UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MAYDAY HEALTH, Plaintiff, v. MARTY J. JACKLEY, Attorney General of South Dakota, in his official capacity, Defendants.	Case No. 1:26-cv-00078-KPF

NOTICE OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

PLEASE TAKE NOTICE that Plaintiff Mayday Health will move this Court, before the Honorable Katherine Polk Failla, United States District Judge, Southern District of New York, on a date to be determined by the Court, for an order pursuant to Rule 65 of the Federal Rules of Civil Procedure, granting Plaintiff's motion for a preliminary injunction. Mayday respectfully requests an order preliminarily enjoining Defendant Marty J. Jackley, the Attorney General of South Dakota, from (1) taking any action, formal or informal, to pressure or force Mayday to take down the truthful public health information on its website, or the signs it has published publicizing that website, and from (2) taking any action, formal or informal, to pressure or force Mayday to refrain from publishing truthful public health information to South Dakotans in the future, both on its website and in signs and other offline communications publicizing its website.

In support of this motion, Plaintiff relies upon the accompanying (1) Memorandum of Law in Support of Plaintiff's Motion for Preliminary Injunction; (2) Declaration of Adam Sieff and the exhibits annexed thereto; and (3) Declaration of Liv Raisner.

Dated: January 14, 2026

Respectfully submitted,

By: */s/ Adam S. Sieff*
Adam S. Sieff

Adam S. Sieff*
DAVIS WRIGHT TREMAINE LLP
350 South Grand Avenue, 27th Floor
Los Angeles, California 90071-3487
213.663.6800 (tel)
adamsieff@dwt.com

Ambika Kumar*
Nicole Saad Bembridge*
DAVIS WRIGHT TREMAINE LLP
920 Fifth Avenue, Suite 3300
Seattle, Washington 98104-1610
206.622.3150 (tel)
ambikakumar@dwt.com
nicolesaadbembridge@dwt.com

Chelsea T. Kelly (SDNY No. CK2016)
Laura R. Handman (SDNY No. RH5353)
DAVIS WRIGHT TREMAINE LLP
1301 K Street NW, Suite 500 East
Washington, D.C. 20005-3317
202 973.4200 (tel)
chelseakelly@dwt.com
laurahandman@dwt.com

*Admitted *pro hac vice*

Attorneys for Plaintiff Mayday Health

AFFIRMATION OF SERVICE

I, Adam Sieff, undersigned counsel for Plaintiff Mayday Health, affirm that my office will be serving the aforementioned Notice of Motion for Preliminary Injunction and accompanying papers on Defendant, Marty J. Jackley, via personal service and certified mail at the Office of the Attorney General of South Dakota, 1302 S.D. E. Highway 1889, Suite 1, Pierre, South Dakota 57501-8501, as Defendant has not yet entered an appearance in this case.

Dated: January 14, 2026

By: */s/ Adam S. Sieff*
Adam S. Sieff

UNITED STATES DISTRICT COURT
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MAYDAY HEALTH,

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v.

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MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Federal Cases

State Statutes

Constitutional Provisions

INTRODUCTION

Plaintiff Mayday Health is a 501(c)(3) non-profit public health education organization—not a medical provider that prescribes, handles, sells, or earns revenue from any healthcare service—dedicated to sharing accurate, evidence-based information about reproductive healthcare. After discovering that Mayday had placed signs at South Dakota gas stations stating "Pregnant? Don't want to be? Learn more at www.mayday.health," South Dakota Governor Larry Rhoden invoked his government's "proud pro-life stance" and asked Attorney General Marty J. Jackley to prosecute Mayday's New York-based website and ban Mayday from publicizing it to South Dakotans, by any means necessary. The Attorney General—who shares the Governor's contempt for the lawful choices people may make with the information Mayday publishes, as well as Mayday's conviction that access to abortion is a human right—has now threatened to do so. Mayday brings this motion to prevent further violation of its First Amendment rights.

Mayday will prevail on the merits of its First Amendment claims because the First Amendment absolutely protects the publication of truthful information of public concern. The U.S. Food and Drug Administration (FDA) has approved abortion pills—mifepristone and misoprostol—for safe and effective use, and adopted official guidance permitting those drugs to be prescribed online and delivered through the mail. The Attorney General may not prevent Mayday from publishing this information to South Dakotans, or information involving the availability of legal abortion services generally, just because South Dakota has made abortion illegal. Nor may the Attorney General hunt down and retaliate against Mayday because of hostility toward Mayday, the information Mayday publishes, and the beliefs that impel Mayday to publish it. The Attorney General's suggestion that Mayday's speech is misleading commercial advertising regulable as a "deceptive trade practice" is meritless and pretextual.

The remaining factors also favor preliminary injunctive relief. Mayday is suffering and

will continue to suffer irreparable injury from the violation of its First Amendment rights. The balance of equities and the public interest strongly favor the vindication of those rights, as the public has a profound interest in the dissemination of truth without fear of reprisal.

Mayday respectfully asks the Court to preliminarily enjoin the Attorney General from taking any further action to deter or prohibit it from publishing truthful public health information.

RELEVANT BACKGROUND

A. Mayday Publishes Truthful Public Health Information on Its Website

Mayday is a nonprofit health education organization that operates an online clearinghouse for reproductive health resources at https://mayday.health. The website was launched in June 2022 in response to the U.S. Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022). Mayday's mission is "to share information about abortion pills, birth control, and gender-affirming care in any state" and "empower people to make their own informed decisions about their own bodies." Declaration of Adam Sieff ("Sieff Decl.") at Ex. 1; Declaration of Liv Raisner ("Raisner Decl.") ¶ 2.

When a reader accesses Mayday's website, they are asked what category of information they are looking for—abortion, morning-after pills, birth control, or gender-affirming care. *See* Sieff Decl. Ex. 1; Raisner Decl. ¶¶ 3-4. For each category, the website provides a series of links to third-party organizations that provide access to such care or resources. For the abortion category, Mayday provides links to well-established third-party websites, including Aid Access, Cambridge Reproductive Health Consultants, A Safe Choice, Abuzz, and We Take Care of Us. Mayday also links to organizations offering supporting services, including the Digital Defense Fund's privacy guide, the Miscarriage and Abortion Hotline, and the If/When/How Repro Legal Helpline. Much of the information to which Mayday's website links is from clinicians, lawyers, and health experts. Raisner Decl. ¶ 3. If medically appropriate, some of these third-party websites may provide access

to abortion pills, such as mifepristone and misoprostol. *Id.* The FDA has repeatedly and as recently as 2025 confirmed the safety of such medication, Sieff Decl. Exs. 2-3, as have independent and rigorous scientific studies published in peer-reviewed journals like the New England Journal of Medicine, *id.* Ex. 4.

