Attorney General has not formally investigated the potential criminal implications of the statements and representations on Mayday’s website and has no intention of doing so provided Mayday ceases and desists from targeting South Dakota consumers with deceptive advertising and soliciting charitable contributions off these deceptive representations. However, as described above, there is no doubt that [MAYDAY.HEALTH](#)’s website messaging “relate[s] to illegal activity” in connection with soliciting consumers to solicit the importation of illegal abortion drugs into South Dakota for the facilitation of illegal abortions and is “more likely to deceive the public than to inform it” in connection with unqualified representations about abortion being “safe,” promoting dangerous off-label usage of abortion pills, encouraging teenaged girls to ingest abortion pills or travel to abortion destinations for the purpose of obtaining an abortion without parental knowledge or consent, and encouraging women and teenaged girls to not seek medical care for post-abortion complications in order to conceal the role of [MAYDAY.HEALTH](#) and its affiliates in procuring illegal abortion drugs.

Mayday argues that *Bigelow v. Virginia*, 421 U.S. 809, 826 (1975), “is controlling” and proves that South Dakota has “no legitimate interest” in regulating or suppressing elements of the [MAYDAY.HEALTH](#)’s website’s messaging. If *Bigelow* is the best Mayday can come up with, then it has effectively conceded that there is no bad faith or harassment here. All that *Bigelow* says is that Virginia law enforcement could not exercise its “internal police powers” to enjoin a Virginia newspaper from advertising that abortion was legal in New York. *Bigelow*, 421 U.S. at 824-825. If Mayday’s message was simply “Abortion is legal in Minnesota and here is a list of clinics who provide it,” then *Bigelow* would be controlling.<sup>7</sup> But read in connection with *Central Hudson*, the *Bigelow* rule only extends to an “advertiser who proposes a transaction in a state where the transaction is legal.” *Washington Mercantile Ass’n v. Williams*, 733 F.2d 687, 691 (9<sup>th</sup> Cir. 1984). Here, however, Mayday is advertising and proposing a transaction in a state where the transaction is not legal.<sup>8</sup> *Bigelow* does not afford First Amendment protection to Mayday for proposing a transaction that is illegal in South Dakota. *Cocroft v. Graham*, 122 F.4<sup>th</sup> 176, 182 (5<sup>th</sup> Cir. 2024).

Like *Bigelow*, *Nat'l Inst. of Family and Life Advocates (NIFLA) v. James*, 160 F.4<sup>th</sup> 360 (2<sup>nd</sup> Cir. 2025), does not help Mayday’s cause here despite some surface similarities. In *James*, the New York Attorney General brought an enforcement action against Heartbeat International (HBI) to enjoin allegedly misleading statements concerning the efficacy of so-called abortion

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<sup>7</sup> In fact, back when abortion was legal in South Dakota but subject to more restrictions than in Minnesota, pro-abortion groups spread this very message in South Dakota for years unrestrained by the Attorney General. They continue to do so today. The Justice Empowerment Network (JEN), like the advertisement in *Bigelow*, informs women where abortion is legal and even assists them with travel. <https://www.jensd.org/>. Unlike Mayday, so far as the Attorney General is aware JEN does not promote abortion pill usage in South Dakota or provide links to abortion pill providers or otherwise propose or facilitate an activity within South Dakota’s borders that is illegal in South Dakota. The South Dakota Attorney General has taken no steps to enjoin JEN’s *Bigelow*-protected activity. Unlike JEN, Mayday’s activity is not *Bigelow*-protected.

<sup>8</sup> Products that are “transferred electronically, or services for delivery into South Dakota” are sales consummated within the State of South Dakota and “treated as a local transaction” for jurisdictional purposes. *South Dakota v. Wayfair*, 585 U.S. 162, 177-178 (2018); *Bates v. State Bar of Arizona*, 433 U.S. 350, 378 (1977)(putting up an advertisement is “penetrating a market”).

reversal pills. *James*, 160 F.4<sup>th</sup> at 365. Like Mayday, HBI’s website provided links to abortion reversal pill providers. NIFLA brought suit to enjoin James from similarly targeting it. The *James* court ruled that NIFLA’s suit was not subject to the restrictions of *Younger* for the obvious reason that the state’s enforcement action was not against NIFLA but HBI. *James*, 160 F.4<sup>th</sup> at 369.

Also, NIFLA’s activities, though similar, were materially different from Mayday’s activities here. For one thing – and it is a big thing – the abortion reversal pill is not illegal in New York. For another, NIFLA did not fundraise off its abortion reversal pill message, taking its message out of the realm of speech motivated by direct or indirect economic gain. *James*, 160 F.4<sup>th</sup> at 377. If Mayday’s message was simply about a *legal* medication and it was not fundraising off that message, then *James* would be controlling. But, per *James*, since Mayday, unlike NIFLA, is a party in a state enforcement proceeding, this case is “squarely controlled by *Younger*.” *James*, 160 F.4<sup>th</sup> at 369. So, to the extent *Bigelow* or *James* are “controlling,” they are not controlling for any proposition that helps Mayday prove bad faith or harassment.

To the extent Mayday’s First Amendment defense enters into the *Younger* bad faith analysis, it must be analyzed in accordance with *Younger*’s deferential bad faith standard, namely was the enforcement action brought without any expectation that it could overcome a First Amendment defense. *Perez*, 401 U.S. at 84. A federal court’s function at this stage is not to adjudicate the actual merits of the First Amendment defense because the federal court does not have the evidence and record that the state court will have. A federal court’s function at this stage is simply to evaluate whether the state brought its enforcement action without any expectation of overcoming Mayday’s First Amendment defense. If not, then it is up to the state court to adjudicate the merits of Mayday’s First Amendment defense. Like New York’s, South Dakota’s state circuit courts adjudicate constitutional defenses – First Amendment, Fourth Amendment, Fifth Amendment, Sixth Amendment – all day long and so “are of course competent to adjudicate

questions of federal constitutional rights.” *Tang v. Appellate Division of New York Supreme Court*, 487 F.2d 138, 141 n.3 (2<sup>nd</sup> Cir. 1973).

Mayday’s own authorities – *Bigelow* and *James* – support the state’s position that Mayday’s website is commercial, non-protected speech. Unlike in *Bigelow*, Mayday’s website “further[s] a criminal scheme in” South Dakota that is well within the reach of the state’s “internal police powers.” *Bigelow*, 421 U.S. at 822, 824. Unlike in *James*, the pills Mayday peddles are illegal, Mayday *is* the target of the subject state enforcement action and, unlike NIFLA, Mayday fundraises off its message of providing abortion pills to states where they are illegal. *James*, 160 F.4<sup>th</sup> at 377.

Thus, both *Bigelow* and *James* soundly support South Dakota’s expectation of prevailing in its enforcement action. As a platform for procuring illegal abortion pill transactions in South Dakota, soliciting charitable contributions off deceptive representations concerning its mission in South Dakota, and providing bogus, ideology-driven medical and legal advice to South Dakotans, Mayday’s “speech” is far out to sea from the safe harbor of non-economic, commercial expression that “concern[s] lawful activity and [is] not . . . misleading.” *Central Hudson*, 447 U.S. at 564; *Pittsburgh Press Co.*, 413 U.S. at 389 (First Amendment protection “is altogether absent when the commercial activity itself is illegal”).

While Mayday claims it is just a conduit to other platforms, for First Amendment purpose a middleman in a transaction is still part of the transaction. Mayday is no different than the newspaper that publishes a want ad for prostitution whom the state can readily enjoin from printing without at all offending the First Amendment. *Pittsburgh Press Co.*, 413 U.S. 376 at 388. But Mayday is no mere middleman, it is not a newspaper that passively accepts and prints ads. It is an active market force that admittedly “exists to provide information about how people can get mail-

order abortion pills . . . in all 50 states, regardless of harmful state restrictions.” KLEMANN AFFIDAVIT, Exhibit A at Exhibit 6. Like a real estate agent, Mayday hustles to connect sellers with buyers, to “reach more people,” to solicit contributions to fund the advertising in states with “abortion bans” for the admitted purpose of illegally supplying mail order abortion pills to people “regardless” of the legality of such transactions in those states. KLEMANN AFFIDAVIT, Exhibit A at Exhibits 6, 18. In addition, Mayday itself supplies terms of sales to consumers such as price quotes and product delivery times. KLEMANN AFFIDAVIT, Exhibit A at Exhibit 18.

Nor do the facts that Mayday allegedly does not directly “profit” from the sale of any pills through commissions or fees for such sales, or physically handle or distribute them, give its commercial speech protected status. An advertiser of illegal activity cannot render state laws or *Younger* or the First Amendment toothless simply by not “profiting” from its otherwise unprotected activities. The test for unprotected commercial speech is not whether the advertiser profits from or handles contraband, it is whether it proposes an illegal transaction or is misleading. *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 455-56 (1978); *Cocroft*, 122 F.4<sup>th</sup> at 182 (advertisements for illegal transactions not protected). And, in any event, Mayday *does* profit by being the mouthpiece and platform for abortion pill providers. Being a non-profit corporation does not mean that Mayday runs a non-profit website. Mayday admits that its “exist[ence]” depends on donations raised from its mission to supply “abortion pills in all 50 states” regardless of legality. KLEMANN AFFIDAVIT, Exhibit A at Exhibit 7. Donated funds pay overhead costs and salaries of Mayday’s officers and directors (which can be handsome in “non-profit” organizations) which ensures the organization’s continued existence, which is a form of profiting from the activities it promotes. Mayday also sells merchandise directly espousing the illegal activity it facilitates.

Whether or not Mayday “profits” (in whatever sense Mayday uses the word), it certainly benefits financially from being a megaphone for abortion pill merchants and illegally procuring

abortion pills for consumers in abortion-illegal states. As noted in *James*, such indirect economic motives bring a message within the scope of commercial speech. *James*, 160 F.4<sup>th</sup> at 377. There can be no bad faith or harassment on the part of the Attorney General in connection with enjoining deceptive and misleading commercial speech that proposes, facilitates and solicits financial contributions by promoting illegal transactions in the State of South Dakota. *Central Hudson*, 447 U.S. at 564; *James*, 160 F.4<sup>th</sup> at 377.

**b. The Attorney General Is Engaged In A Valid Enforcement Action**

The subject enforcement action was not instigated by the Attorney General but by South Dakota Governor Larry Rhoden per his authority under SDCL 1-11-1 to request the Attorney General to prosecute any civil or criminal matter on behalf of the state in which the state may be a party or interested, by a written formal complaint by a gas station owner who asked for his help to remove the placards that Mayday installed though an advertising vendor without the station owners' permission, and by 657 calls to the Consumer Protection Division complaining about the signs. KLEMMAN AFFIDAVIT, Exhibit A at Exhibit 5. Mayday's advertising and donor solicitations violate SDCL 37-24-6(1) in at least the following ways: omitting the material fact that it cannot legally provide "abortion pills in all 50 states," misrepresenting that medicinal abortion is "safe" beyond the FDA-recommended gestational period, counseling against follow-up medical care in order to conceal its role in illegally trafficking in abortion-inducing pills, enticing minors to ingest illegal drugs to induce an illegal abortion without parental knowledge or consent, and omitting material information regarding the actual risks associated with abortion generally and abortions performed contrary to FDA guidance in particular. Mayday cannot realistically argue that an action to restrain concrete violations of state law such as these was "brought without a reasonable expectation" of success. *Kugler*, 421 U.S. at 124; *Perez*, 401 U.S. at 84.

Like the Virginia statute in *Simopoulos*, since SDCL 22-17-5.1’s ban on the sale and importation of abortion pills in South Dakota “was clearly enacted in aid of and for the purpose of facilitating the standards established in the state abortion statute, it unquestionably qualifie[s] for abstention under the ‘quasi-criminal’ standard in *Huffman* [v. *Pursue, Ltd.*, 420 U.S. 592, 610-611 (1975)].” SDCL 37-24-23 just as clearly authorizes the Attorney General to act “in the public interest” to “restrain . . . the use of [an] act or practice” that is “unlawful [under SDCL] 37-24-6.” The chilling effect of the Attorney General’s enforcement action is less than that of SDCL 22-17-5.1 itself because it is civil in nature and thus “does not . . . justify prohibiting the state from carrying out the important and necessary task of enforcing [its] laws.” *Younger*, 401 U.S. at 52. This task outweighs any “incidental ‘chilling effect’” on Mayday’s alleged protected speech. Per *Bigelow* and *James*, the Attorney General’s position that Mayday’s speech crosses the line from non-commercial to commercial is facially not in bad faith but, if Mayday believes otherwise, “the state proceedings afford an adequate opportunity to raise the constitutional claims.” *Younger*, 401 U.S. at 52; *Moore*, 442 U.S. at 430. *Younger* is a dead letter if it does not apply in circumstances such as these.

## CONCLUSION

Mayday has not adjusted to the current reality that there is no longer a uniform, national body of law around abortion and that it now must tailor its messaging to conform to the laws of each state they operate in. As its name implies, Mayday fancies itself as a cyber resistance movement, courageously manning the virtual barricades of web pages, defiantly thrusting its emoji fist skyward, tossing digital Molotov cocktails of abortion disinformation, and running online cells cacheing stores of “abortion pills . . . in all 50 states regardless of . . . state restrictions.”

KLEMANN AFFIDAVIT, Exhibit A at Exhibits 2, 6. But Mayday is no more privileged to “resist” in this fashion in South Dakota than some other website would be in connecting customers

with child pornography or methamphetamine, which the Attorney General would shut down just as fast as Mayday.

Despite the dissident fervor of Mayday’s emergency complaint for TRO, the Attorney General has acted with restraint here. The Attorney General first asked Mayday nicely to stop breaking South Dakota’s law. Then, when Mayday refused, the Attorney General brought a civil enforcement action which sought no penalties, fines or attorney fees for Mayday’s past violations. The Attorney General did not come out swinging the club of criminal prosecution. Only Mayday’s agitated movement mentality would see “bad faith” and “harassment” in the Attorney General’s measured response.

But Mayday’s self-styled resistance activities in South Dakota must stop. Its proposition to supply abortion pills to South Dakotans is patently illegal and places 1 in 10 South Dakota women and teenaged girls in danger of severe complications from medicinal abortion, doubly so those who heed Mayday’s admonition to not seek medical care in order to conceal Mayday’s illegal activities. Were a South Dakota woman or girl to die from abortion pills supplied by Mayday, the criminal consequences would not stop at SDCL 22-17-5.1.

This case really is not even about abortion. Because no matter where a person stands on abortion it is wrong to run a website that propositions women to engage in a criminal scheme (*Bigelow*) and solicits charitable contributions off that illegal scheme (*Bigelow, James*), it is wrong to solicit charitable contributions off telling women to not seek medical care due to complications from medicinal abortion in order to conceal that illegal scheme (*James*), it is wrong to solicit charitable contributions off telling teenaged girls that medicinal abortion is perfectly safe when medical insurance claims data reflects a 1 in 10 probability that she will suffer severe complications from such an abortion (*James*), and it is wrong to tell teenaged girls to travel across

state lines to procure an abortion without her parents' knowledge, consent or protection. Such practices are illegal, deceptive, misleading and a danger to public health.

Mayday's economically motivated propositions to illegally supply abortion pills to South Dakota women and girls are not protected by the First Amendment. Indeed, the ultimate merits of Mayday's First Amendment defense is irrelevant to the *Younger* analysis, which is concerned only with whether there is any expectation that the state's enforcement action can survive Mayday's First Amendment defense and whether the pending civil action provides an adequate forum to assert the defense, which it clearly does.

There is no abortion exception to *Younger*. If *Younger* could be defeated simply by invoking the First Amendment, the extraordinary circumstances exception would swallow the abstention rule. As detailed herein, the pending South Dakota civil enforcement action is far from having no legal basis or probability of success and Mayday's own authorities – *Bigelow* and *James* – do not support its First Amendment defense. But if Mayday thinks its activities are protected by the First Amendment the pending civil enforcement action provides a perfectly adequate forum for it to do so. Under these circumstances, the *Younger* doctrine "commands" federal court abstention. *Simopoulos*, 544 F.2d at 329. Accordingly, the Attorney General asks that the above-captioned matter be dismissed.

Dated this 26<sup>th</sup> day of January 2026.

**MARTY J. JACKLEY  
ATTORNEY GENERAL**

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**CERTIFICATE OF COMPLIANCE**

The undersigned counsel for the Defendant hereby certifies that this Memorandum of Law was prepared using the Microsoft Word Version 2010 word-processing program and contains 7,330 words in compliance with the Individual Rules of Practice in Civil Cases of the Honorable Katherine Polk Failla.

**MARTY J. JACKLEY  
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STATE OF SOUTH DAKOTA	)	IN CIRCUIT COURT
) SS:		
COUNTY OF HUGHES	)	SIXTH JUDICIAL CIRCUIT
STATE OF SOUTH DAKOTA,		32 CIV-_____
Plaintiff,		
v.		
MAYDAY MEDICINES INC. d/b/a		AFFIDAVIT OF
MAYDAY HEALTH, and ALLOVER,		KAYLA KLEMANN, CONSUMER
LLC, d/b/a MOMENTARA,		PROTECTION INVESTIGATOR,
Defendants.		SOUTH DAKOTA OFFICE OF
		ATTORNEY GENERAL

I, Kayla Klemann, Consumer Protection Investigator, South Dakota Office of Attorney General, having been duly sworn upon oath, states as follows:

1. I am a Consumer Protection Investigator for the Office of Attorney General.
2. I have held this position since January 7, 2023.
3. I am responsible for investigating potential consumer protection violations under SDCL Ch. 37-24.
4. I was assigned to investigate Mayday Health Inc. and Momentara regarding advertisements posted at various gas stations throughout the state. A picture of the advertisement is attached as Exhibit 1.
5. On December 8, 2025, Mayday Health issued a press release declaring that it had posted "ads" at nearly thirty gas stations across the state. See Exhibit 2.

6. In a follow-up press release issued on December 10, 2025, Mayday Health acknowledged that only fourteen gas stations throughout the state “will have abortion pill advertisements” and that it was “putting up ads at gas stations because we think that everyone deserves access to accurate medical information[.]” See Exhibit 2.

7. On December 15, 2025, the Office of the Attorney General received a complaint from Cowboy Country Stores explaining that they did not want Mayday Health’s advertisements posted at their store. See Exhibit 5.

8. The advertisements posted by Mayday Health direct South Dakota consumers to Mayday Health’s website. I learned the corporation solicits charitable donations from consumers and sells merchandise with a misleading statement regarding the availability of abortion pills “in all 50 states.” See Exhibits 6 and 7.

9. When a consumer visits the Mayday Health website, the large headline on the main page reads, “What do you need?” There are four clickable links to choose from on the main page: abortion, morning after pills, birth control, and gender-affirming care. See Exhibit 8.

10. If the consumer selects “abortion,” they are asked how long it has been since their last period. See Exhibit 9.

11. If “more than 12 weeks” is selected since the consumer’s last period from the Mayday website, they are directed to a new website, [ineedana.com](http://ineedana.com), which ostensibly means “I need an abortion.” See Exhibit 11.