Mayday does not sell, handle, or benefit financially from abortion pills, and operates independently from organizations that do so. *See* Raisner Decl. ¶ 5. Nor does Mayday itself provide any medical or legal advice, charge any fee, collect any revenue related to the provision of medical or legal services, or obtain any other valuable consideration in exchange for disseminating its message. *Id.* It does not monetize its users' data. *Id.* Rather, Mayday simply wants people to know their options regarding reproductive healthcare. *Id.* ¶ 6. The information it publishes is provided as a donor-funded public service—free to users—as an expression of Mayday's values and beliefs. *Id.* Through its website and advocacy, Mayday provides truthful, non-commercial information of public concern, including resources for individuals seeking to understand their reproductive healthcare options. Mayday believes its work is essential to ensuring that individuals, regardless of their location, can make informed decisions about their health and wellbeing. *Id.*

B. Mayday Publicizes Its Website, Including to South Dakotans

To raise awareness about the availability of reproductive health services to communities across the country, Mayday publicizes its website through social media platforms like TikTok and Instagram, as well as through billboards, plane-pulled banners, art installations, apparel, and other tangible media. Raisner Decl. ¶ 5. As part of these efforts, on December 8, 2025, Mayday placed signs at gas stations around South Dakota. *Id.* ¶ 7. The signs ask "Pregnant? Don't want to be?" with a prompt to "learn more" by visiting Mayday's website. *Id.*

C. The South Dakota Governor Directs the Attorney General to Investigate and Punish Mayday by Any Means Available

The next day, December 9, 2025, South Dakota Governor Larry Rhoden and Attorney General Marty J. Jackley issued a joint press release announcing a formal letter from the Governor urging the Attorney General to "investigate" Mayday for spreading information that "appears to conflict with South Dakota's proud pro-life stance." Raisner Decl. ¶ 8; Sieff Decl. Ex. 5. The press release quotes the Attorney General saying he would do so. *Id.* The Governor's letter asked the Attorney General to drum up charges against Mayday under the State's "pro-life laws, including SDCL § 22-17-5.1 and § 36-4-8," that prohibit administering or providing abortions. Sieff Decl. Ex. 6. The letter accused Mayday of providing information about "an illegal service in the state of South Dakota." *Id.* "South Dakota has the most pro-life laws in the nation," the Governor stated, "I am proud of that fact. Our voters resoundingly supported those laws with the defeat of Amendment G"—which would have legalized abortion in South Dakota—"in the last election." *Id.* He charged that Mayday's signs "threaten[] the lives of children yet to be born in our state," and could "facilitat[e] the mailing of pills into our state, which would be illegal." *Id.*

D. The Attorney General Mails Retaliatory Threats to Mayday in New York

The Attorney General accepted the Governor's charge and commenced an investigation into Mayday. Unable to investigate Mayday under the "pro-life" laws the Governor cited because Mayday does not provide abortions, the Attorney General directed his office to investigate Mayday for possible violations of the South Dakota Deceptive Trade Practices and Consumer Protection Act, SDCL § 37-24-6. *See* Sieff Decl. Ex. 8.

The ensuing "investigation" involved a single official reading Mayday's website and some of the third-party websites to which Mayday's website links. *See* Sieff Decl. Ex. 7. The official did not find that any consumer had been misled by Mayday's website, or by the gas station signs

publicizing it. *Id.* She notes receiving only one complaint from one business, Cowboy Country Stores, that objected to the publication of Mayday's "abortion media campaign" on leased signs in front of its business—an objection to Mayday's expressed point of view, and a contractual matter for Cowboy Country Stores to take up with its media leasing agent, not actionable evidence of consumer deception or confusion that would normally warrant State intervention. *Id.* at ¶ 7. The absence of any evidence of consumer harm is, of course, unsurprising: no one in South Dakota or anywhere else has been or could be deceived by the literally true public health information Mayday publishes and links to on its website, much less by its "Pregnant? Don't want to be?" signs that simply invite people to "learn more."

Despite coming up empty handed, the Attorney General pressed on. On December 10, 2025, the Attorney General sent Mayday a letter to an address in New York (as well as by e-mail) demanding that Mayday immediately desist from publishing information that could be used to facilitate "the delivery of abortion drugs to the State of South Dakota." Sieff Decl. Ex. 8; Raisner Decl. ¶ 10. Failure to comply, he threatened, exposed Mayday to "felony criminal consequences or civil penalties up to $5,000 per violation." Sieff Decl. Ex. 8 at 2. The letter falsely accuses Mayday of "urging women not to seek medical care after taking abortion pills" and claims (*id.* at 1), among other things, that Mayday had engaged in "deceptive act[s] or practice[s]" by republishing official FDA and other medical findings that abortion pills are safe. *Id.* at 2. The Attorney General's allegations refer almost entirely to information published by *third-party* websites that Mayday linked to, but did not author.

Mayday responded by letter through counsel on December 19, 2025. Raisner Decl. ¶¶ 12-13; Sieff Decl. Ex. 9. Objecting to the Attorney General's demand in its entirety, Mayday explained that it was a non-profit information resource that does not sell, handle, provide, offer for

sale, or financially benefit from the sale of abortion medication. Raisner Decl. ¶ 12; Sieff Decl. Ex. 9. at 1. It advised that Mayday accordingly does not engage in "the sale or advertisement of any merchandise" that is subject to the South Dakota deceptive trade practices law. SDCL § 37-24-6(1). Sieff Decl. Ex. 9 at 1. Instead, Mayday explained that it provides truthful information about healthcare options, including but not limited to abortion medications approved by the FDA for safe and effective use. Raisner Decl. ¶ 13; Sieff Decl. Ex. 9 at 1. It stressed this information is not commercial speech subject to regulation under the South Dakota deceptive practices statute and that the First Amendment protected the information it shared under longstanding Supreme Court precedent. Sieff Decl. Ex. 9 at 2.

E. The Attorney General Purports to Seek an Injunction Against Mayday in South Dakota, But Does Not Actually Commence Any Enforcement Action

Disregarding Mayday's response, on December 22, 2025, the Attorney General filed a motion in South Dakota state court purporting to seek an injunction against Mayday and the company that placed Mayday's signs at gas stations in South Dakota. Sieff Decl. Ex. 10. The Attorney General did not properly serve the motion on Mayday and did not file or serve any complaint and summons on Mayday. Raisner Decl. ¶ 16. Mayday only learned about the motion from news reports. *Id.* at ¶ 15. Service still has not been effected, and there is still no complaint or summons on file.

The Attorney General's inchoate motion underscores his threats. The motion seeks a broad and vague injunction that (like his demand letter) refers almost entirely to third-party content to which Mayday's website links—not content published by Mayday itself. Sieff Decl. Ex. 10 at 5-11. The injunction seeks to require Mayday to remove existing content and links from its New York-based website when published to South Dakotans, and to ban Mayday from posting signs at gas stations publicizing its website to audiences in South Dakota. *Id.* at 3-4.

F. Mayday Self-Censors in Response to the Attorney General's Threats

Although Mayday remains committed to its mission of providing truthful, evidence-based information to the public, the Attorney General's actions have forced Mayday to weigh the risks and costs of defending bad faith legal actions against its desire to continue its educational efforts. *See* Raisner Decl. ¶¶ 18-20. Already, Mayday has refrained from engaging in protected speech to avoid incurring future charges and legal costs defending that speech. For example, Mayday is refraining from putting up additional signs at gas stations or other venues in South Dakota. *Id.* ¶ 19. It is also refraining from publishing already-produced content through its social media platforms—to audiences everywhere in the world—sourced from South Dakota residents describing their healthcare challenges. *Id.* And in light of the Attorney General's actions, Mayday is more closely vetting press interview requests and self-censoring the statements it makes publicly—a significant injury for a non-profit whose very mission is to raise awareness through earned media like newspapers, radio, and television stations. *Id.* ¶ 20.