12. Once the link is clicked, the consumer is asked what city they live in, the first day of their last period, and their age. *See Exhibit 12.*

13. No matter what combination of information is entered into these fields (e.g. South Dakota addresses, dates of last period, and age), the consumer is always given three options: driving directions to the nearest out-of-state abortion clinic that can perform a surgical abortion, a link to “order abortion pills online” to self-induce an at-home medical abortion, and the option to fly to another state that performs surgical abortions. *See Exhibit 13.*

14. Minors will see the same options as all other consumers indicated above; however, they are also shown a disclaimer that says, “You are a minor. If you decide to travel for care, you may face additional barriers as a teen. Learn more in our guide for teens.” *See Exhibit 14.*

15. In the guide for teens, children are advised, “[a]bortion is safe, normal, and any reason to have one is a good reason.” *See Exhibit 15.*

16. The website specifically instructs children to 1) conduct their own self-induced, at-home abortions by having abortion-inducing pills sent to their home “or to a trusted friend or family member” or 2) travel to a state that does not have parental consent laws, so [the child] can consent to [their] own abortion without [the child’s] parents or a judge’s permission.” *See Exhibit 16.*

17. If “[l]ess than 12 weeks” is selected since the consumer’s last period on the Mayday Health website, they are directed to a screen that asks if the

consumer lives in a “red state” which is detailed on a map graphic below the question. *See Exhibit 17.*

18. Once the “red state” option is selected, the consumer is directed to a page that lists five separate abortion-inducing pill providers. *See Exhibit 18.*

19. If a consumer clicks on the link for Abuzz, a consumer is told that she may perform her own at-home abortion using abortion-inducing pills if she is less than “13 weeks pregnant[,]” which is “measured from the first day of the last period.” *See Exhibit 19.*

20. When a consumer starts the process to obtain abortion-inducing pills through Abuzz, they are prompted to identify the state in which they reside. *See Exhibit 20.*

21. After South Dakota is selected, an advisement is revealed that proports to provide “information about the potential legal risks of getting abortion pills by mail” in the State of South Dakota. *See Exhibit 21.*

22. If the consumer chooses to click on the information link in the advisement (consumers are not required to view the risks of getting abortion-inducing pills by mail to continue the process), they are taken to a new website, [plancpills.org](http://plancpills.org). *See Exhibit 22.*

23. Instead of advising consumers that it is illegal to mail abortion-inducing pills into the State of South Dakota, consumers are told that “Research shows that hundreds of thousands of people have received and used pills by mail over the past few years with no legal problems. When the question is asked “How do

people get in trouble[,]” the website advises: “they told someone about their abortion and that person reported them; they got follow-up medical care and the provider reported them (many people say they are having a miscarriage to avoid this risk, which is medically what is happening in the body); they were later in pregnancy than they thought and didn’t know what to do with the fetal tissue.” See Exhibit 23.

24. Aid Access informs consumers that they are eligible to self-induce an at-home abortion using abortion-inducing pills in the fourteenth week of their pregnancy, and that this is “very safe.” See Exhibit 24.

25. The FDA issued warning letters to Aid Access for selling unapproved and misbranded abortion-inducing pills (Mifepristone and Misoprostol) over the internet. See Exhibit 25.

26. Aid Access has a South Dakota specific page that in no way advises consumers that it is illegal to mail abortion-inducing pills into the State of South Dakota. See Exhibit 26.

27. On Aid Access’s “legal” FAQs, the website directs consumers to declarations made by the World Health Organization. See Exhibit 27.

28. Despite posting a disclaimer on their own website that they “do not give legal or medical advice,” Mayday Health represents to consumers that their “information comes from top clinicians, lawyers and health experts[.]” See Exhibit 28.

29. Mayday Health provides links to several “trusted organizations” it has approved for legal and medical advice. *See Exhibit 29.*

30. Mayday Health’s FAQs say that the links on their website “have the best content for a certain aspect of abortion care” and that they “only link to other trusted websites and partners.” *See Exhibit 30.*

31. The Mayday Health website contains claims that “abortion pills are safe [and] effective during the first 12 weeks” and that “[i]t is safe to do your own abortion at home with abortion pills.” *See Exhibit 9.*

32. the FDA advises that “[i]n about 1 out of 100 women, bleeding can be so heavy that it requires a surgical procedure (surgical aspiration or D&C).” *See Exhibit 31 at 16.*

33. The FDA issued certain warnings and precautions, as well as adverse side effects for abortion-inducing drugs. *See Exhibit 31 at 5-8.*

34. Exhibit 6 shows other pages from the website. One is a donations page that outlines how donations are meant to fund the advertising of Mayday’s website in states with “abortion bans.”

35. If the medical abortion treatment failed, there is a slight increase in the risk of birth defects such as deformities of the hands or feet and problems with the nerves of the fetus. To treat an ongoing pregnancy, you must repeat a medical or surgical abortion. <https://aidaccess.org/en/page/459/how-do-you-know-if-you-have-abortion-complications>.

36. Exposure of fetuses to Misoprostol can lead to malformations, such as defects in the skull and abnormalities in the limbs (called Mobius Syndrome). <https://aidaccess.org/en/page/465/what-are-the-chances-that-the-fetus-will-be-malformed-if-you-have-an>.

37. I reviewed an article from the FDA that was posted on the internet about abortion inducing medication. See Exhibit 10.

38. Based on the facts I learned during my investigation, I believe Mayday Health, with facilitation from Momentara, engaged in deceptive trade practices and acts in violation of SDCL 37-24-6.

39. The SD Attorney General issued a Cease and Desist letter to Mayday Health on December 10, 2025. See Exhibit 3.

40. On December 19, 2025, Mayday Health issued a response refusing to remove the illegal advertisements. See Exhibit 4.

Dated this 22nd day of December, 2025.



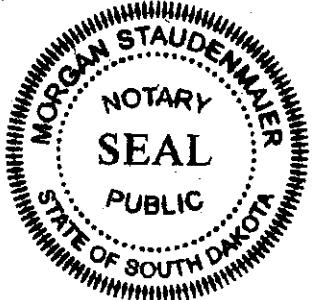
Kayla Klemann, Investigator  
South Dakota Office of Attorney General  
Consumer Protection Division

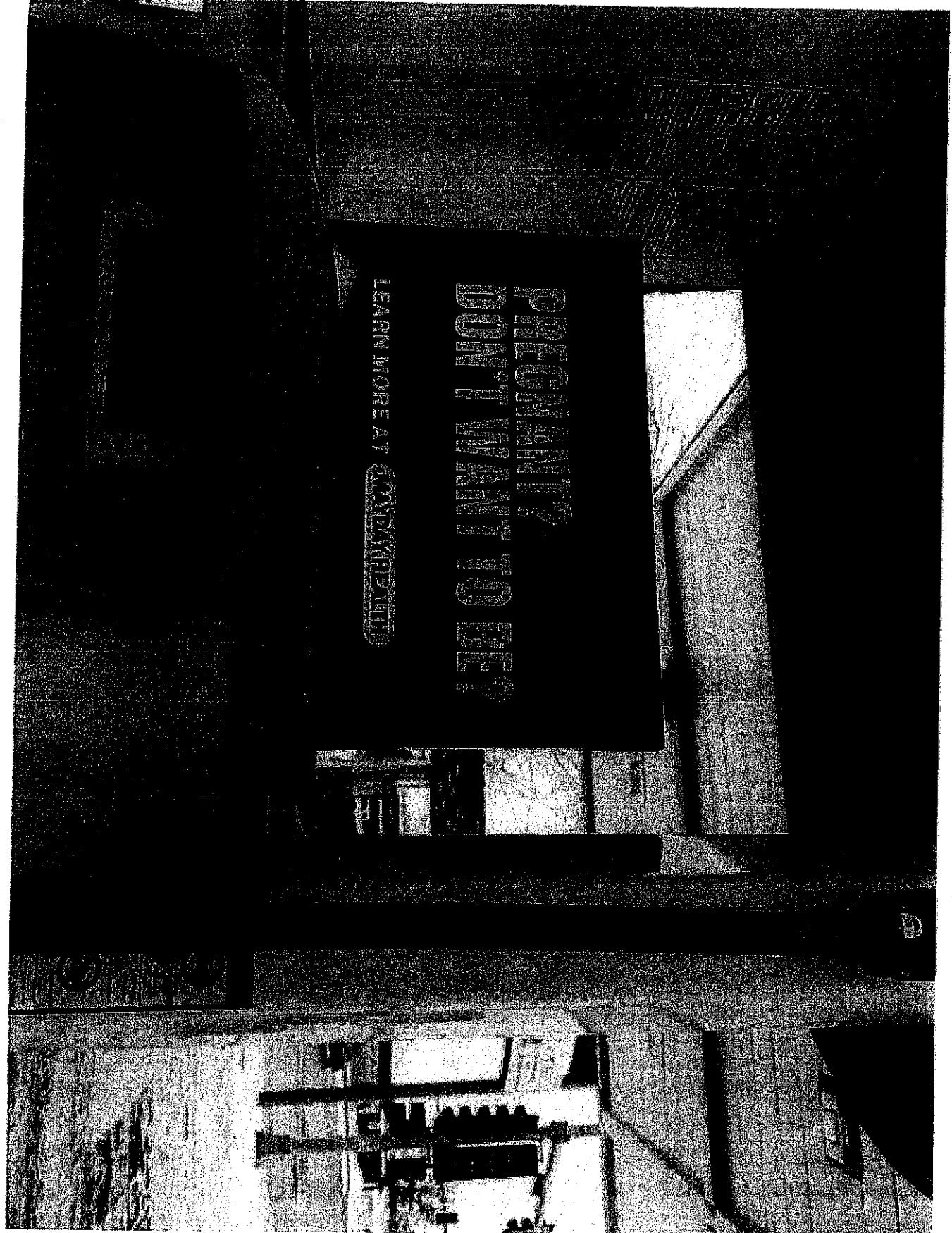
Subscribed and sworn to before me this 22 day of December, 2025, at Pierre, South Dakota.



Notary Public, State of South Dakota  
My Commission expires: 03/28/2031

(Seal)





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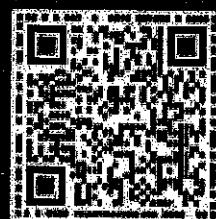
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1



KELOLAND News This Morning



# KELOLAND.COM ORIGINAL

KELOLAND.COM ORIGINAL

## Abortion pill ads hit South Dakota gas stations

by: **Gracie Terrall, Eric Mayer**  
Posted: Dec 8, 2025 / 05:17 PM CST  
Updated: Dec 10, 2025 / 03:55 PM CST

SHARE

*Updated: Mayday Health updated their list from 30 gas stations to 14.*

SIOUX FALLS, S.D. (KELO) – South Dakotans may notice a new abortion campaign at gas stations around the state.

Starting Monday, Dec. 8, 14 gas stations in 11 South Dakota cities will have abortion pill advertisements as a part of Mayday Health's effort to spread information about the pills and abortion options.

Originally, a list of 30 gas stations were given to KELOLAND News on Monday. However, on Wednesday, Mayday Health sent an updated list with only 14 gas stations listed. A representative from Mayday Health told KELOLAND News on Wednesday that the list of 30 stations was "part of the planning phase, albeit not confirmed" and the list was created by a contractor before the campaign went live.

NetShort





### Kristi Noem responds to replacement rumor ➤

The signs, posted above gas pumps, read "Pregnant? Don't want to be?" with a link to the organization's website.

"We're putting up ads at gas stations because we think that everyone deserves access to accurate medical information, and gas stations are great places to spread information," Executive Director Liv Raisner told KELOLAND News.

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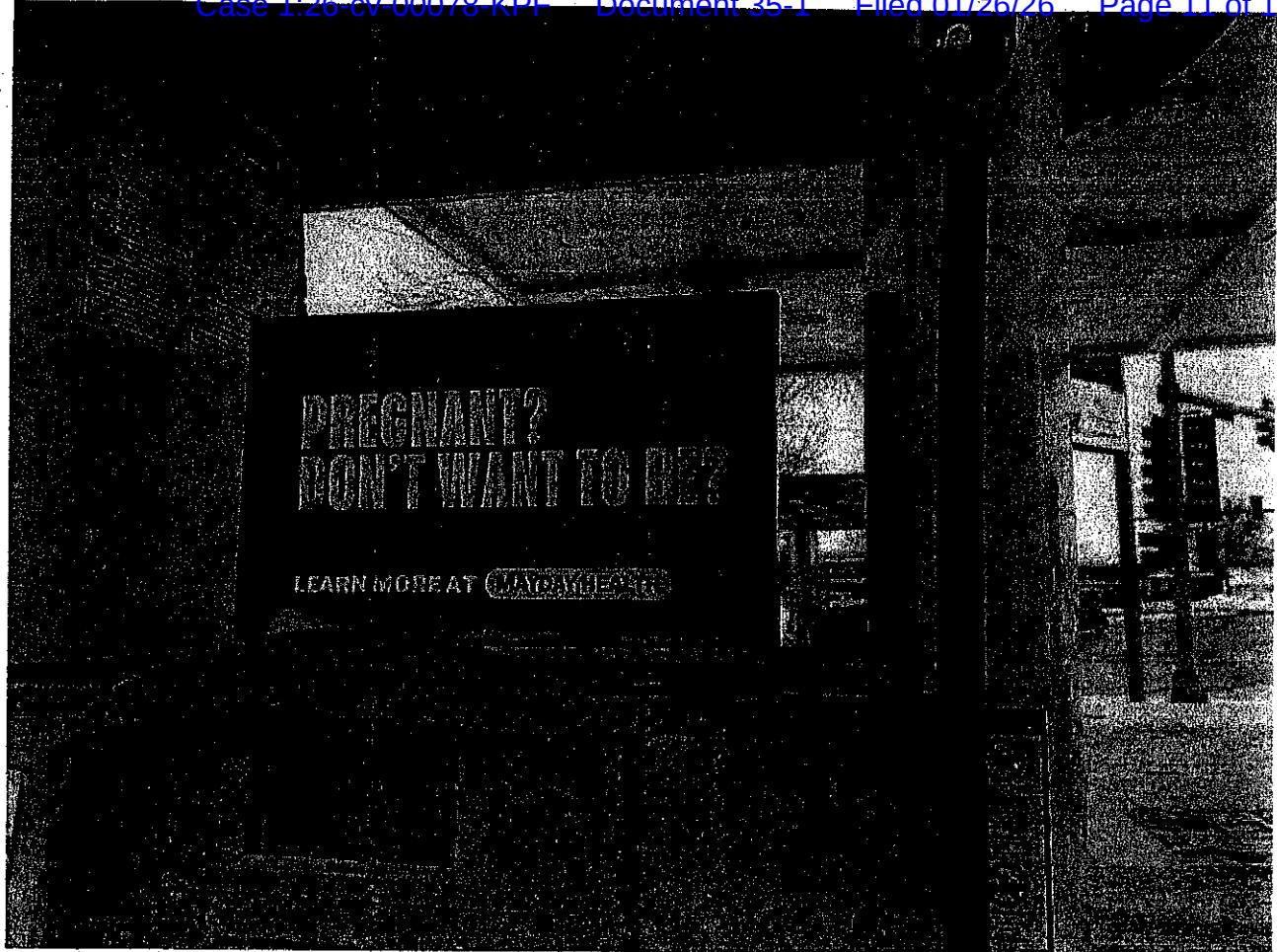
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Mayday Health is a national organization with resources and information about abortion care, specifically abortion pills. They've run similar campaigns in Texas, West Virginia and Kentucky as well.

"We believe that it's critical to reach people with health information at community hubs. Abortion in rural areas is a privacy issue," Raisner said. "If there's one singular health clinic in the area, people talk. We want to make sure that people can learn their options anonymously and privately."

According to the [Guttmacher Institute](#), medicated abortions accounted for nearly 63% of abortions in the United States in 2023.

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Raisner said the organization chose South Dakota as their next state for the campaign due to the state's strict abortion laws, but they hope to spread the message abortion pills to every state.

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**State medical board reprimands 2 M.D.s**

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Under South Dakota's 2006 trigger law, abortion is banned and considered a Class 6 felony punishable by up to two years in prison and up to a \$4,000 fine. The only exception to the law is if there is "appropriate and reasonable medical judgment" that an abortion would save the mother's life. There is no exception for rape or incest.

Mayday Health does not provide or ship abortion pills, they just provide information about the options available.

"Our website just gives people the facts about abortion pills and connects them to resources without judgment," Raisner said. "We just want people to have the right information so they can make informed decisions about their own bodies."

Mayday Health also publishes digital ads on social media targeted to states with strict abortion laws and run campaigns with airplanes and boats during heavily populated events like football games, the Indy 500 and outside concerts.

ADVERTISEMENT

"There's really nowhere we won't go to spread information about abortion pills in states where clinics are banned," Raisner added.

The signs at South Dakota gas stations will be up until January 18.

The owner of Luke Repair in Springfield confirmed that he did agree to display the signs due to the ad revenue it provided, however he said Wednesday that the signs were removed by the wind.

Benny Spies, owner of Cowboy Country Store #3 in Watertown, told KELOLAND News the Mayday Health advertisements won't be on display at his gas station.

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Sara Horning, owner of the Watertown Gas N Goodies, told KELOLAND News she did not authorize the advertisements at her business and will not be allowing them to be displayed.

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Wayne Krump, owner of Gas Barrel in Sioux Falls, said he never agreed to display the signs. Gas Barrel was on the original list of 30 gas stations given, but were not included in the updated list of 14 provided on Wednesday.

"We are so pro-life. This hit us hard. We patronize God," Krump said in an interview with KELOLAND News on Wednesday.

Raisner told KELOLAND News all of the gas stations agreed to display the campaign signs. A representative from Mayday Health said they are not able to provide clarification on whether the local store owners or corporate gas stations gave the initial OK.

Gas stations with Mayday Health abortion signs:

ADVERTISEMENT

**Brookings**

Classic Corner

Schoon's Pump 'n Pak

**Sioux Falls**

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King's Liquor, Cliff Avenue

Roadway Travel Center

Local on E Marson Dr.

**Volga:** AG WRK Co-Op

**Renner:** Renner Corner Locker

**Colome:** Flying D

**Mitchell:** KWIK Phil

**Rapid City:** Rushmore Sinclair

**Springfield:** Luke Repair

**Summerset:** The Pit Stop

**Vermillion:** Pump 'n Pak

**Wagner:** Gus Stop

**ADD AS PREFERRED SOURCE ON GOOGLE**

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STATE OF SOUTH DAKOTA



**OFFICE OF ATTORNEY GENERAL**

1302 East SD Highway 1889, Suite 1  
Pierre, South Dakota 57501-8501

Phone (605) 773-3215  
Fax (605) 773-4106  
<http://atg.sd.gov>

**MARTY J. JACKLEY**  
ATTORNEY GENERAL

**BRENT K. KEMPEMA**  
CHIEF DEPUTY

December 10, 2025

Olivia Raisner  
Mayday Medicines Inc.  
442 5th Ave 1648  
New York, NY 10018

**RE: CEASE AND DESIST**

Dear Ms. Raisner,

The Office of the South Dakota Attorney General is the chief law enforcement officer and consumer protection advocate for the State of South Dakota. The South Dakota Attorney General is therefore empowered to investigate business practices and enforce consumer protection laws where violations exist.

Recently, the South Dakota Attorney General received information that Mayday Medicines Inc. advertises abortion resources indicating that abortion-inducing pills may be obtained in all 50 states, including South Dakota. Abortions are prohibited in South Dakota under SDCL 22-17-5.1, except for specific, extenuating circumstances. SDCL 22-17-5.1 specifically criminalizes administering to and prescribing or procuring for "any pregnant female any medicine, drug, or substance . . . to procure an abortion[.]"

Your advertisement directs South Dakota consumers to resources that insinuate abortion-inducing pills are legal in South Dakota, while also urging women not to seek medical care after taking abortion pills and to keep their abortion a secret.

For example, your advertisement directs consumers to Abuzz.<sup>1</sup> When the State of South Dakota is selected for state-specific resources on abortion-inducing pills, Abuzz provides "information" to South Dakota consumers through Plan C. In a section entitled—"Is this legal? Can someone get in trouble for using abortion pills?"—consumers are advised "research shows that hundreds of thousands of people have received and used pills by mail over the past few years with no legal problems." Likewise, in a section entitled—"How do people get in trouble?"—consumers are advised "the most common ways people have gotten in trouble" are when they "told someone about their abortion," they "got follow-up medical care and

1. Abuzz's mission is "to expand access to abortion by linking people to accurate information, pills by mail, and clinician support if desired."

EXHIBIT

3

the provider reported them,” or they “were later in pregnancy than they thought and didn’t know what to do with the fetal tissue.”

In South Dakota, we do not punish women who undergo abortion. See SDCL 22-17-5.2. The criminal liability falls on the individual who administered the abortion or prescribed or procured the abortion-inducing pills, despite the deceptive and self-protective advice provided through your advertisement.

Moreover, Mayday’s website states that “[a]bortion pills are safe and effective.” But a recent study found that “real-world insurance claims data for 865,727 prescribed mifepristone abortions” shows a “serious adverse event rate of 10.93 percent.” Jamie Bryan Hall & Ryan T. Anderson, *The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event*, Ethics and Public Policy Center (Apr. 28, 2025), <https://tinyurl.com/wxhfsfdf>.

Based on this information, it appears that your business practices constitute a deceptive act or practice under SDCL Ch. 37-24, the South Dakota Deceptive Trade Practices and Consumer Protection Act. The Attorney General of South Dakota therefore demands that you **IMMEDIATELY CEASE AND DESIST** from conducting any advertising related to the delivery of abortion drugs to the State of South Dakota.

If you refuse to comply, the South Dakota Attorney General may bring a lawsuit against you for violations of the South Dakota Deceptive Trade Practices and Consumer Protection Act under SDCL Ch. 37-24. If successful, you may face felony criminal consequences or civil penalties up to \$5,000 per violation.

To avoid further action, please notify the South Dakota Attorney General of the steps you have taken to remedy this situation by December 19, 2025. Your response should be in writing and addressed to:

Marty J. Jackley  
South Dakota Attorney General  
South Dakota Office of Attorney General  
1302 E. S.D. Hwy 1889, Suite 1  
Pierre, SD 57501

Alternatively, you may respond by email to [atghelp@state.sd.us](mailto:atghelp@state.sd.us). You may also use this email address to communicate any questions or concerns about this letter.

Sincerely,



Marty J. Jackley,  
South Dakota Attorney General



Adam S. Sieff  
adamsieff@dwt.com  
213.633.8618

Laura R. Handman  
laurahandman@dwt.com  
202.973.4224

Chelsea T. Kelly  
chelseakelly@dwt.com  
202.973.4260

December 19, 2025

**VIA EMAIL**

Marty J. Jackley  
South Dakota Attorney General  
1302 East S.D. Highway 1889, Suite 1  
Pierre, South Dakota 57501-8501  
[atghelp@state.sd.us](mailto:atghelp@state.sd.us)

Re: “Cease and Desist” to Mayday Medicines, Inc.

Dear Mr. Jackley:

We write regarding your December 10, 2025 letter demanding that Mayday Medicines, Inc. cease and desist “any advertising related to the delivery of abortion drugs to the State of South Dakota.” Mayday objects to your misguided demand in its entirety, and will not allow government intimidation to suppress its right to publish truthful non-commercial information of public concern.

As a threshold matter, there is no jurisdiction over Mayday’s website in South Dakota. Mayday is a non-profit public health education organization incorporated in Delaware and headquartered in New York that operates a globally-accessible website. Nothing in your letter suggests Mayday broke any law by displaying signs at South Dakota gas stations—nor could it, as those signs pose a question (“Pregnant? Don’t want to be?”) and invite readers to “learn more” by visiting Mayday’s website. Instead, your letter misrepresents, and takes issue with, information you claim appears on that website.<sup>1</sup> But Mayday’s “site merely makes information available” to anyone in the world, so its availability in South Dakota “is insufficient to confer personal jurisdiction.” *Johnson v. Arden*, 614 F.3d 785, 796 (8th Cir. 2010).

Nothing about Mayday’s publishing activity identified in your letter, in any event, violates or is even subject to the South Dakota Deceptive Trade Practices and Consumer Protection Act (the “Act”). Mayday is a non-profit information resource. It does not sell, handle, provide, offer for sale, or benefit from the sale of abortion medication, and it has no customers. Mayday accordingly does not engage in “the sale or advertisement of any merchandise,” and none of the statements at issue involve “the solicitation of contributions for charitable purposes.” SDCL § 37-24-6(1). Instead, Mayday provides truthful information about healthcare options, including but not

<sup>1</sup> Your letter falsely asserts that Mayday’s website “urg[es] women not to seek medical care after taking abortion pills.” No such statement appears on Mayday’s website. To the extent your letter takes issue with statements by Abuzz—a third-party organization—your complaint is misdirected, not to mention mischaracterized.



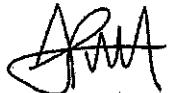
Mr. Marty J. Jackley  
 December 19, 2025  
 Page 2

limited to mifepristone and misoprostol, which are approved by the U.S. Food and Drug Administration (FDA) for safe and effective use.<sup>2</sup> That information is not commercial speech subject to regulation under deceptive practices statutes, *Lowe v. SEC*, 472 U.S. 181, 210-11 & n.58 (1985), much less the more specific kinds of advertisements to which the Act applies. *See Hyde v. Franklin Am. Mortg. Co.*, 453 F. Supp. 3d 1293, 1308 (D.S.D. 2020) (Act had no application to email that “was not an advertisement and [Defendant] was not selling products”); *see also Cheval Int’l v. Smartpak Equine, LLC*, 2016 WL 1064496, at \*12 (D.S.D. Mar. 15, 2016) (similar). In fact, the Act contains a safe harbor that protects “publishers, broadcasters, printers, or other persons” when, like Mayday, they do not engage in any deliberately deceptive commercial advertising. SDCL § 37-24-11.

The First Amendment imposes these limitations. States may not punish people for providing information about abortion services, even in jurisdictions that have made abortion illegal. *See Bigelow v. Virginia*, 421 U.S. 809, 815 n.5 (1975) (explaining that *Bigelow* was “a First Amendment case and not an abortion case”). *Bigelow* is controlling. The case held that a Virginia statute criminalizing the dissemination of information that allegedly “encourage[d] or prompt[ed] the procuring of an abortion” infringed a Virginia newspaper’s constitutionally protected speech. *Id.* at 812. The First Amendment protected the newspaper’s announcement and “editorial endorsement” of an organization that facilitated access to abortions because the content “conveyed information of potential interest and value to a diverse audience—not only to readers possibly in need of the services offered, but also to those with a general curiosity about, or genuine interest in, the subject matter.” *Id.* at 822 & n.7. Virginia had no constitutionally valid “interest in shielding its citizens” from this information. *Id.* at 827-28. South Dakota likewise has no power to “regulat[e] what [South Dakotans] may hear or read” about reproductive healthcare. *Id.*

Your letter baselessly threatens Mayday’s protected speech in violation of Mayday’s—and its readers—First Amendment rights. But Mayday will continue to make important, and truthful, public information available. Mayday reserves all rights to supplement or amend its response.

DAVIS WRIGHT TREMAINE LLP



Adam S. Sieff  
 Laura R. Handman  
 Chelsea T. Kelly

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<sup>2</sup> The FDA has repeatedly confirmed the safety of medication abortion, a conclusion supported by independent and rigorous scientific study. *See, e.g.*, F.D.A. Center for Drug Evaluation & Research, App. No. 020687Orig1s020 at 12 (March 29, 2016) (confirming the “efficacy and safety” of medication abortion based on studying more than 2.5 million U.S. uses); Mifepristone REMS Study Group, *Sixteen Years of Overregulation: Time to Unburden Mifepristone*, 376 N. ENGL. J. MED. 790, 791 (2017) (same); F.D.A., *Mifepristone U.S. Post-Marketing Adverse Events Summary Through Dec. 31, 2024* at 1 (2025) (zero fatalities “causally attributable to mifepristone” “with certainty”).

December 15, 2025

**COWBOY COUNTRY STORES**  
312 9<sup>th</sup> Ave SE; Ste. A  
Watertown, SD 57201

**FORMAL COMPLAINT AGAINST:**

- 1. MAYDAY HEALTH – Liv Raisner**
- 2. MOMENTARA**  
**16355 36<sup>th</sup> Ave. N.**  
**Minneapolis, MN 55446**
- 3. KELOLAND – Gracie Terrall**  
**201 South Phillips Ave.**  
**Sioux Falls, SD 57104**

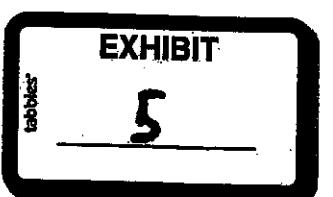
On Tuesday December 9, 2025 it was brought to our attention, by our customers, that Cowboy Country Stores had agreed to participate in an abortion media campaign from **Mayday Health**, where abortion pill advertisements would be posted at our Cowboy 3 location, in Watertown, SD. The inaccurate, false, deceptive, lie our customers referred to came from a story titled, **Abortion Pill Ads Hit South Dakota Gas Stations**, posted on **KELOLAND NEWS** written by **Gracie Terrall**.

Cowboy Country Stores DID NOT agree to be involved in this campaign in any way, shape or form, period. And DID NOT post any advertisements pertaining to the abortion pill at any time.

We believe **Momentara** provided the false information to **Mayday Health** because it is **Momentara** that called our store asking if we would participate. We said NO, period.

**Mayday Health, Liv Raisner, Momentara, KELOLAND News and Gracie Terrall** should be held accountable for their reckless actions, which damaged our reputation.

**COWBOY COUNTRY STORES**



**MAYDAY.HEALTH**

# Donate to Mayday's healthcare education campaign today!

## Choose an Amount

Your contribution will benefit Mayday Health.

**One-Time Donation****Monthly Donation****\$1,000****\$500****\$250****\$100****\$50****\$25****\$10****Choose your own amount**

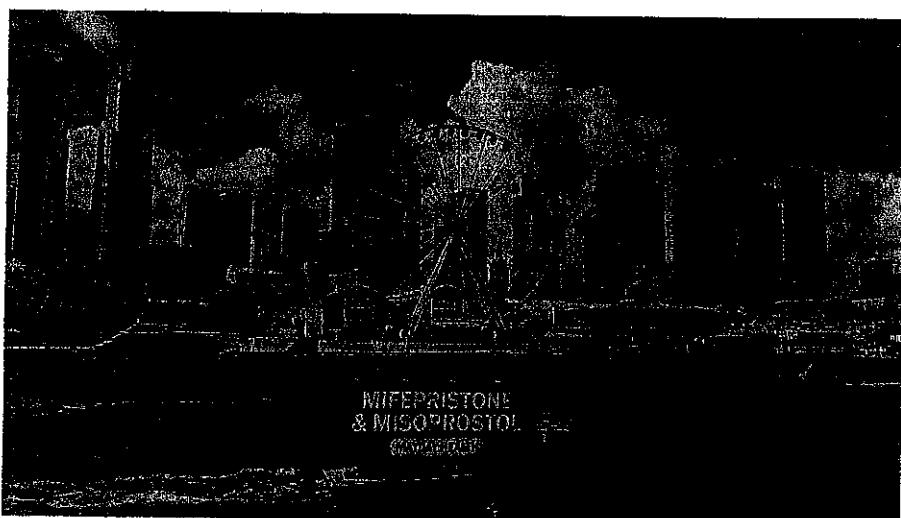
Hi, my name's Charley. I can help you get or manage an abortion. / Hola, mi nombre es Charley. Puedo ayudarte a conseguir o manejar un aborto.

**Donate Today!****EXHIBIT****6**

Mayday Health is a nonprofit that exists to provide information about how people can get mail-order abortion pills, birth control, emergency contraception, and gender affirming care in all 50 states, regardless of harmful state restrictions.

**An investment in Mayday is an investment in those who are most harmed by abortion bans.**

Your gift helps us do this crucial work. Because of you, we will now be able to reach more people with the life-saving information they need to understand every reproductive health care option available to them – regardless of where they live.



---

**Thank you so much for your tax deductible gift to Mayday Medicines, Inc. (DBA Mayday Health).**

[Home](#) [All Products](#)

# MAYDAY.HEALTH

USD [Home](#) » [Store](#) » "They Don't Want You To Know This" Hoodie

## "THEY DON'T WANT YOU TO KNOW THIS" HOODIE

**\$40.00**

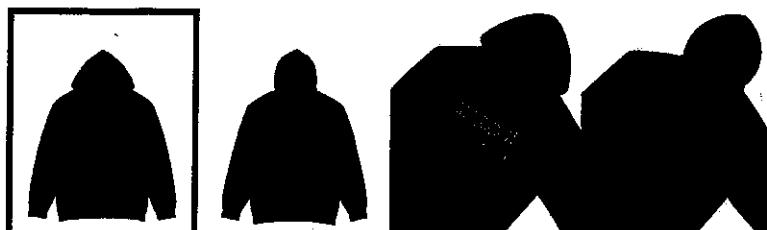
This high-quality outdoor classic is a steal! It features a double-lined hood and comes in colors for any adventure.

- 50% pre-shrunk cotton, 50% polyester
- Midweight fabric (8.0 oz)
- Regular fit

Select size [Size guide](#)

S M L XL

2XL 3XL 4XL 5XL

1 [Add to Cart](#)

**MAYDAY.HEALTH**

# What do you need?

**Abortion****Morning after pills****Birth Control****Gender-Affirming Care**

Did you know you can proactively order abortion pills even if you're not currently pregnant? [Click here](#) for more info.

Interested in the abortion procedure instead? [Go here](#).

**EXHIBIT****8**

This site collects zero data that could identify a visitor.

**MAYDAY.HEALTH**

# How long has it been since your last period?

**Less than 12 weeks**

**More than 12 weeks**

**I don't know**

◀ ▶

Just take me to the abortion pills [»](#)

Did you know you can proactively order abortion pills even if you're not currently pregnant? Click [here](#) for more info.

Interested in the abortion procedure instead? [Go here.](#)

Abortion pills are safe, effective during the first 12 weeks, and FDA-approved to get in the mail in all 50 states. It is safe to do your own abortion at home with abortion pills. Questions about cost, legal risk, and websites we link out to are answered in our [FAQ](#).

**EXHIBIT**

tabloid

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## Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation

Mifepristone (mifepristone) and its generic, Mifepristone Tablets, 200 mg (collectively mifepristone) are approved, in a regimen with misoprostol, to end an intrauterine pregnancy through ten weeks gestation (70 days or less since the first day of a patient's last menstrual period). The FDA first approved Mifepristone in 2000 and approved a generic version of Mifepristone, Mifepristone Tablets, 200 mg, in 2019.

### Risk Evaluation and Mitigation Strategy (REMS) Information

Mifepristone and its generic, Mifepristone Tablets, 200 mg, are available under a single, shared system risk evaluation and mitigation strategy (REMS), known as the Mifepristone REMS Program, which sets forth the requirements that must be followed for prescribing and dispensing mifepristone for medical termination of pregnancy through ten weeks gestation.

Under the Mifepristone REMS Program, mifepristone must be prescribed by certified prescribers and must be dispensed by or under the supervision of a certified prescriber or by a certified pharmacy on a prescription issued by a certified prescriber. Under the Mifepristone REMS Program, mifepristone may be dispensed in person or by mail.

Mifepristone was first approved in 2000 with restrictions to assure its safe use. Mifepristone was deemed to have in effect an approved REMS under the Food and Drug Administration Amendments Act of 2007. In 2019, at the same time the FDA approved the generic version of Mifepristone, the agency approved the Mifepristone REMS Program, a single, shared system REMS for mifepristone products for the medical termination of intrauterine pregnancy through 70 days gestation.

In 2021, after conducting a review of the Mifepristone REMS Program, the FDA determined that the available data and information support modification of the REMS to reduce burden on the health care delivery system and to ensure the benefits of the product outweigh the risks. After reviewing supplemental applications from the applicants for Mifepristone and the approved generic, the FDA approved a modification to the Mifepristone REMS Program on January 3, 2023. As modified, the Mifepristone REMS Program includes the following requirements, among others:

- Mifepristone must be prescribed by a health care provider that meets certain qualifications and is certified under the Mifepristone REMS Program.
- In order to become certified to prescribe mifepristone, health care providers must complete a Prescriber Agreement Form.
- The Patient Agreement Form must be reviewed with and signed by the patient and the health care provider, and the risks of the mifepristone treatment regimen must be fully explained to the patient before mifepristone is prescribed.
- The patient must be provided with a copy of the Patient Agreement Form and mifepristone Medication Guide (FDA-approved information for patients).
- Mifepristone may only be dispensed by or under the supervision of a certified prescriber, or by a certified pharmacy on a prescription issued by a certified prescriber.
- To become certified to dispense mifepristone, pharmacies must complete a Pharmacy Agreement Form.
- Certified pharmacies must be able to ship mifepristone using a shipping service that provides tracking information.
- Certified pharmacies must ensure mifepristone is dispensed to the patient in a timely manner.

To learn more, please see [Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation](#) ([/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation](#)).

### FDA Does Not Recommend Buying Mifepristone Online

Mifepristone prescribed under the Mifepristone REMS Program will be dispensed to you by your health care provider (or someone under the supervision of your health care provider), or by a pharmacy to which your health care provider has submitted your prescription. You can ask your health care provider whether they are certified in the Mifepristone REMS Program (or working under the supervision of someone who is). The FDA does not recommend purchasing mifepristone outside of the Mifepristone REMS Program – e.g. buying it online or personally transporting it from a foreign country. If a person does so, they would be bypassing important safeguards specifically designed to protect their health. Prescription medicines that are approved for use in the United States have been reviewed for safety, effectiveness, and quality by the FDA, and are subject to FDA-regulated manufacturing controls, including inspection of manufacturing facilities. Generally, prescription medicines purchased from foreign sources are not the FDA-approved versions. The FDA does not have regulatory oversight of prescription medicines from outside the drug supply chain; therefore, the FDA cannot ensure the safety, effectiveness, or quality of those medications.