G. Mayday Files This Action to Vindicate Its Constitutional Rights

Mayday filed this action on January 6, 2026, to prevent the Attorney General from censoring and retaliating against its protected speech. *See* Compl. (ECF No. 1).

LEGAL STANDARD

A preliminary injunction should issue where a plaintiff demonstrates a likelihood of success on the merits and a threat of irreparable harm absent relief. *Monserrate v. N.Y. State Senate*, 599 F.3d 148, 154 (2d Cir. 2010). Courts also consider whether equity tips in the plaintiff's favor, and whether the public interest favors an injunction. *New York v. U.S. Dep't of Homeland Sec.*, 969 F.3d 42, 59 (2d Cir. 2020). Where, as here, the government is a party to the lawsuit, the equity and public interest factors "merge." *Id.* at 58-59.

ARGUMENT

I. Mayday Is Likely to Prevail on Its First Amendment Claims.

The reproductive health information Mayday publishes is literally true and of great public interest. The Attorney General's threat to penalize Mayday for publishing that information—or to prevent Mayday from publishing it at all—is both a prior restraint and unconstitutional retaliation against protected speech. Mayday will likely prevail on these claims.

A. The First Amendment Protects Mayday's Speech

"Truth may not be the subject of either civil or criminal sanctions where discussion of public affairs is concerned." *Garrison v. Louisiana*, 379 U.S. 64, 74 (1964); *see Lawrence v. Altice USA*, 841 F. App'x 273, 277 (2d Cir. 2021) (same). Truthful speech about matters of public concern thus enjoys virtually absolute constitutional protection. *See Bartnicki v. Vopper*, 532 U.S. 514, 527, 535 (2001) (First Amendment protected publication of truthful information on public issues even when the information had been leaked unlawfully).

The public health information on Mayday's website—and the signs publicizing it to audiences offline—fall squarely within the First Amendment's protections for truthful speech on matters of public concern. There is no question that "[a]bortion presents a profound moral question" of great public interest. *Dobbs*, 597 U.S. at 302. And the information at issue is literally and undisputedly true. Mifepristone and misoprostol are FDA-approved as safe and effective "to end an intrauterine pregnancy," and may be prescribed and distributed over the internet and by mail across the United States. *See* Sieff Decl. Exs. 11 and 12 at 1 (attaching FDA's current official Risk Evaluation and Mitigation Strategy (REMS) guidance); *see also id.* Exs. 2-4, 15 (FDA and independent studies confirming safety). Mayday likewise truthfully informs readers what third-party providers charge for abortion pills, where those providers mail abortion pills, and how long those providers predict it will take for the pills to arrive. *See id.* Ex. 7 at 51-53. Mayday does not

provide legal advice or direct any action that would violate any state's laws. *Id.* Exs. 13-14; Raisner Decl. ¶ 5. Instead, Mayday links to third-party resources a reader can consult to make their own choices. Sieff Decl. Exs. 13-14; Raisner Decl. ¶ 6

The Second Circuit just last month affirmed that the same publishing activities *by abortion opponents* were fully protected by the First Amendment in *NIFLA v. James*, 160 F.4th 360, 379-80 (2d Cir. 2025). That case involved anti-abortion non-profits' First Amendment rights "to make informational statements on their websites" about options to *reverse* mifepristone-and-misoprostol induced abortions—including by posting "links and instructions for accessing" third-party providers—"so that women can receive more information about" these options and "if they so choose, be matched with a third-party provider." *Id.* at 375. Because the non-profits are "morally motivated," "receive no renumeration or financial benefit for engaging in" their speech, and "do not provide" the procedures themselves, "but rather provide the public with information … and access to third-party providers who can offer" them, the Second Circuit affirmed that the First Amendment protected their websites. *Id.* at 375-76. That conclusion applies here.

It makes no difference that it is now illegal to provide most abortions in South Dakota and some other states. The Supreme Court addressed this exact fact pattern in *Bigelow v. Virginia*, 421 U.S. 809 (1975), holding that a Virginia law criminalizing the dissemination of information with tendency to "encourage or prompt the procuring of an abortion" violated a Virginia newspaper's First Amendment right to publish information about, and endorse an organization that facilitated, access to abortions that were then illegal in Virginia. *Id.* at 811-12. The Court explained that the published material "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," and that Virginia had no

legitimate "interest in shielding its citizens" from this information. *Id.* at 822 & n.7, 827-28. The Attorney General has no legitimate interest here either. *See also, e.g.*, *Matsumoto v. Labrador*, 122 F.4th 787, 812 (9th Cir. 2024) (First Amendment "squarely protect[s]" providing "[i]nformation and instructions regarding the availability and means of procuring an abortion procedure or drug," including "specifics, such as who the provider is, when and where the procedure would take place, or what a drug would cost"); *Welty v. Dunaway*, 791 F. Supp. 3d 818, 831 (M.D. Tenn. 2025) (First Amendment protects sharing information about how "to get abortion pills and do a self-managed abortion or to seek abortion care outside" prohibition states).

The Attorney General also cannot avoid the First Amendment by mischaracterizing Mayday's publications as deceptive or illegal commercial speech. *Cf.* Sieff Decl. Ex. 8 at 2 (making this contention). For one thing, Mayday's speech is not deceptive and does not propose any illegal transaction—it is literally true and provides information for readers to make lawful choices. *Supra* p. 8-9. But just as critically, Mayday's speech is not commercial speech regulable as a deceptive trade practice at all. *See Zauderer v. Off. of the Disciplinary Counsel*, 471 U.S. 626, 638 (1985) (deceptive practices statutes constitutional only to restrict "the dissemination of commercial speech"); *e.g.*, SDCL § 37-24-6(1) (statute invoked by the Attorney General applies only to "the sale or advertisement of any merchandise" or solicitation). Commercial speech at its core "does no more than propose a commercial transaction." *Harris v. Quinn*, 573 U.S. 616, 648 (2014) (citation omitted). Even in close cases—unlike this one—involving speech with a mix of commercial and noncommercial elements, speech is *not commercial* when it is does not advertise the sale of a specific product the speaker has an economic motivation for selling. *See Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66-67 (1983) (setting forth these *Bolger* factors). Thus in *Bose Corp. v. Consumers Union of U.S., Inc.*, 466 U.S. 485, 503-14 (1984), it was not

commercial speech to inform consumers about the price, quality, and availability of a loudspeaker, nor was it commercial speech in *Lowe v. SEC*, 472 U.S. 181, 210 & n.58 (1985), to publish advice and commentary about investments. *See also, e.g.*, *Davis v. Avvo, Inc.*, 345 F. Supp. 3d 534, 540 (S.D.N.Y. 2018) (professional services directory not commercial speech).