Feedback

EXHIBIT

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## Related Information

- [Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation \(/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone\)](#)
- Previous REMS
  - [REMS Approved in 2011 \(/media/164648/download?attachment\)](#)
  - [REMS Approved in 2016 \(/media/164649/download?attachment\)](#)
  - [REMS Approved in 2019 \(/media/164650/download?attachment\)](#)
  - [REMS Approved in 2021 \(/media/164651/download?attachment\)](#)
- [Historical Information on Mifepristone \(marketed as Mifepristone\) \(http://wayback.archive-it.org/7993/20161022205309/http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111334.htm\)](#)  
 (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)

## Labeling and Other Important Information

### Mifepristone (mifepristone)

- [Mifepristone Prescribing Information \(\[https://www.accessdata.fda.gov/drugsatfda\\\_docs/label/2023/020687Orig1s025lbl.pdf\]\(https://www.accessdata.fda.gov/drugsatfda\_docs/label/2023/020687Orig1s025lbl.pdf\)\)](#)
- [Mifepristone Medication Guide \(\[https://www.accessdata.fda.gov/drugsatfda\\\_docs/label/2023/020687Orig1s025lbl.pdf#page=16\]\(https://www.accessdata.fda.gov/drugsatfda\_docs/label/2023/020687Orig1s025lbl.pdf#page=16\)\)](#)
- [Mifepristone Patient Agreement Form  
\(\[https://www.accessdata.fda.gov/drugsatfda\\\_docs/rems/Mifepristone\\\_2023\\\_01\\\_03\\\_Patient\\\_Agreement\\\_Form.pdf\]\(https://www.accessdata.fda.gov/drugsatfda\_docs/rems/Mifepristone\_2023\_01\_03\_Patient\_Agreement\_Form.pdf\)\)](#)
- [Mifepristone Prescriber Agreement Form  
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- [Mifepristone Pharmacy Agreement Form  
\(\[https://www.accessdata.fda.gov/drugsatfda\\\_docs/rems/Mifepristone\\\_2023\\\_01\\\_03\\\_Pharmacy\\\_Agreement\\\_Form\\\_Danco\\\_Laboratories.pdf\]\(https://www.accessdata.fda.gov/drugsatfda\_docs/rems/Mifepristone\_2023\_01\_03\_Pharmacy\_Agreement\_Form\_Danco\_Laboratories.pdf\)\)](#)

### Mifepristone Tablets, 200 mg

- [Mifepristone Tablets, 200 mg Prescribing Information \(/media/164653/download?attachment\)](#)
- [Mifepristone Tablets, 200 mg Medication Guide \(/media/164654/download?attachment\)](#)
- [Mifepristone Tablets, 200 mg Patient Agreement Form  
\(\[https://www.accessdata.fda.gov/drugsatfda\\\_docs/rems/Mifepristone\\\_2023\\\_01\\\_03\\\_Patient\\\_Agreement\\\_Form.pdf\]\(https://www.accessdata.fda.gov/drugsatfda\_docs/rems/Mifepristone\_2023\_01\_03\_Patient\_Agreement\_Form.pdf\)\)](#)
- [Mifepristone Tablets, 200 mg Prescriber Agreement Form  
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- [Mifepristone Tablets, 200 mg Pharmacy Agreement Form  
\(\[https://www.accessdata.fda.gov/drugsatfda\\\_docs/rems/Mifepristone\\\_2023\\\_01\\\_03\\\_Pharmacy\\\_Agreement\\\_Form\\\_GenBioPro\\\_Inc.pdf\]\(https://www.accessdata.fda.gov/drugsatfda\_docs/rems/Mifepristone\_2023\_01\_03\_Pharmacy\_Agreement\_Form\_GenBioPro\_Inc.pdf\)\)](#)

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## FDA.gov Site Customer Feedback

Help us improve FDA.gov! We will use your responses to improve the experience for millions of people who visit FDA.gov.  
Fields marked with an asterisk (\*) are required.

1. Which of the following best categorizes the information you were looking for on FDA.gov today?
2. Which of the following best describes the information you were looking for on FDA.gov today?
3. Did you find the information you were looking for on FDA.gov today?

4. For this visit to the FDA site, which of the following roles best describes you? If you are a consultant or an attorney, please select the role of the individual or organization that you represent.

5. How frequently do you visit FDA.gov?

6. On a scale from 0-10, based on your experience today, how likely are you to recommend this website to a friend or colleague?

7) Overall, how satisfied or dissatisfied were you with your experience on the FDA website today?

Navigation

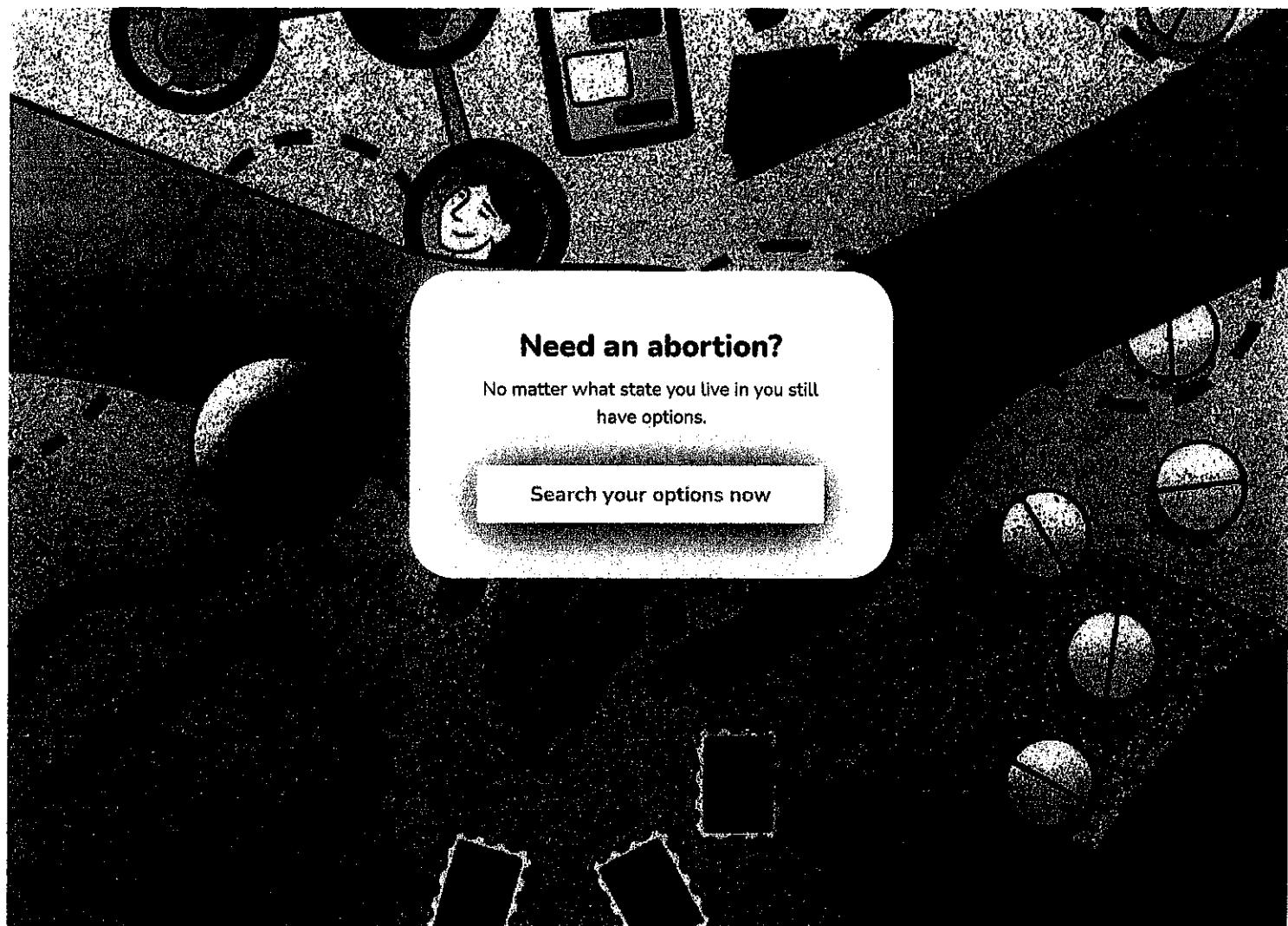
Look & Feel

Using FDA's search feature

Understandability of the content

Overall Experience

X



## Find verified abortion clinics and abortion pills by mail safely & privately

I Need An A can help you learn about all your abortion options and find the most up to date information about abortion clinics, pills by mail, state abortion laws, and support. We've designed ineedana.com to protect your privacy by not storing anything you enter when you search your options and keeping your digital footprint small.

If you are using a shared device and trying to keep your information private, we recommend you remove this site from your browser history and in the future use "incognito" or "private" browsing to look up information.

[Get more info on digital privacy](#)

**EXHIBIT**



## Need an abortion? We're here to help.

To find your best options, we need a bit of information from you. None of what you enter will be stored or shared, ever. [Learn why we ask for this.](#)

Location \*Required

What's your city or zipcode?

Pick first day of last period

I'm not sure

mm/dd/yyyy

If you're under 18, enter your age

?

How old are you?

Search

Advanced Search

EXHIBIT

12



EN ✓

## Need an abortion? We're here to help.

To find your best options, we need a bit of information from you. None of what you enter will be stored or shared, ever. [Learn why we ask for this.](#)

Location \*Required

Pierre, SD 57501, USA

Pick first day of last period

05/21/2025

(30 weeks, 5 days)

I'm not sure

If you're under 18, enter your age

19

?

Search

Advanced Search

!

EXHIBIT

13

tabler

/

 Open filter menu

Reset filters

Filtered by: 30 weeks or more

 8 hrs 39 min drive**A Women's Choice**

Aurora, Colorado



In-Clinic Procedure



Abortion Pills

A small icon of a computer monitor with a web page, representing a website link.

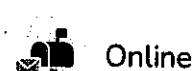
Go to website

A small icon of a telephone handset, representing a phone number.

(303) 418-8660

A small icon of a magnifying glass over a document, representing more information.

More Information



Online

### Community Network - Idaho Access

This service is verified and medically very safe, but it can come with legal risk in your state.



A small icon of a computer monitor with a web page, representing a website link.

Go to website

A small icon of a magnifying glass over a document, representing more information.

More Information



~1 hr 40 min direct flight

Fly from Pierre, SD (PIR) to  
Denver, Colorado

There is 1 clinic near Denver, Colorado that offers



In-Clinic Procedure



Abortion Pills

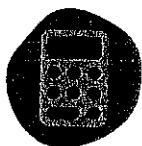


Pills By Mail

## More Information

Show more

# What are your biggest questions?



**How much do abortions cost in South Dakota?**



**What if I need help paying?**



**What's an in-clinic abortion like?**



**What are the abortion laws in South Dakota?**





I need help. Who can I talk to? >

## The most important thing to know: You're not alone.

**People from all walks of life have abortions. These are some of their stories.**

video after 15 weeks +9

video written +9

***Why was it so complicated for me to get an abortion.. in the...***

▶ Video length 50:00

Watch here

video certain +6

***Trans people build families and have abortions, too.***

▶ Video length 4:40

Watch @ WeTestify

## Shout Your Abortion Stories Volume 3

▶ Video length 1:41

Watch @ Shout Your Abortion

See more stories

### Your safety and privacy are our top priorities

As such, we'll never ask you for personally identifiable information or store anything you've input.

If you are using a shared device and trying to keep your information private, we recommend you remove this site from your browser history. We can help you [learn how](#) to do that and other ways to reduce your digital footprint.

[Learn more about privacy](#)



## About ineedana.com

Built by people who've had abortions for people who will, ineedana.com launched in 2016 as the first comprehensive and regularly updated resource for abortion seekers in the US. Since then, we've been called the "Quintessential Post-Roe Resource" by The Nation, appeared on John Oliver's Last Week Tonight, and, most importantly to us, have helped more than 1.4 million people learn about their options. As a small and independent non-profit project, we couldn't do it without the support of our volunteers and donors.

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Find all your abortion options

Providers, laws, costs, and support updated daily

Search now 





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To find your best options, we need a bit of information from you. None of what you enter will be stored or shared, ever. [Learn why we ask for this.](#)

Location \*Required

Pierre, SD 57501, USA

Pick first day of last period

10/30/2025

(7 weeks, 4 days)

I'm not sure

If you're under 18, enter your age

14

?

Search

Advanced Search

**You are a minor**

**If you decide to travel for care, you may face additional barriers as a teen.**

**Learn more in our guide for teens**

 Open filter menu

Reset filters

Filtered by: 7 weeks or more

 6 hrs 6 min drive**Red River Women's Clinic**

Moorhead, Minnesota



In-Clinic Procedure



Abortion Pills

 Go to website (218) 477-3191[More Information](#) Online**Aid Access via provider in a "shield law" state**

This service is verified and medically very safe, but it can come with legal risk in your state.

 Pills By Mail Go to website



~1 hr 40 min direct flight

**Fly from Pierre, SD (PIR) to  
Denver, Colorado**

**There are 4 clinics near Denver, Colorado that offer**



**In-Clinic Procedure**



**Abortion Pills**



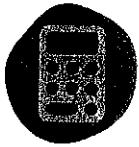
**Pills By Mail**

**up to 33 weeks**

**More Information**

**Show more**

**What are your biggest questions?**



**How much do abortions cost in South Dakota?**



**What if I need help paying?**



**What's an in-clinic abortion like? >****What happens with abortion pills? >****What are the abortion laws in South Dakota? >****I need help. Who can I talk to? >**

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## **Shout Your Abortion Stories Volume 3**

▶ Video length 1:41

Watch @ Shout Your Abortion

See more stories

**Your safety and privacy are our top priorities**

As such, we'll never ask you for personally identifiable information or store anything you've input.

If Case 1:26-cv-00078-KPF Document 35-1 Filed 01/26/26 Page 44 of 100  
You are using a shared device and trying to keep your information private, we recommend you remove this site from your browser history. We can help you learn how to do that and other ways to reduce your digital footprint.

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Find all your abortion options

Providers, laws, costs, and support updated daily

Search now 

[Blog](#)

## A Teen's Guide to Accessing Abortion

Posted July 1, 2024

Abortion is safe, normal, and any reason to have one is a good reason. Unfortunately, accessing abortion care can be challenging especially for young people. But you're not alone - we can give you an overview of everything so you can make the best decision for yourself and can connect you with trusted organizations that can help.

### **Let's start with parental involvement laws, what are they?**

There are currently 24 states that require parental notification or consent when a minor is seeking an abortion -- these are called parental involvement laws. In most states, a legal minor is someone who is under 18 years old. **The requirements for parental involvement laws depend on your state and the clinic.** In some states it means the clinic would have to notify your parent or legal guardian. In others, it means your parent or legal guardian must be with you at the clinic to sign consent forms. If you can't find the information at ineedana.com, calling the local abortion clinic is a great resource or contact the **Repro Legal Helpline by calling 1-844-868-2812.**

A rectangular stamp with a double-line border. The word "EXHIBIT" is printed in bold capital letters at the top. Below it, the number "15" is written in a large, bold, black font. The word "tabbed" is printed vertically along the left edge of the stamp.

Digitized by srujanika@gmail.com

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There are also two other sections to consider when the terms

1. Having medication abortion pills sent to your home [or to a trusted friend/family member] and having an abortion at home.
2. Traveling to a state that does not have parental involvement laws, so you can consent to your own abortion without your parents or a

**Places that don't have parental involvement laws:** Alaska, California, Connecticut, Hawaii, Illinois, Maine, Minnesota, Nevada, New Jersey, New Mexico, New York, Oregon, Vermont, Washington, Washington

**If you are 16 years old or older, you do not need to involve your parents in Delaware, Massachusetts, and Montana. If you are 17 years old or older, you do not need parental consent in South Carolina. Maryland has a parental notification law but can be waived by a**



**MAYDAY.HEALTH**

# Do you live in a red state on the map below?

Just take me to the abortion pills >

Interested in the abortion procedure instead? [Go here.](#)

**Yes**

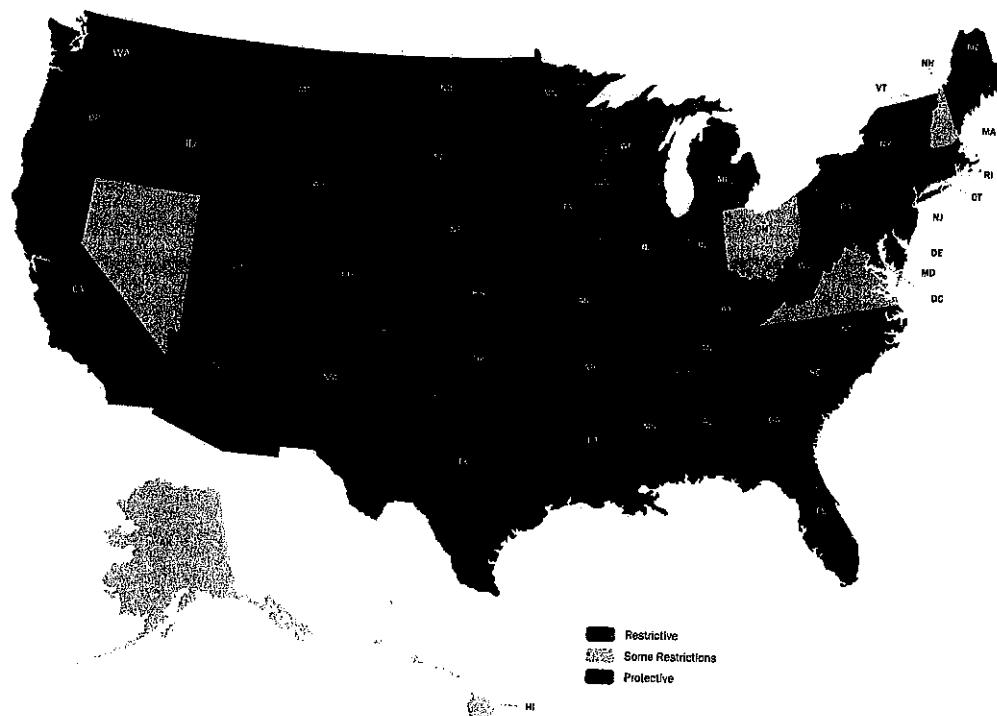
**No**

< >

Hi, my name's Charley. I can help you get or manage an abortion. / Hola, mi nombre es Charley. Puedo ayudarte a conseguir o manejar un aborto.

**EXHIBIT**

**17**



Abortion pills are safe, effective during the first 12 weeks, and FDA- approved to get in the mail in all 50 states. It is safe to do your own abortion at home with abortion pills. Questions about cost, legal risk and websites we link out to are answered in our [FAQ](#).

# Mayday Videos

**MAYDAY.HEALTH**

Before going to any external websites below, you can  
take these steps for digital privacy.

## Order from:

### Aid Access

SHIPS TO ALL 50 STATES

COST: SLIDING SCALE

DELIVERY WITHIN 5 DAYS

### Abuzz

SHIPS TO SELECT STATES

COST: SLIDING SCALE

Hi, my name's Charley. I can help you get or manage an abortion. / Hola, mi nombre es Charley. Puedo ayudarte a conseguir o manejar un aborto.

EXHIBIT

18

## The MAP

SHIPS TO ALL 50 STATES

COST: SLIDING SCALE

DELIVERY WITHIN 5 DAYS

## A Safe Choice

SHIPS TO ALL STATES

COST: \$150

DELIVERY WITHIN 4 DAYS

## We Take Care of Us

SHIPS TO ALL 50 STATES

COST: SLIDING SCALE

DELIVERY WITHIN 3 BUSINESS DAYS

# FAQs

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**How are health care providers able to get me pills?**



---

**Questions about cost, legal risk, and websites we link out to?**



---

**Want more information and other ways to get pills?**

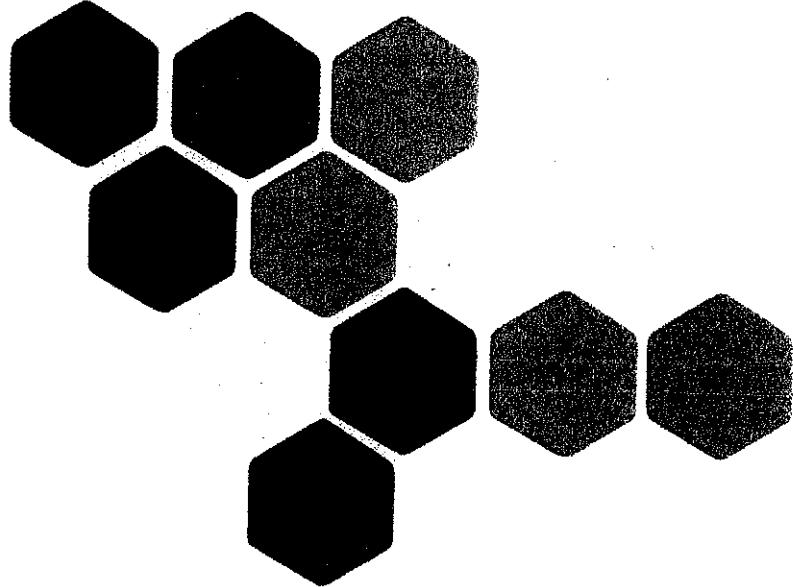


---

**data** that could identify a visitor.

This site collects **zero data** that could identify a visitor.

This site cc



## 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? →  
(<https://www.abuzzhealth.com/pregnancy-calculator/>)

## 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.

EXHIBIT

19

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- PREVIOUS

1

## Important Information

Here is information about the potential legal risks of getting abortion pills by mail in the state you selected. You can also contact the [Repro Legal Helpline](#) for questions.

You can see other options [here](#) or press next to continue.

← PREV / QUS

NEXT →

tabbies®  
**EXHIBIT**  
**21**

**PLAN C****Español**

# How people get abortion pills online in every state

**Frequently asked questions** about abortion pills and abortion pill access by mail.

[Finding abortion pills](#)

[About abortion pills](#)

[Using abortion pills](#)

[Legal and safety considerations](#)

## Where people get abortion pills

Options for at-home abortion pill access will vary by location. Click below to find options by state or territory.

**Location \***

Search by state or territory

**EXHIBIT****21**

# Finding abortion pills

---

**Where can people find abortion pills?**

---

**Can people still get abortion pills by mail if their state bans abortion?**

---

**Do people need to get any medical tests?**

---

**Can people buy abortion pills in advance, to use later?**

---

**How long are abortion pills good for?**

---

**Does insurance or Medicaid cover abortion pills?**

---

**Can people buy abortion pills from Amazon?**

---

**What are online pharmacies, or websites that sell abortion pills, and how do people order from them?**

---

**What does "sliding scale" mean?**

---



**I've heard about period pills. Are they different from abortion pills?**

---



## **About abortion pills**

---

**What is "abortion with pills," or a medication abortion? How do the pills work?**

---



**Do people need a prescription for abortion pills?**

---



**How far into a pregnancy can a person take abortion pills?**

---



**How much do abortion pills cost?**

---



**Is the abortion pill the same as Plan B, the morning-after pill?**

---



## **Using abortion pills**

---

**Where can people find instructions for using the pills?**

---

**What can a person expect after taking abortion pills?**

---

**What is the difference between getting pills from a medical service or getting them from alternative suppliers?**

---

**What kind of real-time support is available?**

---

## **Legal and safety considerations**

---

**Is this legal? Can someone get in trouble for using abortion pills?**

---

**Are abortion pills safe? What are the health risks?**

---

**What options do minors have if their state requires parental notification or consent for an abortion?**

---

**How does Plan C do research and test services?**

---

How can someone avoid false information or abortion scams?



## 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.

Email \*

Your email

## Follow @plancpills



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Site by [Eyes Open](#)



**Abortion Care Network**

Where can people find instructions for using the pills?

---



What can a person expect after taking abortion pills?

---



What is the difference between getting pills from a medical service or getting them from alternative suppliers?

---



What kind of real-time support is available?

---



## Legal and safety considerations

---

Is this legal? Can someone get in trouble for using abortion pills?

---



- Research shows that hundreds of thousands of people have received and used pills by mail over the past few years with no legal problems.
- But, in rare cases (less than 1%), people have gotten in legal trouble, even though most states don't have laws against doing your own abortion.
- Legal risk can depend on where someone lives, their identity and how far along they are in pregnancy. Also know that even if something isn't a crime, people can still be targeted by law enforcement.

The Repro Legal Helpline provides free, confidential information that can help people better understand legal risk:

**Repro Legal Helpline**

[reprolegalhelpline.org](http://reprolegalhelpline.org)

**EXHIBIT**

**23**

Ineedana.com also has a state legal directory.

### How do people get into trouble?

Research by the legal organization If/When/How suggests these are the most common ways people have gotten into trouble:

- they told someone about their abortion and that person reported them.
- they got follow-up medical care and the provider reported them (many people say they are having a miscarriage to avoid this risk, which is medically what is happening in the body).
- they were later in pregnancy than they thought and didn't know what to do with the fetal tissue (this calculator can help people understand how pregnant they are).

In the end, it is up to every individual to decide what level of legal risk they are willing to take. Read more about legal risk and find examples [here](#).

### What about online activity? Can that get someone in trouble?

People who have been criminalized for accessing or using pills have mostly been reported based on telling someone they know, or via a provider. That said, digital footprints (messages, browser history) also can be used as evidence against someone by authorities. Learn how to protect the privacy of your healthcare information and communications here.

---

Are abortion pills safe? What are the health risks?

---

What options do minors have if their state requires parental notification or consent for an abortion?

---

# Aid Access

## Get abortion and miscarriage care, wherever you are.

An abortion or miscarriage treatment can be done at home with pills or in a clinic with a medical procedure.

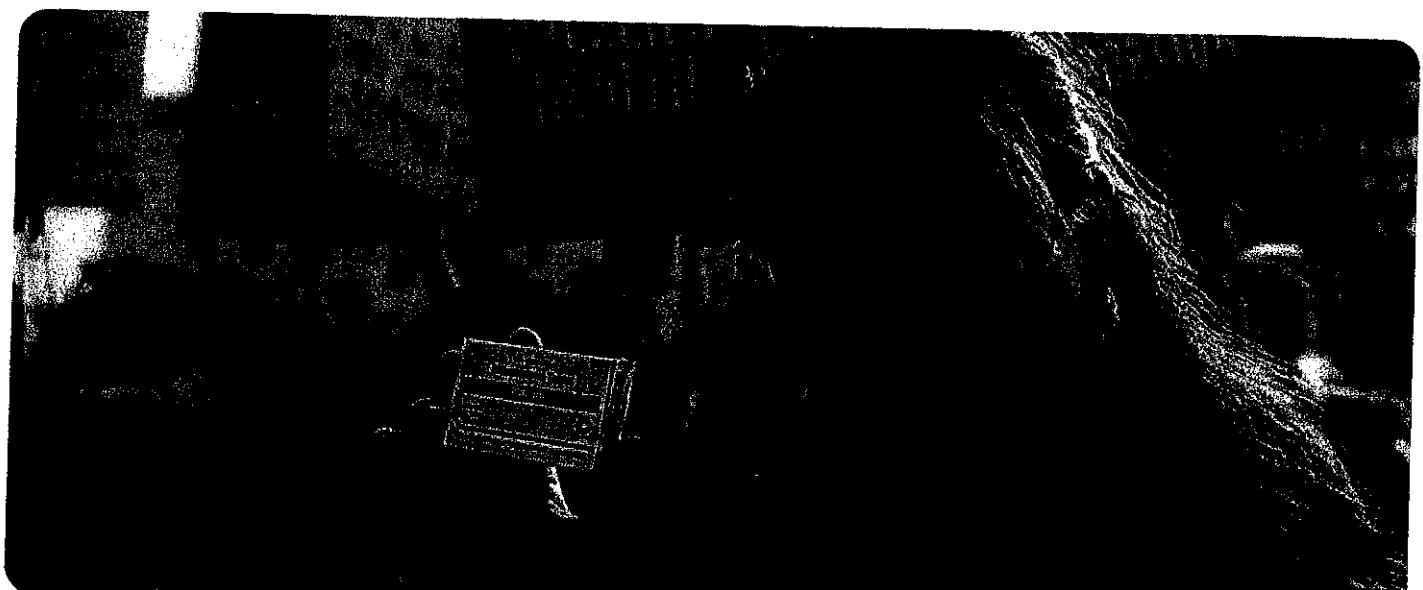
**Less than 14 weeks pregnant?** Get pills shipped to you. The pills are the same ones you get in a clinic. They are medically very safe. The pills are prescribed by a medical professional and packaged in a plain envelope.

**Unsure how far along you are?** We can help you figure it out.

[Get pills](#)

**More than 14 weeks pregnant?** You will need to have an abortion in a clinic.

[Find a clinic](#)



EXHIBIT

24

**WARNING LETTER****Aidaccess.org****MARCS-CMS 575658 — MARCH 08, 2019**[More Warning Letters \(/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters\)](#)**Product:**

Drugs

**Recipient:**

Aidaccess.org

United States

**Issuing Office:**

Center for Drug Evaluation and Research

10903 New Hampshire Ave

Silver Spring, MD 20903

United States

Feedback

TO: Aidaccess.org

FROM: The United States Food and Drug Administration

RE: Causing the Introduction of a Misbranded and Unapproved New Drug into Interstate Commerce

DATE: March 8, 2019

**WARNING LETTER**

The United States (U.S.) Food and Drug Administration (FDA) recently reviewed your website, <http://www.aidaccess.org>, and determined that you cause the introduction into interstate commerce of misbranded and unapproved new drugs in violation of sections 301(a), 301(d), and 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. §§ 331(a), 331(d), and 355(a)).

The sale of misbranded and unapproved new drugs poses an inherent risk to consumers who purchase those products. Unapproved new drugs do not have the same assurance of safety and effectiveness as those drugs subject to FDA oversight. Drugs that have circumvented regulatory safeguards may be contaminated; counterfeit, contain varying amounts of active ingredients, or contain different ingredients altogether.

FDA requests that you immediately cease causing the introduction of these violative drugs into U.S. commerce.

**Unapproved New Drug****EXHIBIT****25**

Aidaccess.org states on its website, "Aid Access supports women who are not able to access local services. If you are healthy and less than 9 weeks pregnant, you can do the online consultation. The abortion pills mifepristone and misoprostol will be delivered to you by mail." By facilitating the sale of unapproved mifepristone and misoprostol to consumers in the U.S., Aidaccess.org causes the introduction of unapproved new drugs into U.S. commerce in violation of the FD&C Act. These products are drugs within the meaning of section 201(g) of the FD&C Act (21 U.S.C. § 321(g)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or because they are intended to affect the structure or function of the body. These drugs are also new drugs as defined by section 201(p) of the FD&C Act (21 U.S.C. § 321(p)], because they are not generally recognized as safe and effective for their labeled use. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FD&C Act (21 U.S.C. § 355(a)].

Aidaccess.org facilitates the sale to U.S. consumers of unapproved mifepristone in a regimen with unapproved misoprostol labeled for the termination of pregnancy, including "(b)(4), (b)(6)," a combination pack that includes both mifepristone and misoprostol tablets. The "(b)(4), (b)(6)" product is labeled as a "CombiPack of Mifepristone Tablets IP & Misoprostol Tablets IP" and is manufactured by (b)(4), (b)(6). The patient insert accompanying the product states that "(b)(4), (b)(6)" is "indicated for early medical abortion for up to 9 weeks." The product labeling states that "(b)(4), (b)(6)" is "Marketed by: (b)(4), (b)(6)."

No approved applications pursuant to section 505 of the FD&C Act are in effect for this product. Accordingly, its introduction or delivery for introduction into interstate commerce violates sections 301(d) (21 U.S.C. § 331(d)] and 505(a) (21 U.S.C. § 355(a)] of the FD&C Act.

There is an FDA-approved prescription mifepristone drug product that is marketed in the U.S. under the brand name "Mifeprex" and indicated in a regimen with FDA-approved misoprostol, for the termination of early pregnancy (10 weeks or less since last menstrual period began). However, there are no approved drug applications pursuant to section 505 of the FD&C Act in effect for the "(b)(4), (b)(6)" product manufactured by (b)(4), (b)(6), caused to be introduced into U.S. commerce via Aidaccess.org.

The substitution of unapproved drugs for FDA-approved prescription drugs poses significant health risks to U.S. consumers. For example, in this case, use of the unapproved drug would not be subject to the same protections as use of the FDA approved product. Mifeprex labeling bears a boxed warning indicating that the drug carries a risk of serious or even life-threatening adverse effects, including serious and sometimes fatal infections and prolonged heavy bleeding, which may be a sign of incomplete abortion or other complications. As further noted in the Mifeprex labeling, Mifeprex is only available in the U.S. through a Risk Evaluation and Mitigation Strategy (REMS) program. The REMS program is intended to mitigate the risk of serious complications associated with Mifeprex by: requiring healthcare providers who prescribe Mifeprex to be certified in the Mifeprex REMS program; ensuring that Mifeprex is only dispensed in certain healthcare settings by or under the supervision of a certified prescriber; and informing patients about the risk of serious complications associated with Mifeprex. Consistent with the REMS, Mifeprex is not sold through retail pharmacies or over the internet. Use of the unapproved "(b)(4), (b)(6)" product would not be subject to these FDA-approved REMS provisions.

### **Misbranded Drug**

A drug is misbranded under section 502(f)(1) of the FD&C Act (21 U.S.C. § 352(f)(1)) if it fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 CFR 201.5). Prescription drugs, as defined in section 503(b)(1) of the FD&C Act (21 U.S.C. § 353(b)(1)], include those that, because of their toxicity or other potentiality for harmful effect, and/or the method of their use, and/or the collateral measures necessary for their use, are not safe for use except under supervision of a practitioner licensed by law to administer them. Prescription drugs, as defined in section 503(b)(1)(A) of the FD&C Act, can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Because the "(b)(4), (b)(6)" product contains prescription drugs intended for a condition that is not amenable to self-diagnosis and treatment by a layperson, adequate directions cannot be written such that a layperson can use the product safely for its intended use. Consequently, the labeling for "(b)(4), (b)(6)" fails to bear adequate directions for its intended use, causing it to be misbranded under section 502(f)(1) of the FD&C Act. In addition, because "(b)(4), (b)(6)" is not approved in the U.S., it is also not exempt under 21 CFR 201.115(a) from the requirements of section 502(f)(1) of the FD&C Act.

The "(b)(4), (b)(6)" product is also misbranded under section 502(f)(2) of the FD&C Act (21 U.S.C. § 352(f)(2)) because it fails to bear "adequate warnings against use ... where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application ...." This is particularly concerning because FDA-approved mifepristone indicated for medical termination of early pregnancy is subject to a REMS program. The REMS program for Mifeprex restricts dispensing to certain healthcare settings, specifically clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber. Healthcare providers who prescribe Mifeprex must be certified in the Mifeprex REMS program. In order to be certified, the prescriber must have the ability to: assess the duration of the pregnancy accurately, diagnose ectopic pregnancies, and provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made arrangements for others to provide such care. Healthcare providers must be able to ensure that women have access to medical facilities for emergency care, and must agree to other responsibilities, including reviewing & and signing the Patient Agreement Form with the patient and providing each patient with a copy of the signed Patient Agreement Form and the Medication Guide. In addition, the REMS program contains specific requirements for distributors including, but not limited to, following processes and procedures for storage, handling, shipping, tracking package serial numbers, proof of delivery and controlled returns of Mifeprex. By facilitating the sale of the unapproved and misbranded "(b)(4), (b)(6)" product, Aidaccess.org is causing important safety measures that are put in place for FDA-approved mifepristone for medical termination of early pregnancy to be bypassed.

By facilitating the sale of "(b)(4), (b)(6)" to U.S. consumers, Aidaccess.org is causing the introduction of a misbranded drug into interstate commerce in violation of section 301(a) of the FD&C Act (21 U.S.C. § 331(a)).

\*\*\*

FDA is taking this action against Aidaccess.org because of the risks posed by its conduct in causing the introduction of a misbranded and unapproved new drug into U.S. commerce. FDA's regulation and oversight of the drug approval process protects consumers by requiring rigorous scientific standards for new drug approval, labeling review for accuracy and completeness, and manufacturing procedures and testing performed under closely controlled conditions at FDA-registered and inspected facilities. Sourcing drugs from outside of the legitimate U.S. drug supply chain can pose serious risks to patients who may receive medications that are adulterated and are not shipped and/or stored properly.

This letter is not intended to identify all the ways in which your activities might be in violation of U.S. law. You should promptly cease causing the sale of unapproved new drugs and misbranded drugs to U.S. consumers and correct all other violations of the FD&C Act. Failure to correct these violations may result in FDA regulatory action, including seizure or injunction, without further notice.

Please notify this office in writing within 15 working days of receipt of this letter of any steps you have taken or will take to correct the violations set forth above and to prevent their recurrence. If the corrective action(s) cannot be completed within 15 working days, state the reason for the delay and the time within which the correction(s) will be completed. If you believe that this product is not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

Your response and any other inquiries concerning this letter should be sent to FDA's Internet Pharmacy Task Force at [FDIAgentInternetPharmacyTaskForce-CDER@fda.hhs.gov](mailto:FDAIInternetPharmacyTaskForce-CDER@fda.hhs.gov).

/S/

Thomas Christi  
Director  
Office of Drug Security, Integrity, and Response  
Office of Compliance  
Center for Drug Evaluation and Research  
Food and Drug Administration

Cc:

Dr. Rebecca Gomperts  
(b)(4), (b)(6)

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4. For this visit to the FDA site, which of the following roles best describes you? If you are a consultant or an attorney, please select the role of the individual or organization that you represent.

5. How frequently do you visit FDA.gov?

6. On a scale from 0-10, based on your experience today, how likely are you to recommend this website to a friend or colleague?

7) Overall, how satisfied or dissatisfied were you with your experience on the FDA website today?

Navigation

Look & Feel

Using FDA's search feature

Understandability of the content

Overall Experience

X

# Get Abortion Pills in South Dakota - Order Here

You can buy an abortion pill online and get it by mail in South Dakota. The FDA has approved abortion pills by mail from U.S. based abortion providers for all 50 U.S. states including South Dakota.

Aid Access will help you order abortion pills and get mifepristone and misoprostol tablets delivered to your SD home in Sioux Falls, Rapid City, Aberdeen, Brookings, Watertown, or anywhere else in South Dakota.

## South Dakota abortion pill online orders:

- South Dakota abortion pill online orders costs \$150 USD
- Reliable abortion pill shipping to South Dakota in 1-5 days
- Tracking numbers provided when the pills are mailed
- Help desk support available in English and Spanish

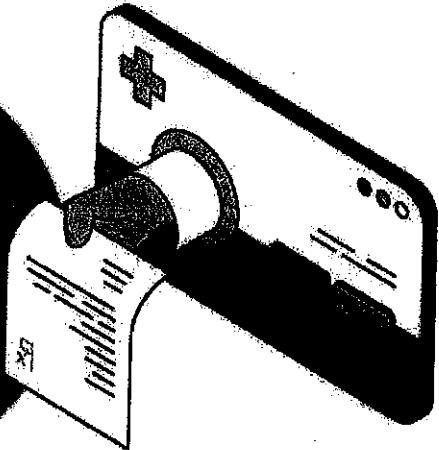
EXHIBIT

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# How to get an abortion pill in South Dakota

## Submit our online consultation form

We need to ask a few questions about your health & pregnancy to ensure you are eligible



1

## Our doctors will review your order

Our medical team will immediately review your consultation and we will email you the next steps.