The Second Circuit's decision in *NIFLA* is again dispositive. 160 F.4th at 374-75. As the Attorney General does here, the New York Attorney General there asserted authority to regulate anti-abortion organizations' websites pursuant to New York's consumer protection laws (N.Y. Gen. Bus. Laws §§ 349-50), claiming the organizations published commercial speech that was "false or misleading because they misrepresented the efficacy and safety" of abortion-pill reversal procedures and "induced individuals" to undertake them. *Id.* at 365-66. The court rejected this contention and held that the non-profits' speech advising readers as to the availability of these services was informational and educational. *Id.* at 375-76. Predicting *this very case*, the court warned any other ruling would "subject a sweeping range of non-profits to regulation of their speech for providing the public with information," including "a reproductive rights group in a state with abortion restrictions that provides information about out-of-state organizations that will help women obtain the procedure." *Id.* at 376. The First Amendment protects Mayday's truthful non-commercial speech without qualification.

B. The Attorney General's Threats Violate the First Amendment

The Attorney General's threats to Mayday's protected speech violate at least two separate First Amendment doctrines. First, the Attorney General's attempt to punish and prevent Mayday's truthful speech of public concern is a prior restraint and content-based restriction of speech that fails strict scrutiny. Second, the Attorney General's actions violate the First Amendment by retaliating against Mayday for engaging in protected activity. *See, e.g.*, *NRA of Am. v. Vullo*, 602 U.S. 175, 203 (2024) (Jackson, J., concurring) (noting the First Amendment violation alleged in

that case could be described as both a prior restraint and retaliation).

1. The First Amendment bars viewpoint-based prior restraints against truthful speech of public concern.

"[S]tate action to punish the publication of truthful information seldom can satisfy constitutional standards." *Bartnicki*, 532 U.S. at 527 (citation omitted). The Supreme Court has never upheld state action to prevent or punish the publication of such information, whether they be state secrets, *New York Times Co. v. United States*, 403 U.S. 713, 714 (1971), names of juvenile delinquents, *Smith v. Daily Mail Publishing Co.*, 443 U.S. 97, 105-06 (1979), identities of rape victims, *The Florida Star v. B.J.F.*, 491 U.S. 524, 532-41 (1989), or even information obtained through "a stranger's illegal conduct," *Bartnicki*, 532 U.S. at 527, 535. Even when the Supreme Court has "hypothesiz[ed]" what "state interest[s] of the highest order" might justify restricting truthful speech on issues of public concern under the strictest imaginable scrutiny, it has confined those interests to the extreme margins of ordinary discourse, such as preventing "publication of the sailing dates of transports or the number and location of troops" at sea in wartime. *Fla. Star*, 491 U.S. at 532-33 (quoting *Near v. Minnesota*, 283 U.S. 697, 716 (1931)).

This strictest possible scrutiny applies to the Attorney General's threats not only because they seek to impose formal and informal prior restraints preventing Mayday from publishing truthful information about reproductive healthcare, *Bantam Books, Inc. v. Sullivan*, 372 U.S. 58, 67 (1963) (explaining that "the threat of invoking legal sanctions" against protected speech is an "informal" prior restraint subject to strict scrutiny), but also because the Attorney General's reasons for silencing Mayday are transparently predicated on contempt for "the specific motivating ideology" behind Mayday's publications. *Rosenberger v. Rector & Visitors of Univ. of Virginia*, 515 U.S. 819, 829 (1995). This kind of viewpoint-based censorship is the most "egregious form" of speech restriction, *id.*, because it seeks through suppression "to prescribe what shall be orthodox

in politics, nationalism, religion, or other matters of opinion." *W. Va. Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943). Viewpoint-based prior restraints are thus arguably not just subject to strict scrutiny, but "unconstitutional per se." *Cath. Charities v. Whitmer*, --- F. 4th ----, 2025 WL 3653774, at *6 (6th Cir. Dec. 17, 2025); *see also Otto v. City of Boca Raton*, 981 F.3d 854, 864 (11th Cir. 2020) (citing cases); *Junior Sports Mags. Inc. v. Bonta*, 80 F.4th 1109, 1124 & 1124 n.1 (9th Cir. 2023) (Van Dyke, J., concurring) (same).

The Attorney General cannot justify his threats even assuming strict scrutiny applies. "Strict scrutiny is unforgiving" and effectively "fatal" "absent truly extraordinary circumstances." *Free Speech Coalition, Inc. v. Paxton*, 606 U.S. 461, 484-85 (2025). State action subject to strict scrutiny is presumptively invalid unless the government shows it is necessary to achieve a compelling interest and uses the least restrictive means. *See Reed v. Town of Gilbert*, 576 U.S. 155, 163 (2015); *United States v. Playboy Ent. Grp., Inc.*, 529 U.S. 803, 813, 817 (2000). This is the government's burden. *NIFLA*, 160 F.4th at 378. To survive review, the Attorney General "must specifically identify an actual problem in need of solving, and the curtailment of free speech must be actually necessary to the solution." *Id.* (quotation omitted).

Nothing justifies the Attorney General's threats to censor Mayday's speech under this standard. If the Attorney General's interest is preventing the dissemination of information that could enable readers to make the informed choice to obtain a legal abortion, that is not a compelling—much less legitimate—interest his office may pursue. *See Bigelow*, 421 U.S. at 822 & n.7, 827-28. If the interest is preventing *illegal* abortions, the Attorney General has less restrictive tools at his disposal that do not involve suppressing truthful public health information, including enforcing the "pro-life laws" Governor Rhoden identified (Sieff Decl. Ex. 6)—SDCL § 22-17-5.1 and § 36-4-8—against abortion providers who violate them. *See McCullen v. Coakley*,

573 U.S. 464, 490-92 (2014) (abortion-related speech regulation failed even intermediate scrutiny when the only conduct it legitimately proscribed was already criminalized by other state laws); *e.g.*, *Brooklyn Branch of NAACP v. Kosinski*, 735 F. Supp. 3d 421, 448 (S.D.N.Y. 2024) (Failla, J.) (same applying strict scrutiny). His failure to do so is dispositive.

2. The First Amendment also bars retaliation against protected speech.

The First Amendment also "prohibits government officials from subjecting individuals to 'retaliatory actions' after the fact for having engaged in protected speech." *Houston Cmty. Coll. Sys. v. Wilson*, 595 U.S. 468, 474 (2022) (citation omitted). A violation occurs when a plaintiff (1) has an interest protected by the First Amendment, (2) the government takes adverse action against the plaintiff motivated by, or substantially caused, by the exercise of that right, and (3) the government's actions effectively chilled the exercise of his First Amendment right. *Curley v. Vill. of Suffern*, 268 F.3d 65, 73 (2d Cir. 2001). Once shown, the government "can prevail only by showing that the [action] would have been initiated without respect to retaliation." *Nieves v. Bartlett*, 587 U.S. 391, 404 (2019) (citation omitted). All three elements are established.

First, the First Amendment protects Mayday's website, and Mayday's signs publicizing it, because the speech is truthful and on a matter of public concern. *Supra* § I.A.

Second, it is clear the Attorney General threatened Mayday with a sham "deceptive practices" investigation and enforcement action because Mayday published protected speech into South Dakota—the threats literally respond to, and seek to silence, that speech. Although that alone satisfies the nexus element, *e.g.*, *Holley v. Cnty. of Orange, NY*, 625 F. Supp. 2d 131, 141 (S.D.N.Y. 2009) (retaliatory nexus shown where officer "sought to silence plaintiff" for protected speech, even though officer erroneously believed the speech was not protected), the evidence here is more damning because it shows the Attorney General not only intends to silence Mayday, but do so because *he disagrees with* the ideas Mayday shares and the viewpoint behind it. *See, e.g.*,

Huminski v. Rutland Cnty., 134 F. Supp. 2d 362, 365 (D. Vt. 2001) (retaliation shown where government refused to allow plaintiff to enter public buildings "because they disapproved of the message he had displayed"); *see also Decker Advert. Inc. v. Delaware Cnty., N.Y.*, 765 F. Supp. 3d 128, 142-43 (N.D.N.Y. 2025) (withdrawing newspaper's privilege of printing official county notices was cognizable retaliation for its disfavorable coverage of county officials).

This animus is plain from the "sequence of events leading up to" the Attorney General's demand and threatened lawsuit, *Vill. of Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 266-67 (1977) (considering this factor to determine whether an impermissible purpose "was a motivating factor" for government action), as well as the fact that the threatened claims are so objectively frivolous that they "must have been undertaken for some improper purpose," *Schlaifer Nance & Co. v. Est. of Warhol*, 194 F.3d 323, 338 (2d Cir. 1999). Consider:

- Mayday only came onto the Attorney General's radar because, on **December 8**, it placed signs at South Dakota gas stations inviting readers to "learn more" about their options to terminate a pregnancy. Raisner Decl. ¶ 7.
- The next day, **December 9**, before any investigation, the Governor and Attorney General issued a joint press release announcing the Governor's request to prosecute Mayday under any "pro-life" pretext the Attorney General could devise. Sieff Decl. Ex. 5; Raisner Decl. ¶ 8.
- On **December 10**, still before an investigation, the Attorney General sent a cease-and-desist letter to Mayday in New York. He threatened Mayday under the South Dakota Deceptive Trade Practices and Consumer Protection Act, SDCL § 37-24, even though Mayday's publications are not trade or commerce regulable by that law. Sieff Decl. Ex. 8; Raisner Decl. ¶ 10.

- At some point between **December 15** and **December 22**, the Attorney General's office conducted a perfunctory "investigation" finding that no one had reported being deceived by Mayday's signs or its website. Sieff Decl. Ex. 7. In fact, the Attorney General received only one complaint from one business, Cowboy Country Stores, that objected to Mayday's "abortion media" on leased signs in front of its storefronts—an objection to Mayday's *point of view*, and possibly a contractual matter for Cowboy Country Stores to take up with its media leasing agent, not evidence of consumer deception that would warrant State intervention. *Id.* at ¶ 7.
- On **December 19,** Mayday sent the Attorney General a response explaining that Mayday is a non-profit that does not sell, handle, provide, offer for sale, or benefit from the sale of abortion medication, and that its speech is truthful noncommercial speech protected by the First Amendment and not regulable by the statute the Attorney General cited. *Id.* at Ex. 9; Raisner Decl. ¶¶ 12-13.
- On **December 22**, the Attorney General rushed to file a motion to enjoin Mayday's speech, but in fact initiated no proceedings and even failed to serve Mayday with its defective pleading. Sieff Decl. Ex. 10; Raisner Decl. ¶ 15. The motion makes assertions that ignore Mayday's letter, levies false claims that could have been debunked with minimal research, and focuses almost entirely on *third parties' speech*—not Mayday's.

All of this makes plain what was obvious from the start: the Attorney General's aim was to "put[] investigators to work" "searching the law books" "to pin some offense" on Mayday in retaliation for its speech, not to undertake a normal good faith investigation following up on any real suspicion of wrongdoing. *Morrison v. Olson*, 487 U.S. 654, 728 (1988) (Scalia, J., dissenting). (quoting R. Jackson, The Federal Prosecutor, Address Delivered at the Second Annual Conference

of United States Attorneys, April 1, 1940). This is textbook retaliation. When "the prosecutor picks some person whom he dislikes or desires to embarrass, or selects some group of unpopular persons and then looks for an offense" it presents "the greatest danger of abuse" known to our judicial system. *Id.* at 728 (Scalia, J., dissenting) (quoting same).

Third, and finally, the Attorney General's actions have chilled Mayday's speech, to the extent that element even needs to be established. *See Holley*, 625 F. Supp. 2d at 141 (noting there is "no need" to prove a chilling effect "in a retaliatory prosecution action" where there is no "probable cause" to support the government's asserted violation) (citing cases). Although Mayday has not stopped speaking altogether, it has unwillingly refrained from engaging in protected speech to avoid incurring future charges and legal costs defending that speech. Raisner Decl. ¶¶ 18-21. It has foregone publishing ready-to-post content to its social media channels, refrained from posting new signs in South Dakota, and its leadership has had to restrict what they say to press about Mayday's campaign lest those innocuous protected statements, too, become baseless grounds for further government harassment. *Id.* ¶¶ 19-20. Those "changes in" Mayday's "behavior" is more than enough to establish a chilling effect. *Bartels v. Inc. Vill. of Lloyd*, 751 F. Supp. 2d 387, 401 (E.D.N.Y. 2010) (chilling effect could be proven with evidence that plaintiff "stopped attending" public meetings and "ceased writing" some letters to the village council). Mayday will accordingly prevail on its retaliation theory, as well.

II. Mayday Will Suffer Irreparable Harm Absent an Injunction.

Mayday has already and will continue to suffer irreparable injury absent relief. Raisner Decl. ¶¶ 18-21. The "loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Elrod v. Burns*, 427 U.S. 347, 373 (1976). Because Mayday has shown that it is likely to succeed on the merits of its First Amendment claims, that is enough to establish irreparable harm. *See N.Y. Progress & Prot. PAC v. Walsh*, 733 F.3d 483,

486-87 (2d Cir. 2013) (irreparable harm from likelihood of success on First Amendment claim). Additionally, even if Mayday chose *not* to comply with the State's demand, it would face potentially crippling penalties. Raisner Decl. ¶ 21. That choice, too, would result in irreparable harm. *See Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992) (forcing such a choice threatens irreparable injury); *e.g.*, *Satellite TV of N.Y. Assocs. v. Finneran*, 579 F. Supp. 1546, 1551 (S.D.N.Y. 1984) (choice between complying with law or incurring a fine "readily" satisfied irreparable harm inquiry).

III. Mayday Satisfies the Remaining Preliminary Injunction Factors.

The remaining factors—the balance of equity and the public interest—"merge" when the government is the defendant. *New York v. U.S. Dept. of Homeland Sec.*, 969 F.3d 42, 58-59 (2d Cir. 2020). They favor an injunction here. Absent a preliminary injunction, Mayday will suffer a loss of its First Amendment rights and/or substantial civil penalties. Raisner Decl. ¶¶ 18-21. In contrast, the Attorney General "does not have an interest in the enforcement of an unconstitutional" demand. *725 Eatery Corp. v. City of N.Y.*, 408 F. Supp. 3d 424, 470 (S.D.N.Y. 2019). The public interest further supports "securing First Amendment rights," *N.Y. Progress & Prot. PAC*, 733 F.3d at 488, "and it is decidedly against the public interest to abide the continued enforcement of an unconstitutional policy," *Deferio v. City of Syracuse*, 193 F. Supp. 3d 119, 131 (N.D.N.Y. 2016).