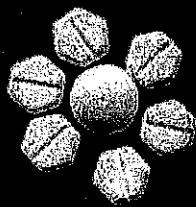


## Receive pills by mail in 1-5 days

The abortion pills will be mailed to your address within 24 hours of your order being approved.

3





# AidAccess

## How to get abortion pills by mail in South Dakota

You can get a prescription from Aid Access and have abortion pills delivered to your home in South Dakota. [Order abortion pills by mail here](#). These are the steps to get abortion pills delivered to your home by mail:

### **Start your online consultation for abortion pills in South Dakota**

Once you begin your online consultation for abortion pills in South Dakota, you will be asked some questions about your health and pregnancy to ensure you are eligible. All information you share with us is private and protected.

### **Our U.S. based doctors approve your online abortion pill order**

Your consultation will immediately be reviewed by our medical team. Our help desk will email you the next steps, ask you to send a donation of \$150 USD, and then approve your online abortion pill order within 24 hours.

### **Receive abortion pills by mail in SD in 1-5 days**

The abortion pills will be shipped by mail to your home in SD within 24 hours of your order being approved. You will receive a tracking number so you can follow your package as it moves through the mail.

**Start now: [Get the abortion pill online here](#)**

# How much does the abortion pill cost in South Dakota?

As of 2024, the price of the abortion pill in South Dakota is \$150. How much it costs to get abortion pills in South Dakota also changes on a sliding scale so cheaper or free abortion pill kits may be available. Ask our help desk for more info after you submit our free online health screening form.

## More ways to get South Dakota abortion pill access

If Aid Access is not able to meet your reproductive health needs, there are multiple ways people get South Dakota abortion pill access. To learn about other online telehealth services that are available to you, visit the Plan C Guide to Abortion Pills: [How to Order an Abortion Pill Online in South Dakota](#)

## South Dakota abortion clinic guides from Plan C Pills

If you determine that abortion pills will not meet your reproductive health needs, you can find information about local abortion support resources near you in the [South Dakota Abortion Clinic Guide](#) from Plan C Pills.

Additional guides to abortion clinics near South Dakota from Plan C Pills:

### [Abortion clinics near Sioux Falls, SD](#)

## Abortion laws in the State of South Dakota

For the most up to date information about abortion laws in South Dakota, visit [Guttmacher Institute](#), [Center for Reproductive Rights](#), or [AbortionFinder.org](#).

Begin here: [Order abortion pills online from Aid Access](#)

## Where to buy mifepristone and misoprostol in South Dakota?

Aid access helps people buy mifepristone and misoprostol throughout the state of South Dakota. You can order abortion pills by mail in all of these cities and everywhere in between:

### **Order the abortion pill in Brookings, South Dakota**

If you are in Brookings, you can order the abortion pill [here](#).

### **Get abortion pills in Aberdeen, South Dakota**

If you are in Aberdeen, you can get abortion pills [here](#).

### **Buy an abortion pill in Rapid City, South Dakota**

If you are in Rapid City, you can buy an abortion pill [here](#).

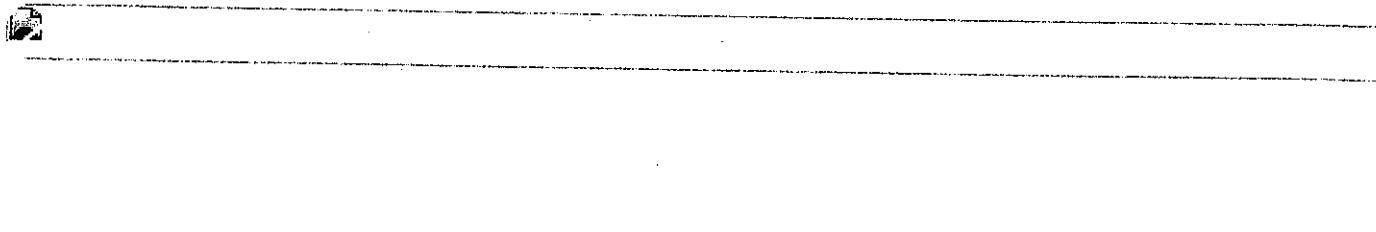
### **Buy abortion pills in Sioux Falls, South Dakota**

If you are in Sioux Falls, you can buy abortion pills [here](#).

**Get started: Order an abortion pill online here**

← [Back to FAQs General Questions](#)

## Is it legal?



### In the USA

People needing and having abortions in the USA are not breaking the law in any state! We realize there is a lot of confusing information out there. For legal questions or to get legal support call the Repro Legal Helpline at 844-868-2812. Or go to their website [reprolegalhelpline.org](http://reprolegalhelpline.org).

### International Situation

The World Health Organization (WHO) listed the abortion medicines mifepristone and misoprostol as essential medicines since 2005. [1]

Access to essential medicines as part of the right to the highest attainable standard of health ("the right to health") is well-founded in numerous international human rights treaties, such as:

1. The Universal Declaration of Human Rights: Article 25.1 in 1948;
2. The International Convention on the Elimination of All Forms of Racial Discrimination; Article 5 (e) (iv) in 1965;
3. The International Covenant on Economic, Social and Cultural Rights: Article 12.1 in 1966;
4. The Convention on the Elimination of All Forms of Discrimination against Women; Articles 11 (1) (f), 12 and 14 (2) (b) in 1979;
5. The 1989 Convention on the Rights of the Child; Article 24;
6. The International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families; Articles 28, 43 (e) and 45 (c) in 1990;



The authoritative General Comment 14 (2000) further applies the principles of accessibility, availability, appropriateness and assured quality to goods and services, which include essential medicines "as defined by the WHO Action Program on Essential Drugs."<sup>[2]</sup>

## United Nations Report

In October 2011, Anand Grover, the UN Special Rapporteur on the Right to Health, submitted a report to the UN General Assembly which stated, "Criminal laws penalizing and restricting induced abortion are the paradigmatic examples of impermissible barriers to the realization of women's right to health and must be eliminated. These laws infringe women's dignity and autonomy by severely restricting decision-making by women in respect of their sexual and reproductive health."<sup>[3]</sup>

General comment No. 22 (2016) on the right to sexual and reproductive health (article 12 of the International Covenant on Economic, Social and Cultural Rights) states that, "Essential medicines should also be available, including a wide range of contraceptive methods, such as condoms and emergency contraception, medicines for abortion and for post-abortion care, and medicines, including generic medicines, for the prevention and treatment of sexually transmitted infections and HIV."<sup>[4]</sup>

## World Health Organization

The World Health Organization's definition of health is: "Health is a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity."<sup>[5]</sup>

On October 30, 2018, the Human rights committee stated in the General comment No. 36 (2018) on article 6 of the International Covenant on Civil and Political Rights, on the right to life:

*"Although States parties may adopt measures designed to regulate voluntary terminations of pregnancy, such measures must not result in violation of the right to life of a pregnant woman or girl, or her other rights under the Covenant. Thus, restrictions on the ability of women or girls to seek abortion must not, inter alia, jeopardize their lives, subject them to physical or mental pain or suffering which violates article 7, discriminate against them or arbitrarily interfere with their privacy. States parties must provide safe, legal and effective*

access to abortion where the life and health of the pregnant woman or girl is at risk, and where carrying a pregnancy to term would cause the pregnant woman or girl substantial pain or suffering, most notably where the pregnancy is the result of rape or incest or is not viable. In addition, States parties may not regulate pregnancy or abortion in all other cases in a manner that runs contrary to their duty to ensure that women and girls do not have to undertake unsafe abortions, and they should revise their abortion laws accordingly. For example, they should not take measures such as criminalizing pregnancies by unmarried women or apply criminal sanctions against women and girls undergoing abortion or against medical service providers assisting them in doing so, since taking such measures compel women and girls to resort to unsafe abortion. States parties should not introduce new barriers and should remove existing barriers that deny effective access by women and girls to safe and legal abortion, including barriers caused as a result of the exercise of conscientious objection by individual medical providers. States parties should also effectively protect the lives of women and girls against the mental and physical health risks associated with unsafe abortions. In particular, they should ensure access for women and men, and, especially, girls and boys, to quality and evidence-based information and education about sexual and reproductive health and to a wide range of affordable contraceptive methods, and prevent the stigmatization of women and girls seeking abortion. States parties should ensure the availability of, and effective access to, quality prenatal and post-abortion health care for women and girls, in all circumstances, and on a confidential basis.

## Citations

[1] <https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf?sequence=1&isAllowed=y>

[2] [https://www.who.int/medicines/areas/human\\_rights/en/](https://www.who.int/medicines/areas/human_rights/en/)

[3] <https://www.un.org/press/en/2011/gashc4018.doc.htm>

[4] <https://www.ohchr.org/en/press-releases/2009/10/statement-professor-philip-alston-un-special-rapporteur-extrajudicial?LangID=E&NewsID=9219#sthash.MfGe1y5D.XSS87v3P.dpufh>

[5] <https://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf?ua=1>

This site collects **zero data** that could identify a visitor.

This site collects **zero data** that could identify a visitor.

# Mayday is a reproductive health education nonprofit

## Our Mission

Our mission is to share information about abortion pills, birth control, and gender-affirming care in any state. We hope to empower people to make their own informed decisions about their own bodies.

Our information comes from top clinicians, lawyers and health experts.

Mayday does not ask for any personal info. We do not track info that could be used to identify a visitor to this website. We do not sell, handle or benefit from abortion pills. We are not affiliated with any telehealth providers. We do not give medical or legal advice.

We just want people to know their options.

EXHIBIT

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# Additional Resources

Links to trusted organizations.

Before going to any external websites below, you can  
take these steps for digital privacy.

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**Abortion decision support**



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**Abortion pill FAQs**



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**What to expect**



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**Financial support**



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**Questions on logistics/delivery times/support  
while waiting**



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**Online/phone medical support**



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**In-person medical support**



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**Emotional support**



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**Legal support**



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**Privacy support**



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**Reproductive Justice**



**MAYDAY.HEALTH**

# Frequently Asked Questions

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**What if I'm concerned about the cost?** >

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**What is my legal risk?** >

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**Are abortion pills safe?** >

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**Why do other buttons send me to other websites? Can I trust them?** ▼

Some of our links go to other websites because they have the best content for a certain aspect of abortion care. We only link to other trusted websites and partners. You can go [here](#) to see how to best protect your digital privacy before leaving Mayday.

---

Hi, my name's Charley. I can help you get or manage an abortion. / Hola, mi nombre es Charley. Puedo ayudarte a conseguir o manejar un aborto.

## Mayday Videos

EXHIBIT

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**HIGHLIGHTS OF PRESCRIBING INFORMATION**

These highlights do not include all the information needed to use MIFEPREX safely and effectively. See full prescribing information for MIFEPREX.

**MIFEPREX®** (mifepristone) tablets, for oral use

Initial U.S. Approval: 2000

**WARNING: SERIOUS AND SOMETIMES FATAL INFECTIONS OR BLEEDING**

*See full prescribing information for complete boxed warning.*

Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following MIFEPREX use.

- **Atypical Presentation of Infection.** Patients with serious bacterial infections and sepsis can present without fever, bacteremia or significant findings on pelvic examination. A high index of suspicion is needed to rule out serious infection and sepsis. (5.1)
- **Bleeding.** Prolonged heavy bleeding may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed. (5.2)

MIFEPREX is only available through a restricted program called the Mifepristone REMS Program (5.3).

Before prescribing MIFEPREX, inform the patient about these risks. Ensure the patient knows whom to call and what to do if they experience sustained fever, severe abdominal pain, prolonged heavy bleeding, or syncope, or if they experience abdominal pain or discomfort or general malaise for more than 24 hours after taking misoprostol.

**INDICATIONS AND USAGE**

MIFEPREX is a progestin antagonist indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. (1)

**DOSAGE AND ADMINISTRATION**

- 200 mg MIFEPREX on Day 1, followed 24-48 hours after MIFEPREX dosing by 800 mcg buccal misoprostol. (2.1)
- Instruct the patient what to do if significant adverse reactions occur. (2.2)
- Follow-up is needed to confirm complete termination of pregnancy. (2.3)

**DOSAGE FORMS AND STRENGTHS**  
Tablets containing 200 mg of mifepristone each, supplied as 1 tablet on one blister card (3)

**CONTRAINDICATIONS**

- Confirmed/suspected ectopic pregnancy or undiagnosed adnexal mass (4)
- Chronic adrenal failure (4)
- Concurrent long-term corticosteroid therapy (4)
- History of allergy to mifepristone, misoprostol, or other prostaglandins (4)
- Hemorrhagic disorders or concurrent anticoagulant therapy (4)
- Inherited porphyria (4)
- Intrauterine device (IUD) in place (4)

**WARNINGS AND PRECAUTIONS**

- Ectopic pregnancy: Exclude before treatment. (5.4)
- Rhesus immunization: Prevention needed as for surgical abortion. (5.5)

**ADVERSE REACTIONS**

Most common adverse reactions (>15%) are nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Danco Laboratories, LLC at 1-877-432-7596 or [medicaldirector@earlyoptionpill.com](mailto:medicaldirector@earlyoptionpill.com) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

**DRUG INTERACTIONS**

- CYP3A4 inducers can lower mifepristone concentrations. (7.1)
- CYP3A4 inhibitors can increase mifepristone concentrations. Use with caution. (7.2)
- CYP3A4 substrate concentrations can be increased. Caution with coadministration of substrates with narrow therapeutic margin. (7.3)

**USE IN SPECIFIC POPULATIONS**

- **Pregnancy:** Risk of fetal malformations in ongoing pregnancy if not terminated is unknown. (8.1)

See 17 for PATIENT COUNSELING INFORMATION, Medication Guide.

Revised: 01/2023

**FULL PRESCRIBING INFORMATION: CONTENTS\*****WARNING: SERIOUS AND SOMETIMES FATAL INFECTIONS OR BLEEDING****1 INDICATIONS AND USAGE****2 DOSAGE AND ADMINISTRATION**

- 2.1 Dosing Regimen
- 2.2 Patient Management Following Misoprostol Administration
- 2.3 Post-treatment Assessment: Day 7 to 14
- 2.4 Contact for Consultation

**3 DOSAGE FORMS AND STRENGTHS****4 CONTRAINDICATIONS****5 WARNINGS AND PRECAUTIONS**

- 5.1 Infections and Sepsis
- 5.2 Uterine Bleeding
- 5.3 Mifepristone REMS Program
- 5.4 Ectopic Pregnancy
- 5.5 Rhesus Immunization

**6 ADVERSE REACTIONS**

- 6.1 Clinical Trials Experience
  - 6.2 Postmarketing Experience
- 7.1 Drugs that May Reduce MIFEPREX Exposure (Effect of CYP 3A4 Inducers on MIFEPREX)

**7.2 Drugs that May Increase Exposure (Effect of CYP 3A4 Inhibitors on MIFEPREX)****7.3 Effects of MIFEPREX on Other Drugs (Effect of MIFEPREX on CYP 3A4 Substrates)****8 USE IN SPECIFIC POPULATIONS**

- 8.1 Pregnancy
- 8.2 Lactation
- 8.4 Pediatric Use

**10 OVERDOSAGE****11 DESCRIPTION****12 CLINICAL PHARMACOLOGY**

- 12.1 Mechanism of Action
- 12.2 Pharmacodynamics
- 12.3 Pharmacokinetics

**13 NONCLINICAL TOXICOLOGY**

- 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

**14 CLINICAL STUDIES****16 HOW SUPPLIED/STORAGE AND HANDLING****17 PATIENT COUNSELING INFORMATION**

\*Sections or subsections omitted from the full prescribing information are not listed.

**EXHIBIT**

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## FULL PRESCRIBING INFORMATION

### WARNING: SERIOUS AND SOMETIMES FATAL INFECTIONS OR BLEEDING

**Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following MIFEPREX use. No causal relationship between the use of MIFEPREX and misoprostol and these events has been established.**

- **Atypical Presentation of Infection.** Patients with serious bacterial infections (e.g., *Clostridium sordellii*) and sepsis can present without fever, bacteremia, or significant findings on pelvic examination following an abortion. Very rarely, deaths have been reported in patients who presented without fever, with or without abdominal pain, but with leukocytosis with a marked left shift, tachycardia, hemoconcentration, and general malaise. A high index of suspicion is needed to rule out serious infection and sepsis [see *Warnings and Precautions (5.1)*].
- **Bleeding.** Prolonged heavy bleeding may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed. Advise patients to seek immediate medical attention if they experience prolonged heavy vaginal bleeding [see *Warnings and Precautions (5.2)*].

Because of the risks of serious complications described above, MIFEPREX is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Mifepristone REMS Program [see *Warnings and Precautions (5.3)*].

Before prescribing MIFEPREX, inform the patient about the risk of these serious events. Ensure that the patient knows whom to call and what to do, including going to an Emergency Room if none of the provided contacts are reachable, if they experience sustained fever, severe abdominal pain, prolonged heavy bleeding, or syncope, or if they experience abdominal pain or discomfort, or general malaise (including weakness, nausea, vomiting, or diarrhea) for more than 24 hours after taking misoprostol.

## 1 INDICATIONS AND USAGE

MIFEPREX is indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation.

## 2 DOSAGE AND ADMINISTRATION

### 2.1 Dosing Regimen

For purposes of this treatment, pregnancy is dated from the first day of the last menstrual period. The duration of pregnancy may be determined from menstrual history and clinical examination. Assess the pregnancy by ultrasonographic scan if the duration of pregnancy is uncertain or if ectopic pregnancy is suspected.

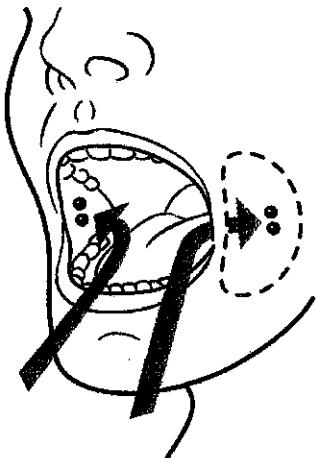
Remove any intrauterine device ("IUD") before treatment with MIFEPREX begins [see *Contraindications (4)*].

The dosing regimen for MIFEPREX and misoprostol is:

- MIFEPREX 200 mg orally + misoprostol 800 mcg buccally
  - **Day One:** MIFEPREX Administration  
One 200 mg tablet of MIFEPREX is taken in a single oral dose.
  - **Day Two or Three:** Misoprostol Administration (minimum 24-hour interval between MIFEPREX and misoprostol)  
Four 200 mcg tablets (total dose 800 mcg) of misoprostol are taken by the buccal route.

Tell the patient to place two 200 mcg misoprostol tablets in each cheek pouch (the area between the cheek and gums) for 30 minutes and then swallow any remnants with water or another liquid (see Figure 1).

**Figure 1**



**2 pills between cheek and gum on left side + 2 pills between cheek and gum on right side**

Patients taking MIFEPREX must take misoprostol within 24 to 48 hours after taking MIFEPREX. The effectiveness of the regimen may be lower if misoprostol is administered less than 24 hours or more than 48 hours after mifepristone administration.

Because most women will expel the pregnancy within 2 to 24 hours of taking misoprostol [see *Clinical Studies (14)*], discuss with the patient an appropriate location for them to be when taking the misoprostol, taking into account that expulsion could begin within 2 hours of administration.

## **2.2 Patient Management Following Misoprostol Administration**

During the period immediately following the administration of misoprostol, the patient may need medication for cramps or gastrointestinal symptoms [see *Adverse Reactions (6)*].

Give the patient:

- Instructions on what to do if significant discomfort, excessive vaginal bleeding or other adverse reactions occur
- A phone number to call if the patient has questions following the administration of the misoprostol
- The name and phone number of the healthcare provider who will be handling emergencies.

### **2.3 Post-treatment Assessment: Day 7 to 14**

Patients should follow-up with their healthcare provider approximately 7 to 14 days after the administration of MIFEPREX. This assessment is very important to confirm that complete termination of pregnancy has occurred and to evaluate the degree of bleeding. Termination can be confirmed by medical history, clinical examination, human Chorionic Gonadotropin (hCG) testing, or ultrasonographic scan. Lack of bleeding following treatment usually indicates failure; however, prolonged or heavy bleeding is not proof of a complete abortion.

The existence of debris in the uterus (e.g., if seen on ultrasonography) following the treatment procedure will not necessarily require surgery for its removal.

Patients should expect to experience vaginal bleeding or spotting for an average of 9 to 16 days. Women report experiencing heavy bleeding for a median duration of 2 days. Up to 8% of women may experience some type of bleeding for more than 30 days. Persistence of heavy or moderate vaginal bleeding at the time of follow-up, however, could indicate an incomplete abortion.

If complete expulsion has not occurred, but the pregnancy is not ongoing, patients may be treated with another dose of misoprostol 800 mcg buccally. There have been rare reports of uterine rupture in women who took MIFEPREX and misoprostol, including women with prior uterine rupture or uterine scar and women who received multiple doses of misoprostol within 24 hours. Patients who choose to use a repeat dose of misoprostol should have a follow-up visit with their healthcare provider in approximately 7 days to assess for complete termination.

Surgical evacuation is recommended to manage ongoing pregnancies after medical abortion [see *Use in Specific Populations (8.1)*]. Advise the patient whether you will provide such care or will refer them to another provider as part of counseling prior to prescribing MIFEPREX.

### **2.4 Contact for Consultation**

**For consultation 24 hours a day, 7 days a week with an expert in mifepristone, call Danco Laboratories at 1-877-4 Early Option (1-877-432-7596).**

## **3 DOSAGE FORMS AND STRENGTHS**

Tablets containing 200 mg of mifepristone each, supplied as 1 tablet on one blister card. MIFEPREX tablets are light yellow, cylindrical, and bi-convex tablets, approximately 11 mm in diameter and imprinted on one side with "MF."

## **4 CONTRAINDICATIONS**

- Administration of MIFEPREX and misoprostol for the termination of pregnancy (the "treatment procedure") is contraindicated in patients with any of the following conditions:
  - Confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass (the treatment procedure will not be effective to terminate an ectopic pregnancy) [see *Warnings and Precautions (5.4)*]
  - Chronic adrenal failure (risk of acute adrenal insufficiency)
  - Concurrent long-term corticosteroid therapy (risk of acute adrenal insufficiency)
  - History of allergy to mifepristone, misoprostol, or other prostaglandins (allergic reactions including anaphylaxis, angioedema, rash, hives, and itching have been reported [see *Adverse Reactions (6.2)*])
  - Hemorrhagic disorders or concurrent anticoagulant therapy (risk of heavy bleeding)

- Inherited porphyrias (risk of worsening or of precipitation of attacks)
- Use of MIFEPREX and misoprostol for termination of intrauterine pregnancy is contraindicated in patients with an intrauterine device ("IUD") in place (the IUD might interfere with pregnancy termination). If the IUD is removed, MIFEPREX may be used.

## 5 WARNINGS AND PRECAUTIONS

### 5.1 Infection and Sepsis

As with other types of abortion, cases of serious bacterial infection, including very rare cases of fatal septic shock, have been reported following the use of MIFEPREX [see *Boxed Warning*]. Healthcare providers evaluating a patient who is undergoing a medical abortion should be alert to the possibility of this rare event. A sustained (> 4 hours) fever of 100.4°F or higher, severe abdominal pain, or pelvic tenderness in the days after a medical abortion may be an indication of infection.

A high index of suspicion is needed to rule out sepsis (e.g., from *Clostridium sordellii*) if a patient reports abdominal pain or discomfort or general malaise (including weakness, nausea, vomiting, or diarrhea) more than 24 hours after taking misoprostol. Very rarely, deaths have been reported in patients who presented without fever, with or without abdominal pain, but with leukocytosis with a marked left shift, tachycardia, hemoconcentration, and general malaise. No causal relationship between MIFEPREX and misoprostol use and an increased risk of infection or death has been established. *Clostridium sordellii* infections have also been reported very rarely following childbirth (vaginal delivery and caesarian section), and in other gynecologic and non-gynecologic conditions.

### 5.2 Uterine Bleeding

Uterine bleeding occurs in almost all patients during a medical abortion. 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. Counsel patients to seek immediate medical attention if they experience prolonged heavy vaginal bleeding following a medical abortion [see *Boxed Warning*].

Women should expect to experience vaginal bleeding or spotting for an average of 9 to 16 days. Women report experiencing heavy bleeding for a median duration of 2 days. Up to 8% of all subjects may experience some type of bleeding for 30 days or more. In general, the duration of bleeding and spotting increased as the duration of the pregnancy increased.

Decreases in hemoglobin concentration, hematocrit, and red blood cell count may occur in patients who bleed heavily.

Excessive uterine bleeding usually requires treatment by uterotronics, vasoconstrictor drugs, surgical uterine evacuation, administration of saline infusions, and/or blood transfusions. Based on data from several large clinical trials, vasoconstrictor drugs were used in 4.3% of all subjects, there was a decrease in hemoglobin of more than 2 g/dL in 5.5% of subjects, and blood transfusions were administered to ≤ 0.1% of subjects. Because heavy bleeding requiring surgical uterine evacuation occurs in about 1% of patients, special care should be given to patients with hemostatic disorders, hypocoagulability, or severe anemia.

### **5.3 Mifepristone REMS Program**

MIFEPREX is available only through a restricted program under a REMS called the Mifepristone REMS Program, because of the risks of serious complications [see *Warnings and Precautions* (5.1, 5.2)].

Notable requirements of the Mifepristone REMS Program include the following:

- Prescribers must be certified with the program by completing the Prescriber Agreement Form.
- Patients must sign a Patient Agreement Form.
- MIFEPREX must only be dispensed to patients by or under the supervision of a certified prescriber, or by certified pharmacies on prescriptions issued by certified prescribers.

Further information is available at 1-877-4 Early Option (1-877-432-7596).

### **5.4 Ectopic Pregnancy**

MIFEPREX is contraindicated in patients with a confirmed or suspected ectopic pregnancy because MIFEPREX is not effective for terminating ectopic pregnancies [see *Contraindications* (4)]. Healthcare providers should remain alert to the possibility that a patient who is undergoing a medical abortion could have an undiagnosed ectopic pregnancy because some of the expected symptoms experienced with a medical abortion (abdominal pain, uterine bleeding) may be similar to those of a ruptured ectopic pregnancy. The presence of an ectopic pregnancy may have been missed even if the patient underwent ultrasonography prior to being prescribed MIFEPREX.

Patients who became pregnant with an IUD in place should be assessed for ectopic pregnancy.

### **5.5 Rhesus Immunization**

The use of MIFEPREX is assumed to require the same preventive measures as those taken prior to and during surgical abortion to prevent rhesus immunization.

## **6 ADVERSE REACTIONS**

The following adverse reactions are described in greater detail in other sections:

- Infection and sepsis [see *Warnings and Precautions* (5.1)]
- Uterine bleeding [see *Warnings and Precautions* (5.2)]

### **6.1 Clinical Trials Experience**

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice.

Information presented on common adverse reactions relies solely on data from U.S. studies, because rates reported in non-U.S. studies were markedly lower and are not likely generalizable to the U.S. population. In three U.S. clinical studies totaling 1,248 women through 70 days gestation who used mifepristone 200 mg orally followed 24-48 hours later by misoprostol 800 mcg buccally, women reported adverse reactions in diaries and in interviews at the follow-up visit. These studies enrolled generally healthy women of reproductive age without contraindications to mifepristone or misoprostol use according to the MIFEPREX product label. Gestational age was assessed prior to study enrollment using the date of the woman's last menstrual period, clinical evaluation, and/or ultrasound examination.

About 85% of patients report at least one adverse reaction following administration of MIFEPREX and misoprostol, and many can be expected to report more than one such reaction. The most commonly reported adverse reactions (>15%) were nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness (see Table 1). The frequency of adverse reactions varies between studies and may be dependent on many factors, including the patient population and gestational age.

Abdominal pain/cramping is expected in all medical abortion patients and its incidence is not reported in clinical studies. Treatment with MIFEPREX and misoprostol is designed to induce uterine bleeding and cramping to cause termination of an intrauterine pregnancy. Uterine bleeding and cramping are expected consequences of the action of MIFEPREX and misoprostol as used in the treatment procedure. Most patients can expect bleeding more heavily than they do during a heavy menstrual period [see *Warnings and Precautions* (5.2)].

Table 1 lists the adverse reactions reported in U.S. clinical studies with incidence >15% of women.

**Table 1**  
**Adverse Reactions Reported in Women Following Administration of Mifepristone (oral) and Misoprostol (buccal) in U.S. Clinical Studies**

Adverse Reaction	# U.S. studies	Number of Evaluable Women	Range of frequency (%)	Upper Gestational Age of Studies Reporting Outcome
<b>Nausea</b>	3	1,248	51-75%	70 days
<b>Weakness</b>	2	630	55-58%	63 days
<b>Fever/chills</b>	1	414	48%	63 days
<b>Vomiting</b>	3	1,248	37-48%	70 days
<b>Headache</b>	2	630	41-44%	63 days
<b>Diarrhea</b>	3	1,248	18-43%	70 days
<b>Dizziness</b>	2	630	39-41%	63 days

One study provided gestational-age stratified adverse reaction rates for women who were 57-63 and 64-70 days; there was little difference in frequency of the reported common adverse reactions by gestational age.

Information on serious adverse reactions was reported in six U.S. and four non-U.S. clinical studies, totaling 30,966 women through 70 days gestation who used mifepristone 200 mg orally followed 24-48 hours later by misoprostol 800 mcg buccally. Serious adverse reaction rates were similar between U.S. and non-U.S. studies, so rates from both U.S. and non-U.S. studies are presented. In the U.S. studies, one studied women through 56 days gestation, four through 63 days gestation, and one through 70 days gestation, while in the non-U.S. studies, two studied women through 63 days gestation, and two through 70 days gestation. 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**  
**Serious Adverse Reactions Reported in Women Following Administration of Mifepristone (oral) and Misoprostol (buccal) in U.S. and Non-U.S. Clinical Studies**

Adverse Reaction	U.S.			Non-U.S.		
	# of studies	Number of Evaluable Women	Range of frequency (%)	# of studies	Number of Evaluable Women	Range of frequency (%)
<b>Transfusion</b>	4	17,774	0.03-0.5%	3	12,134	0-0.1%
<b>Sepsis</b>	1	629	0.2%	1	11,155	<0.01%*
<b>ER visit</b>	2	1,043	2.9-4.6%	1	95	0
<b>Hospitalization Related to Medical Abortion</b>	3	14,339	0.04-0.6%	3	1,286	0-0.7%
<b>Infection without sepsis</b>	1	216	0	1	11,155	0.2%
<b>Hemorrhage</b>	NR	NR	NR	1	11,155	0.1%

NR= Not reported

\* This outcome represents a single patient who experienced death related to sepsis.

## 6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of MIFEPREX and misoprostol. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

**Infections and infestations:** post-abortal infection (including endometritis, endomyometritis, parametritis, pelvic infection, pelvic inflammatory disease, salpingitis)

**Blood and the lymphatic system disorders:** anemia

**Immune system disorders:** allergic reaction (including anaphylaxis, angioedema, hives, rash, itching)

**Psychiatric disorders:** anxiety

**Cardiac disorders:** tachycardia (including racing pulse, heart palpitations, heart pounding)

**Vascular disorders:** syncope, fainting, loss of consciousness, hypotension (including orthostatic), light-headedness

**Respiratory, thoracic and mediastinal disorders:** shortness of breath

**Gastrointestinal disorders:** dyspepsia

**Musculoskeletal, connective tissue and bone disorders:** back pain, leg pain

**Reproductive system and breast disorders:** uterine rupture, ruptured ectopic pregnancy, hematometra, leukorrhea

**General disorders and administration site conditions:** pain

## 7 DRUG INTERACTIONS

### 7.1 Drugs that May Reduce MIFEPREX Exposure (Effect of CYP 3A4 Inducers on MIFEPREX)

CYP450 3A4 is primarily responsible for the metabolism of mifepristone. CYP3A4 inducers such as rifampin, dexamethasone, St. John's Wort, and certain anticonvulsants (such as phenytoin, phenobarbital, carbamazepine) may induce mifepristone metabolism (lowering serum concentrations of mifepristone). Whether this action has an impact on the efficacy of the dose

regimen is unknown. Refer to the follow-up assessment [see *Dosage and Administration (2.3 )*] to verify that treatment has been successful.

## **7.2 Drugs that May Increase MIFEPREX Exposure (Effect of CYP 3A4 Inhibitors on MIFEPREX)**

Although specific drug or food interactions with mifepristone have not been studied, on the basis of this drug's metabolism by CYP 3A4, it is possible that ketoconazole, itraconazole, erythromycin, and grapefruit juice may inhibit its metabolism (increasing serum concentrations of mifepristone). MIFEPREX should be used with caution in patients currently or recently treated with CYP 3A4 inhibitors.

## **7.3 Effects of MIFEPREX on Other Drugs (Effect of MIFEPREX on CYP 3A4 Substrates)**

Based on *in vitro* inhibition information, coadministration of mifepristone may lead to an increase in serum concentrations of drugs that are CYP 3A4 substrates. Due to the slow elimination of mifepristone from the body, such interaction may be observed for a prolonged period after its administration. Therefore, caution should be exercised when mifepristone is administered with drugs that are CYP 3A4 substrates and have narrow therapeutic range.

# **8 USE IN SPECIFIC POPULATIONS**

## **8.1 Pregnancy**

### Risk Summary

MIFEPREX is indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. Risks to pregnant patients are discussed throughout the labeling.

Refer to misoprostol labeling for risks to pregnant patients with the use of misoprostol.

The risk of adverse developmental outcomes with a continued pregnancy after a failed pregnancy termination with MIFEPREX in a regimen with misoprostol is unknown; however, the process of a failed pregnancy termination could disrupt normal embryo-fetal development and result in adverse developmental effects. Birth defects have been reported with a continued pregnancy after a failed pregnancy termination with MIFEPREX in a regimen with misoprostol. In animal reproduction studies, increased fetal losses were observed in mice, rats, and rabbits and skull deformities were observed in rabbits with administration of mifepristone at doses lower than the human exposure level based on body surface area.

### Data

#### *Animal Data*

In teratology studies in mice, rats and rabbits at doses of 0.25 to 4.0 mg/kg (less than 1/100 to approximately 1/3 the human exposure based on body surface area), because of the antiprogestational activity of mifepristone, fetal losses were much higher than in control animals. Skull deformities were detected in rabbit studies at approximately 1/6 the human exposure, although no teratogenic effects of mifepristone have been observed to date in rats or mice. These deformities were most likely due to the mechanical effects of uterine contractions resulting from inhibition of progesterone action.

## **8.2 Lactation**

MIFEPREX is present in human milk. Limited data demonstrate undetectable to low levels of the drug in human milk with the relative (weight-adjusted) infant dose 0.5% or less as compared to maternal dosing. There is no information on the effects of MIFEPREX in a regimen with

misoprostol in a breastfed infant or on milk production. Refer to misoprostol labeling for lactation information with the use of misoprostol. The developmental and health benefits of breast-feeding should be considered along with any potential adverse effects on the breast-fed child from MIFEDEX in a regimen with misoprostol.

#### 8.4 Pediatric Use

Safety and efficacy of MIFEDEX have been established in pregnant females. Data from a clinical study of MIFEDEX that included a subset of 322 females under age 17 demonstrated a safety and efficacy profile similar to that observed in adults.

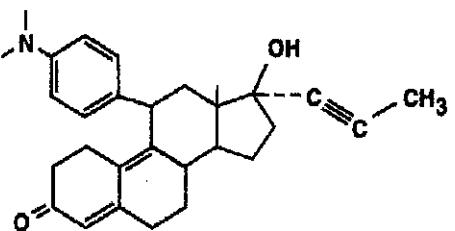
### 10 OVERDOSAGE

No serious adverse reactions were reported in tolerance studies in healthy non-pregnant female and healthy male subjects where mifepristone was administered in single doses greater than 1800 mg (ninemfold the recommended dose for medical abortion). If a patient ingests a massive overdose, the patient should be observed closely for signs of adrenal failure.

### 11 DESCRIPTION

MIFEDEX tablets each contain 200 mg of mifepristone, a synthetic steroid with antiprogestational effects. The tablets are light yellow in color, cylindrical, and bi-convex, and are intended for oral administration only. The tablets include the inactive ingredients colloidal silica anhydrous, corn starch, povidone, microcrystalline cellulose, and magnesium stearate.

Mifepristone is a substituted 19-nor steroid compound chemically designated as 11 $\beta$ -[ $\rho$ -(Dimethylamino)phenyl]-17 $\beta$ -hydroxy-17-(1-propynyl)estra-4,9-dien-3-one. Its empirical formula is C<sub>29</sub>H<sub>35</sub>NO<sub>2</sub>. Its structural formula is:



The compound is a yellow powder with a molecular weight of 429.6 and a melting point of 192-196°C. It is very soluble in methanol, chloroform and acetone and poorly soluble in water, hexane and isopropyl ether.

### 12 CLINICAL PHARMACOLOGY

#### 12.1 Mechanism of Action

The anti-progestational activity of mifepristone results from competitive interaction with progesterone at progesterone-receptor sites. Based on studies with various oral doses in several animal species (mouse, rat, rabbit, and monkey), the compound inhibits the activity of endogenous or exogenous progesterone, resulting in effects on the uterus and cervix that, when combined with misoprostol, result in termination of an intrauterine pregnancy.

During pregnancy, the compound sensitizes the myometrium to the contraction-inducing activity

of prostaglandins.

## 12.2 Pharmacodynamics

Use of MIFEPREX in a regimen with misoprostol disrupts pregnancy by causing decidual necrosis, myometrial contractions, and cervical softening, leading to the expulsion of the products of conception.

Doses of 1 mg/kg or greater of mifepristone have been shown to antagonize the endometrial and myometrial effects of progesterone in women.

**Antiglucocorticoid and antiandrogenic activity:** Mifepristone also exhibits antiglucocorticoid and weak antiandrogenic activity. The activity of the glucocorticoid dexamethasone in rats was inhibited following doses of 10 to 25 mg/kg of mifepristone. Doses of 4.5 mg/kg or greater in human beings resulted in a compensatory elevation of adrenocorticotropic hormone (ACTH) and cortisol. Antiandrogenic activity was observed in rats following repeated administration of doses from 10 to 100 mg/kg.

## 12.3 Pharmacokinetics

Mifepristone is rapidly absorbed after oral ingestion with non-linear pharmacokinetics for Cmax after single oral doses of 200 mg and 600 mg in healthy subjects.