CONCLUSION

Mayday respectfully requests an order preliminarily enjoining the Attorney General from (1) taking any action, formal or informal, to pressure or force Mayday to take down the truthful public health information on its website, or the signs it has published publicizing that website, and from (2) taking any action, formal or informal, to pressure or force Mayday to refrain from publishing truthful public health information to South Dakotans in the future, both on its website

and in signs and other offline communications publicizing its website.[1]

Dated: Los Angeles, California
January 14, 2026

Respectfully submitted,

By: */s/ Adam S. Sieff*
Adam S. Sieff

Adam S. Sieff*
DAVIS WRIGHT TREMAINE LLP
350 South Grand Avenue, 27th Floor
Los Angeles, California 90071-3487
213.663.6800 (tel)
adamsieff@dwt.com

Ambika Kumar*
Nicole Saad Bembridge*
DAVIS WRIGHT TREMAINE LLP
920 Fifth Avenue, Suite 3300
Seattle, Washington 98104-1610
206.622.3150 (tel)
ambikakumar@dwt.com
nicolesaadbembridge@dwt.com

Chelsea T. Kelly (SDNY No. CK2016)
Laura R. Handman (SDNY No. RH5353)
DAVIS WRIGHT TREMAINE LLP
1301 K Street NW, Suite 500 East
Washington, D.C. 20005-3317
202 973.4200 (tel)
chelseakelly@dwt.com
laurahandman@dwt.com

*Admitted *pro hac vice*

Attorneys for Plaintiff Mayday Health

[1] The Court should not require Mayday to post a bond since the State will not incur any costs or damages if the Court wrongfully enjoins the Act. *725 Eatery Corp.*, 408 F. Supp. 3d at 470.

CERTIFICATION OF WORD COUNT

I certify that the qualifying portions of the foregoing memorandum of law contains 5,837 words and therefore complies with Local Rule 7.1(c) and this Court's Individual Rules of Practice in Civil Cases.

/s/ Adam S. Sieff
Adam S. Sieff

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MAYDAY HEALTH, Plaintiff, v. MARTY J. JACKLEY, Attorney General of South Dakota, in his official capacity, Defendants.	Case No. 1:26-cv-00078-KPF

DECLARATION OF ADAM S. SIEFF IN SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

I, Adam Sieff, declare as follows:

1. I am a partner with the law firm of Davis Wright Tremaine LLP and represent Plaintiff Mayday Health. I make this declaration based on personal knowledge, except where specified as made on information and belief. If called, I would testify competently thereto.

2. Attached hereto as **Exhibit 1** is a true and correct copy of Mayday Health's main web page, captured January 12, 2026, available at https://www.mayday.health/.

3. Attached hereto as **Exhibit 2** is a true and correct copy of the U.S. Food Drug Administration Center for Drug and Research, Approval Package for Application Number 020687/Orig.1s20, dated March 29, 2016, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020Approv.pdf.

4. Attached hereto as **Exhibit 3** is a true and correct copy of a report by the U.S. Food and Drug Administration titled *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2024*, dated 2025, available at https://www.fda.gov/media/185245/download.

5. Attached hereto as **Exhibit 4** is a true and correct copy of a study written by Mifeprex REMS Study Group titled *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, published by the New England Journal of Medicine, dated February 23, 2017, available at https://www.nejm.org/doi/full/10.1056/NEJMsb1612526.

6. Attached hereto as **Exhibit 5** is a true and correct copy of a joint press release from South Dakota Governor Larry Rhoden and South Dakota Attorney General Marty J. Jackley, dated December 9, 2025, available at https://news.sd.gov/news?id=news_kb_article_view&sys_id=f134c698477d3690da219464336d431a.

7. Attached hereto as **Exhibit 6** is a true and correct copy of a letter from South Dakota Governor Larry Rhoden to Attorney General Marty Jackley, dated December 9, 2025, available at https://governor.sd.gov/doc/Letter-to-AttorneyGeneral_12-9-2025.pdf.

8. Attached hereto as **Exhibit 7** is a true and correct copy of the Affidavit of Kayla Klemann, Consumer Protection Investigator, South Dakota Office of the Attorney General in the matter of *State of South Dakota v. Mayday Medicines, Inc.*, 32CIV25-000339 (6th Judicial Cir.), dated December 22, 2025.

9. Attached hereto as **Exhibit 8** is a true and correct copy of a cease and desist letter from Attorney General Marty Jackley to Mayday Health, dated December 10, 2025

10. Attached hereto as **Exhibit 9** is a true and correct copy of a letter from Adam S. Sieff to Attorney General Marty J. Jackley in response to the cease and desist letter, dated December 19, 2025.

11. Attached hereto as **Exhibit 10** is a true and correct copy of Plaintiff's Motion for a Preliminary and Permanent Injunction Pursuant to SDCL 37-24-23 in the matter of *State of South Dakota v. Mayday Medicines, Inc.*, 32CIV25-000339 (6th Judicial Cir.), dated December 22, 2025.

12. Attached hereto as **Exhibit 11** is a true and correct copy of a U.S. Food and Drug Administration web page titled *Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, dated January 17, 2025, available at https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

13. Attached hereto as **Exhibit 12** is a true and correct copy of a U.S. Food and Drug Administration web page titled *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, dated February 11, 2025, available at https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

14. Attached hereto as **Exhibit 13** is a true and correct copy of Mayday Health's Frequently Asked Questions web page, captured January 12, 2026, available at https://www.mayday.health/faq/.

15. Attached hereto as **Exhibit 14** is a true and correct copy of Mayday Health's Options page of external links, captured January 12, 2026, available at https://www.mayday.health/options-2/.

16. Attached hereto as **Exhibit 15** is a true and correct copy of a report by Sophie Dilek and others, titled *The US Food and Drug Administration's Regulation of Mifepristone*, published

by JAMA Network, dated January 12, 2026, available at https://jamanetwork.com/journals/jama/article-abstract/2843710.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: Los Angeles, California
January 14, 2026

By: */s/ Adam S. Sieff*
Adam S. Sieff

Exhibit 1


This site collects zero data that could identify a visitor.
Quick Exit
ES
MAYDAY.HEALTH
Donate
Merch
Resources
What do you need?
Abortion
Morning after pills
Birth Control
Gender-Affirming Care
Hi, my name's Charley. I can help you get or manage an abortion. / Hola, mi nombre es Charley. Puedo ayudarte a
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.
Before going to any external websites, you can take these steps for digital privacy.
This site collects zero data that could identify a visitor.
Mayday is a reproductive health education nonprofit
Our Mission
Additional Resources
Links to trusted organizations.
Before going to any external websites below, you can take these steps for digital privacy.

- Abortion decision support
- Abortion pill FAQs
- What to expect
- Financial support
- Questions on logistics/delivery times/support while waiting
- Online/phone medical support
- In-person medical support
- Emotional support
- Legal support
- Privacy support
- Reproductive Justice
- State-by-state guide to pills

Donate or Share

Donate Today

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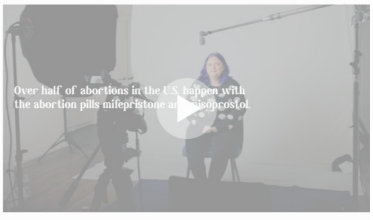
Mayday Videos



Mayday Featured

The New York Times · TIME · The Atlantic · AP · MPB Mississippi Public Broadcasting
The Guardian · The Washington Post · univision · Bloomberg · teenVOGUE
yahoo!finance · COSMOPOLITAN · NOW THIS · AXIOS · IndyStar.

MAYDAY.HEALTH

For media inquiries only:
media@mayday.health

Privacy Policy FAQ

Exhibit 2

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

020687Orig1s020

Trade Name:	Mifeprex Tablets
Generic Name:	mifepristone
Sponsor:	Danco Laboratories, LLC
Approval Date:	March 29, 2016
Indication:	For use through 70 days gestation, revise the labeled dose and dosing regimen and modify the REMS

CENTER FOR DRUG EVALUATION AND RESEARCH

020687Orig1s020

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Other Action Letters	
Labeling	X
REMS	X
Summary Review	X
Officer/Employee List	
Office Director Memo	
Cross Discipline Team Leader Review	X
Medical Review(s)	X
Chemistry Review(s)	X
Environmental Assessment	
Pharmacology Review(s)	X
Statistical Review(s)	X
Microbiology / Virology Review(s)	
Clinical Pharmacology/Biopharmaceutics Review(s)	X
Other Reviews	X
Risk Assessment and Risk Mitigation Review(s)	X
Proprietary Name Review(s)	
Administrative/Correspondence Document(s)	X

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

020687Orig1s020

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020687/S-020

SUPPLEMENT APPROVAL

Danco Laboratories, LLC
(b) (6)
P.O. Box 4816
New York, NY 10185

Dear (b) (6):

Please refer to your Supplemental New Drug Application (sNDA) dated May 28, 2015, received May 29, 2015, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mifeprex (mifepristone) Tablets.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated July 17, 2015.

This "Prior Approval" supplemental new drug application proposes to provide for use through 70 days gestation, revise the labeled dose and dosing regimen and modify the REMS.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

We request that the labeling approved today be available on your website within 10 days of receipt of this letter.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for pre-menarcheal patients because the use of this product before menarche is not indicated, and we have determined that you have fulfilled the pediatric study requirement for post-menarcheal patients.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Mifeprex (mifepristone) Tablets was originally approved on June 8, 2011. The REMS consisted of a Medication Guide, elements to assure safe use, an implementation system, and a timetable for submission of assessments of the REMS. Your proposed modifications to the REMS included revisions to both the prescriber and patient agreement forms.

Other changes proposed in the efficacy supplement prompted additional revisions to the Mifeprex REMS materials. During review of this efficacy supplement, we also assessed the current REMS program to determine whether each Mifeprex REMS element remains necessary to ensure that the drug's benefits outweigh the risks.

After consultations between the (b) (6) and the (b) (6) we have determined that the approved REMS for Mifeprex should be modified to continue to ensure that the benefits of Mifeprex outweigh its risks and to minimize the burden on the healthcare delivery system of complying with the REMS. The REMS modifications submitted by you on March 29, 2016 are approved.

We have determined that it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Mifeprex outweigh its risks. The

Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208. Like other labeling, Medication Guides are subject to the safety labeling change provisions of section 505(o)(4) of the FDCA.

Your proposed modified REMS, submitted on July 17, 2015, and appended to this letter, is approved as amended. The modified REMS consists of elements to assure safe use (A, C and D), an implementation system, and a timetable for submission of assessments of the REMS.

The timetable for submission of assessments of the REMS remains the same as that approved on June 8, 2011.

The REMS assessment plan will include the information submitted to FDA on March 29, 2016.

The revised REMS assessment plan must include, but is not limited to, the following:

REMS Assessment Plan

1. Number of prescribers enrolled (cumulative)
2. Number of new prescribers enrolled during reporting period
3. Number of prescribers ordering Mifeprex during reporting period
4. Number of healthcare providers who attempted to order Mifeprex who were not enrolled; describe actions taken (during reporting period and cumulative).
5. Number of women exposed to Mifeprex (during reporting period and cumulative)
6. Summary and analysis of any program deviations and corrective action taken
7. Based on the information reported, an assessment and analysis of whether the REMS is meeting its goals and whether modifications to the REMS are needed

The requirements for assessments of an approved REMS under section 505-1(g)(3) include with respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal or whether 1 or more such goals or such elements should be modified.

We remind you that in addition to the REMS assessments submitted according to the timetable in the approved REMS, you must include an adequate rationale to support any proposed REMS modification for the addition, modification, or removal of any of goal or element of the REMS, as described in section 505-1(g)(4) of the FDCA.

We also remind you that you must submit a REMS assessment when you submit any future supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of the FDCA. This assessment should include:

a) An evaluation of how the benefit-risk profile will or will not change with the new indication;

b) A determination of the implications of a change in the benefit-risk profile for the current REMS;

c) *If the new indication for use introduces unexpected risks*: A description of those risks and an evaluation of whether those risks can be appropriately managed with the currently approved REMS.

d) *If a REMS assessment was submitted in the 18 months prior to submission of the supplemental application for a new indication for use*: A statement about whether the REMS was meeting its goals at the time of that the last assessment and if any modifications of the REMS have been proposed since that assessment.

e) *If a REMS assessment has not been submitted in the 18 months prior to submission of the supplemental application for a new indication for use:* Provision of as many of the currently listed assessment plan items as is feasible.

f) *If you propose a REMS modification based on a change in the benefit-risk profile or because of the new indication of use, submit an adequate rationale to support the modification, including*: Provision of the reason(s) why the proposed REMS modification is necessary, the potential effect on the serious risk(s) for which the REMS was required, on patient access to the drug, and/or on the burden on the health care delivery system; and other appropriate evidence or data to support the proposed change. Additionally, include any changes to the assessment plan necessary to assess the proposed modified REMS. *If you are not proposing REMS modifications*, provide a rationale for why the REMS does not need to be modified.

If the assessment instruments and methodology for your REMS assessments are not included in the REMS supporting document, or if you propose changes to the submitted assessment instruments or methodology, you should update the REMS supporting document to include specific assessment instrument and methodology information at least 90 days before the assessments will be conducted. Updates to the REMS supporting document may be included in a new document that references previous REMS supporting document submission(s) for unchanged portions. Alternatively, updates may be made by modifying the complete previous REMS supporting document, with all changes marked and highlighted. Prominently identify the submission containing the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

NDA 020687 REMS CORRESPONDENCE
(insert concise description of content in bold capital letters, e.g.,
UPDATE TO REMS SUPPORTING DOCUMENT - ASSESSMENT METHODOLOGY

An authorized generic drug under this NDA must have an approved REMS prior to marketing. Should you decide to market, sell, or distribute an authorized generic drug under this NDA, contact us to discuss what will be required in the authorized generic drug REMS submission.