### Absorption

The absolute bioavailability of a 20 mg mifepristone oral dose in females of childbearing age is 69%. Following oral administration of a single dose of 600 mg, mifepristone is rapidly absorbed, with a peak plasma concentration of  $1.98 \pm 1.0$  mg/L occurring approximately 90 minutes after ingestion.

Following oral administration of a single dose of 200 mg in healthy men (n=8), mean Cmax was  $1.77 \pm 0.7$  mg/L occurring approximately 45 minutes after ingestion. Mean  $AUC_{0-\infty}$  was  $25.8 \pm 6.2$  mg\*hr/L.

### Distribution

Mifepristone is 98% bound to plasma proteins, albumin, and  $\alpha_1$ -acid glycoprotein. Binding to the latter protein is saturable, and the drug displays nonlinear kinetics with respect to plasma concentration and clearance.

### Elimination

Following a distribution phase, elimination of mifepristone is slow at first (50% eliminated between 12 and 72 hours) and then becomes more rapid with a terminal elimination half-life of 18 hours.

### Metabolism

Metabolism of mifepristone is primarily via pathways involving N-demethylation and terminal hydroxylation of the 17-propynyl chain. *In vitro* studies have shown that CYP450 3A4 is primarily responsible for the metabolism. The three major metabolites identified in humans are: (1) RU 42 633, the most widely found in plasma, is the N-monodemethylated metabolite; (2) RU 42 848, which results from the loss of two methyl groups from the 4-dimethylaminophenyl in position 11 $\beta$ ; and (3) RU 42 698, which results from terminal hydroxylation of the 17-propynyl chain.

### Excretion

By 11 days after a 600 mg dose of tritiated compound, 83% of the drug has been accounted for by the feces and 9% by the urine. Serum concentrations are undetectable by 11 days.

### Specific Populations

The effects of age, hepatic disease and renal disease on the safety, efficacy and pharmacokinetics of mifepristone have not been investigated.

## **13 NONCLINICAL TOXICOLOGY**

### **13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

#### Carcinogenesis

No long-term studies to evaluate the carcinogenic potential of mifepristone have been performed.

#### Mutagenesis

Results from studies conducted *in vitro* and in animals have revealed no genotoxic potential for mifepristone. Among the tests carried out were: Ames test with and without metabolic activation; gene conversion test in *Saccharomyces cerevisiae* D4 cells; forward mutation in *Schizosaccharomyces pombe* P1 cells; induction of unscheduled DNA synthesis in cultured HeLa cells; induction of chromosome aberrations in CHO cells; *in vitro* test for gene mutation in V79 Chinese hamster lung cells; and micronucleus test in mice.

#### Impairment of Fertility

In rats, administration of 0.3 mg/kg mifepristone per day caused severe disruption of the estrus cycles for the three weeks of the treatment period. Following resumption of the estrus cycle, animals were mated and no effects on reproductive performance were observed.

## **14 CLINICAL STUDIES**

Safety and efficacy data from clinical studies of mifepristone 200 mg orally followed 24-48 hours later by misoprostol 800 mcg buccally through 70 days gestation are reported below. Success was defined as the complete expulsion of the products of conception without the need for surgical intervention. The overall rates of success and failure, shown by reason for failure based on 22 worldwide clinical studies (including 7 U.S. studies) appear in Table 3.

The demographics of women who participated in the U.S. clinical studies varied depending on study location and represent the racial and ethnic variety of American females. Females of all reproductive ages were represented, including females less than 18 and more than 40 years of age; most were 27 years or younger.

**Table 3**  
**Outcome Following Treatment with Mifepristone (oral) and Misoprostol (buccal)**  
**Through 70 Days Gestation**

	U.S. Trials	Non-U.S. Trials
N	16,794	18,425
<b>Complete Medical Abortion</b>	97.4%	96.2%
<b>Surgical Intervention*</b>	2.6%	3.8%
<b>Ongoing Pregnancy**</b>	0.7%	0.9%

\* Reasons for surgical intervention include ongoing pregnancy, medical necessity, persistent or heavy bleeding after treatment, patient request, or incomplete expulsion.  
 \*\* Ongoing pregnancy is a subcategory of surgical intervention, indicating the percent of women who have surgical intervention due to an ongoing pregnancy.

The results for clinical studies that reported outcomes, including failure rates for ongoing pregnancy, by gestational age are presented in Table 4.

**Table 4**  
**Outcome by Gestational Age Following Treatment with Mifepristone and**  
**Misoprostol (buccal) for U.S. and Non-U.S. Clinical Studies**

	≤49 days			50-56 days			57-63 days			64-70 days		
	N	%	Number of Evaluable Studies	N	%	Number of Evaluable Studies	N	%	Number of Evaluable Studies	N	%	Number of Evaluable Studies
Complete medical abortion	12,046	98.1	10	3,941	96.8	7	2,294	94.7	9	479	92.7	4
Surgical intervention for ongoing pregnancy	10,272	0.3	6	3,788	0.8	6	2,211	2	8	453	3.1	3

One clinical study asked subjects through 70 days gestation to estimate when they expelled the pregnancy, with 70% providing data. Of these, 23-38% reported expulsion within 3 hours and over 90% within 24 hours of using misoprostol.

## 16 HOW SUPPLIED/STORAGE AND HANDLING

is only available through a restricted program called the Mifepristone REMS Program [see *Warnings and Precautions (5.3)*].

MIFEPREX is supplied as light yellow, cylindrical, and bi-convex tablets imprinted on one side with "MF." Each tablet contains 200 mg of mifepristone. One tablet is individually blistered on one blister card that is packaged in an individual package (National Drug Code 64875-001-01).

Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [see USP Controlled Room Temperature].

## 17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide), included with each package of MIFEPREX. Additional copies of the Medication Guide are available by contacting Danco Laboratories at 1-877-4 Early Option (1-877-432-7596) or from [www.earlyoptionpill.com](http://www.earlyoptionpill.com).

### Serious Infections and Bleeding

- Inform the patient that uterine bleeding and uterine cramping will occur [see *Warnings and Precautions (5.2)*].
- Advise the patient that serious and sometimes fatal infections and bleeding can occur very rarely [see *Warnings and Precautions (5.1, 5.2)*].
- MIFEPREX is only available through a restricted program called the Mifepristone REMS Program [see *Warnings and Precautions (5.3)*]. Under the Mifepristone REMS Program:
  - Patients must sign a Patient Agreement Form.
  - MIFEPREX is only dispensed by or under the supervision of certified prescribers or by certified pharmacies on prescriptions issued by certified prescribers.

### Provider Contacts and Actions in Case of Complications

- Ensure that the patient knows whom to call and what to do, including going to an Emergency Room if none of the provided contacts are reachable, or if the patient experiences complications including prolonged heavy bleeding, severe abdominal pain, or sustained fever [see *Boxed Warning*].
- 

### Compliance with Treatment Schedule and Follow-up Assessment

- Advise the patient that it is necessary to complete the treatment schedule, including a follow-up assessment approximately 7 to 14 days after taking MIFEPREX [see *Dosage and Administration (2.3)*].
- Explain that
  - prolonged heavy vaginal bleeding is not proof of a complete abortion,
  - if the treatment fails and the pregnancy continues, the risk of fetal malformation is unknown,
  - it is recommended that ongoing pregnancy be managed by surgical termination [see *Dosage and Administration (2.3)*]. Advise the patient whether you will provide such care or will refer them to another provider.

### Subsequent Fertility

- Inform the patient that another pregnancy can occur following medical abortion and before resumption of normal menses.
- Inform the patient that contraception can be initiated as soon as pregnancy expulsion has been confirmed, or before resuming sexual intercourse.

MIFEPREX is a registered trademark of Danco Laboratories, LLC.

Manufactured for:  
*Danco Laboratories, LLC*  
P.O. Box 4816  
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[www.earlyoptionpill.com](http://www.earlyoptionpill.com)

03/2023

## MEDICATION GUIDE

### Mifepristex (MIF-eh-prex) (mifepristone tablets, for oral use)

Read this information carefully before taking Mifepristex and misoprostol. It will help you understand how the treatment works. This Medication Guide does not take the place of talking with your healthcare provider.

#### What is the most important information I should know about Mifepristex?

**What symptoms should I be concerned with?** 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. Seeking medical attention as soon as possible is needed in these circumstances. Serious infection has resulted in death in a very small number of cases. There is no information that use of Mifepristex and misoprostol caused these deaths. If you have any questions, concerns, or problems, or if you are worried about any side effects or symptoms, you should contact your healthcare provider. You can write down your healthcare provider's telephone number here \_\_\_\_\_.

**Be sure to contact your healthcare provider promptly if you have any of the following:**

- **Heavy Bleeding.** Contact your healthcare provider right away if you bleed enough to soak through two thick full-size sanitary pads per hour for two consecutive hours or if you are concerned about heavy bleeding. In about 1 out of 100 women, bleeding can be so heavy that it requires a surgical procedure (surgical aspiration or D&C).
- **Abdominal Pain or "Feeling Sick."** If you have abdominal pain or discomfort, or you are "feeling sick," including weakness, nausea, vomiting, or diarrhea, with or without fever, more than 24 hours after taking misoprostol, you should contact your healthcare provider without delay. These symptoms may be a sign of a serious infection or another problem (including an ectopic pregnancy, a pregnancy outside the womb).
- **Fever.** In the days after treatment, if you have a fever of 100.4°F or higher that lasts for more than 4 hours, you should contact your healthcare provider right away. Fever may be a symptom of a serious infection or another problem.

**If you cannot reach your healthcare provider, go to the nearest hospital emergency room.**

**What to do if you are still pregnant after Mifepristex with misoprostol treatment.** If you are still pregnant, your healthcare provider will talk with you about a surgical procedure to end your pregnancy. In many cases, this surgical procedure can be done in the office/clinic. The chance of birth defects if the pregnancy is not ended is unknown.

**Talk with your healthcare provider.** Before you take Mifepristex, you should read this Medication Guide and you and your healthcare provider should discuss the benefits and risks of your using Mifepristex.

### What is Mifeprax?

**Mifeprax is used in a regimen with another prescription medicine called misoprostol, to end an early pregnancy.** Early pregnancy means it is 70 days (10 weeks) or less since your last menstrual period began. Mifeprax is not approved for ending pregnancies that are further along. Mifeprax blocks a hormone needed for your pregnancy to continue. When you use Mifeprax on Day 1, you also need to take another medicine called misoprostol 24 to 48 hours after you take Mifeprax, to cause the pregnancy to be passed from your uterus.

The pregnancy is likely to be passed from your uterus within 2 to 24 hours after taking Mifeprax and misoprostol. When the pregnancy is passed from the uterus, you will have bleeding and cramping that will likely be heavier than your usual period. About 2 to 7 out of 100 women taking Mifeprax will need a surgical procedure because the pregnancy did not completely pass from the uterus or to stop bleeding.

### Who should not take Mifeprax?

Some patients should not take Mifeprax. Do not take Mifeprax if you:

- Have a pregnancy that is more than 70 days (10 weeks). Your healthcare provider may do a clinical examination, an ultrasound examination, or other testing to determine how far along you are in pregnancy.
- Are using an IUD (intrauterine device or system). It must be taken out before you take Mifeprax.
- Have been told by your healthcare provider that you have a pregnancy outside the uterus (ectopic pregnancy).
- Have problems with your adrenal glands (chronic adrenal failure).
- Take a medicine to thin your blood.
- Have a bleeding problem.
- Have porphyria.
- Take certain steroid medicines.
- Are allergic to mifepristone, misoprostol, or medicines that contain misoprostol, such as Cytotec or Arthrotec.

Ask your healthcare provider if you are not sure about all your medical conditions before taking this medicine to find out if you can take Mifeprax.

### What should I tell my healthcare provider before taking Mifeprax?

**Before you take Mifeprax, tell your healthcare provider if you:**

- cannot follow-up within approximately 7 to 14 days of your first visit
- are breastfeeding. Mifeprax can pass into your breast milk. The effect of the Mifeprax and misoprostol regimen on the breastfed infant or on milk production is unknown.
- are taking medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Mifeprax and certain other medicines may affect each other if they are used together. This can cause side effects.

### How should I take Mifeprex?

- Mifeprex will be given to you by a healthcare provider or pharmacy.
- You and your healthcare provider will plan the most appropriate location for you to take the misoprostol, because it may cause bleeding, cramps, nausea, diarrhea, and other symptoms that usually begin within 2 to 24 hours after taking it.
- Most women will pass the pregnancy within 2 to 24 hours after taking the misoprostol tablets.

### Follow the instruction below on how to take Mifeprex and misoprostol:

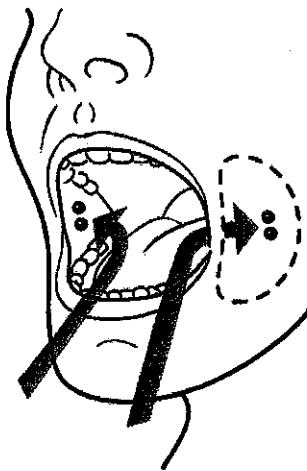
#### Mifeprex (1 tablet) orally + misoprostol (4 tablets) buccally

##### Day 1:

- Take 1 Mifeprex tablet by mouth.

##### 24 to 48 hours after taking Mifeprex:

- Take 4 misoprostol tablets by placing 2 tablets in each cheek pouch (the area between your teeth and cheek - see Figure A) for 30 minutes and then swallow anything left over with a drink of water or another liquid.
- The medicines may not work as well if you take misoprostol sooner than 24 hours after Mifeprex or later than 48 hours after Mifeprex.
- Misoprostol often causes cramps, nausea, diarrhea, and other symptoms. Your healthcare provider may send you home with medicines for these symptoms.



**Figure A** (2 tablets between your left cheek and gum and 2 tablets between your right cheek and gum).

##### Follow-up Assessment at Day 7 to 14:

- This follow-up assessment is very important. You must follow-up with your healthcare provider about 7 to 14 days after you have taken Mifeprex to be sure you are well and that you have had bleeding and the pregnancy has passed from your uterus.
- Your healthcare provider will assess whether your pregnancy has passed from your uterus. If your pregnancy continues, the chance that there may be birth defects is unknown. If you are still pregnant, your healthcare provider will talk with you about a surgical procedure to end your pregnancy.
- If your pregnancy has ended, but has not yet completely passed from your uterus, your provider will talk with you about other choices you have, including waiting, taking another dose of misoprostol, or having a surgical procedure to empty your uterus.

#### **When should I begin birth control?**

You can become pregnant again right after your pregnancy ends. If you do not want to become pregnant again, start using birth control as soon as your pregnancy ends or before you start having sexual intercourse again.

#### **What should I avoid while taking Mifeprex and misoprostol?**

Do not take any other prescription or over-the-counter medicines (including herbal medicines or supplements) at any time during the treatment period without first asking your healthcare provider about them because they may interfere with the treatment. Ask your healthcare provider about what medicines you can take for pain and other side effects.

#### **What are the possible side effects of Mifeprex and misoprostol?**

**Mifeprex may cause serious side effects. See "What is the most important information I should know about Mifeprex?"**

**Cramping and bleeding.** Cramping and vaginal bleeding are expected with this treatment. Usually, these symptoms mean that the treatment is working. But sometimes you can get cramping and bleeding and still be pregnant. This is why you must follow-up with your healthcare provider approximately 7 to 14 days after taking Mifeprex. See "How should I take Mifeprex?" for more information on your follow-up assessment. If you are not already bleeding after taking Mifeprex, you probably will begin to bleed once you take misoprostol, the medicine you take 24 to 48 hours after Mifeprex. Bleeding or spotting can be expected for an average of 9 to 16 days and may last for up to 30 days. Your bleeding may be similar to, or greater than, a normal heavy period. You may see blood clots and tissue. This is an expected part of passing the pregnancy.

The most common side effects of Mifeprex treatment include: nausea, weakness, fever/chills, vomiting, headache, diarrhea and dizziness. Your provider will tell you how to manage any pain or other side effects. These are not all the possible side effects of Mifeprex.

Call your healthcare provider for medical advice about any side effects that bother you or do not go away. You may report side effects to FDA at 1-800-FDA-1088.

#### **General information about the safe and effective use of Mifeprex.**

**Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. This Medication Guide summarizes the most important information about Mifeprex. If you would like more information, talk with your healthcare provider. You may ask your healthcare provider for information about Mifeprex that is written for healthcare professionals.**

**For more information about Mifeprex, go to [www.earlyoptionpill.com](http://www.earlyoptionpill.com) or call 1-877-4 Early Option (1-877-432-7596).**

Manufactured for: *Danco Laboratories, LLC*  
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1-877-4 Early Option (1-877-432-7596) [www.earlyoptionpill.com](http://www.earlyoptionpill.com)

This Medication Guide has been approved by the U.S. Food and Drug Administration. Approval 03/2023

[Drug Databases \(https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020687\)](https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020687)

# Drugs@FDA: FDA-Approved Drugs

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New Drug Application (NDA): 020687

Company: DANCO LABS LLC

[EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=020687\)](mailto:MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=020687)

- [Medication Guide](#)  
([https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2023/020687Orig1s026lbl.pdf#page=16](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s026lbl.pdf#page=16))
- [Summary Review](#)  
([http://www.accessdata.fda.gov/drugsatfda\\_docs/summary\\_review/2023/020687Orig1s025SumR.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/summary_review/2023/020687Orig1s025SumR.pdf))
- [REMS](#) (<https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390>)
- [Original REMS Approved in 2011](#) ([http://www.accessdata.fda.gov/drugsatfda\\_docs/rems/Mifepristone\\_2011-06-08\\_Full.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2011-06-08_Full.pdf))
- [Other Important Information from FDA](#)  
(<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111323.htm>)

## Products on NDA 020687

[CSV](#) [Excel](#) [Print](#)

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
MIFEPRISTONE	MIFEPRISTONE	200MG	TABLET;ORAL	Prescription	AB	Yes	Yes

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## Approval Date(s) and History, Letters, Labels, Reviews for NDA 020687

## Labels for NDA 020687

[CSV](#) [Excel](#) [Print](#)

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
03/23/2023	SUPPL-26	REMS - MODIFIED - D-N-A	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s026">Label (PDF)</a> (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s026)
01/03/2023	SUPPL-25	REMS - MODIFIED - D-N-A	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025">Label (PDF)</a> (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025)
04/11/2019	SUPPL-22	REMS-Modified	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020687s022lbl.pdf">Label (PDF)</a> (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020687s022lbl.pdf)
03/29/2016	SUPPL-20	Efficacy-New Dosing Regimen	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf">Label (PDF)</a> (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf)
06/08/2011	SUPPL-14	REMS-Proposal	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020687s014lbl.pdf">Label (PDF)</a> (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020687s014lbl.pdf)
06/08/2011	SUPPL-14	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020687s014lbl.pdf">Label (PDF)</a> (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020687s014lbl.pdf)
04/24/2009	SUPPL-15	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020687s015lbl.pdf">Label (PDF)</a> (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020687s015lbl.pdf)
07/19/2005	SUPPL-13	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020687s013lbl.pdf">Label (PDF)</a> (https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020687s013lbl.pdf)
11/15/2004	SUPPL-10	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/020687s010lbl.pdf">Label (PDF)</a> (https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/020687s010lbl.pdf)
09/28/2000	ORIG-1	Approval	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687">Label (PDF)</a> (https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687)

Showing 1 to 10 of 10 entries

**Therapeutic Equivalents for NDA 020687**