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

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

NDA 020687 REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 020687/S-000
CHANGES BEING EFFECTED IN 30 DAYS
PROPOSED MINOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR NDA 020687/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED MAJOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR NDA 020687/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED REMS MODIFICATIONS DUE TO SAFETY LABEL CHANGES
SUBMITTED IN SUPPLEMENT XXX

or

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 020687/S-000
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

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

REMS REVISIONS FOR NDA 020687

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

If you do not submit electronically, please send 5 copies of REMS-related submissions.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate: (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

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

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

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call (b) (6) .

Sincerely,

{See appended electronic signature page}

(b) (6)

Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
REMS

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

(b) (6)

03/29/2016

Exhibit 3

TTT # 2022-2468
NDA 020687
ANDA 091178
Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2024

The following information is from United States (U.S.) post-marketing reports received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use, and other possible medical or surgical treatments and conditions. The estimated number of women who have used mifepristone in the U.S. for medical termination of pregnancy through the end of December 2024 is approximately 7.5 million women.

For informational purposes, fatal foreign cases that were reported after U.S. approval of mifepristone for medical termination of pregnancy are also included in a footnote in Table 1.

Table 1. Cumulative Post-Marketing Fatal and Ectopic Pregnancy Reports in U.S. Women Who Used Mifepristone for Medical Termination of Pregnancy

Date range of cumulative reports	09/28/00[†] - 12/31/24
Died [‡]	36
*Ectopic pregnancies [||]	97

[†] U.S. approval date

[‡] The fatal cases are included regardless of causal attribution to mifepristone. Deaths were associated with sepsis in 13 of the 36 reported fatalities (9 cases tested positive for *Clostridium sordellii*, 1 case tested positive for *Clostridium perfringens*, 2 cases had negative blood cultures, and 1 case did not have blood culture data). Ten of the 13 fatal sepsis cases reported vaginal misoprostol use; 2 cases reported buccal misoprostol use; 1 case did not report the route of misoprostol use. Twenty-two of the 23 remaining U.S. deaths involved 2 cases of homicide, 2 cases of combined drug intoxication/overdose, 2 cases of ruptured ectopic pregnancy, 2 cases of drug intoxication, 2 cases of suicide, and 1 case each of the following: substance abuse/drug overdose; methadone overdose; suspected homicide; delayed onset toxic shock-like syndrome; hemorrhage; bilateral pulmonary thromboemboli; unintentional overdose resulting in liver failure; probable anaphylactic medication reaction; septic shock due to necrotizing fasciitis; sepsis with multiple complications possibly secondary to toxic shock syndrome 82 days after mifepristone; sudden death of undetermined etiology despite performance of an autopsy; and a case of natural death due to severe pulmonary emphysema. In the 23rd case, the cause of death could not be established despite performance of an autopsy; tissue samples were negative for *Clostridium sordellii*. There were 13 additional reported deaths in women in foreign countries who used mifepristone for medical termination of pregnancy. These fatal cases were associated with the following: sepsis (*Clostridium sordellii* identified in tissue samples) in a foreign clinical trial; sepsis (Group A *Streptococcus pyogenes*); a ruptured gastric ulcer; severe hemorrhage; severe hemorrhage and possible sepsis; "multivisceral failure;" thrombotic thrombocytopenic purpura leading to intracranial hemorrhage; toxic shock syndrome (*Clostridium sordellii* was identified through uterine biopsy cultures); sepsis (*Enterococcus faecalis* and *Escherichia coli* were identified in blood culture); asthma attack with cardiac arrest; thromboembolism; respiratory decompensation with secondary pulmonary infection 30 days after mifepristone in a patient on the lung transplant list with diabetes, a jejunostomy feeding tube, and severe cystic fibrosis; and a case of *Clostridium septicum* sepsis (from a published literature report).

* The majority of these women are included in the hospitalized category in Table 2.

[||] Administration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus).

Table 2. Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Medical Termination of Pregnancy

Date ranges of reports received	09/28/00[†] - 10/31/12	11/01/12 - 12/31/24[‡]
Cases with any adverse event	2740	1512
Hospitalized, excluding deaths	768	288
*Experienced blood loss requiring transfusions [§]	416	190
Infections [||] (*Severe infections [¶])	308 (57)	114 (22)

[†] U.S. approval date

[‡] FDA implemented the FDA Adverse Event Reporting System (FAERS) on September 10, 2012, and migrated all the data from the previous reporting system (AERS) to FAERS. Differences may exist when comparing case counts in AERS and FAERS. FDA validated and recoded product information as the AERS reports were migrated to FAERS. As a result of this change, it is not recommended to calculate a cumulative number when reviewing the data provided in Table 2.

* The majority of these women are included in the hospitalized category in Table 2.

[§] As stated in the approved labeling for Mifeprex (mifepristone) and its approved generic version, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days. Excessive vaginal bleeding usually requires treatment by uterotonics, vasoconstrictor drugs, curettage, administration of saline infusions, and/or blood transfusions.

[||] This category includes endometritis (inflammation resulting from an infection involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious systemic infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as chlamydia and gonorrhea, cystitis, and toxic shock syndrome not associated with a pelvic infection.

[¶] This subset of infections includes cases that were determined to be severe based on medical review of the available case details. Severe infections generally result in death or hospitalization for at least 2-3 days, require intravenous antibiotics for at least 24 hours and total antibiotic usage for at least 3 days, or have other physical or clinical findings, laboratory data, or surgery that suggest a severe infection.

Exhibit 4

The NEW ENGLAND JOURNAL of MEDICINE

SOUNDING BOARD

Sixteen Years of Overregulation: Time to Unburden Mifeprex

Mifeprex REMS Study Group

On March 29, 2016, the Food and Drug Administration (FDA) approved an updated label for Mifeprex (mifepristone 200-mg tablets, Danco Laboratories), the product that is commonly used in the United States in combination with misoprostol to induce a medical abortion. The changes made to the label were sweeping: they included a more effective dosing regimen containing less mifepristone and more misoprostol, expansion of the gestational limit for treatment from 49 to 70 days, omission of the recommendation for in-person follow-up, removal of language indicating that the prescriber must be a physician, and elimination of the requirement to report nonfatal adverse events. These revisions were supported by extensive data about mifepristone that have been accumulated since the FDA first approved the drug in 2000.[1-7] Professional guidelines for medical abortion had already incorporated many of the new procedures,[8-10] and thus the FDA's action brought the drug label into line with current standard practice.

The new label will undoubtedly have substantial benefits. Because the label now conforms with scientific evidence, it will reduce confusion among women, providers, and policymakers about the appropriate use of the drug. Moreover, it is expected to make abortion less expensive, more convenient, and more widely available in the handful of states where legislatures have enacted laws requiring adherence to the FDA-approved Mifeprex label.[11]

We suggest, however, that in merely updating the label, the FDA did not go far enough: the distribution of Mifeprex remains substantially and unnecessarily encumbered by a Risk Evaluation and Mitigation Strategy (REMS), which was left fundamentally unchanged.

A REMS is a set of restrictions beyond the label that the FDA may impose under the authority of the federal Food, Drug, and Cosmetic Act (FDCA) when necessary to ensure that the benefits of a drug outweigh its risks.[12,13] REMS programs are intended for drugs that are known or suspected to cause serious adverse effects that cannot be mitigated simply by the label instructions. The FDCA includes six factors that the FDA should consider when deciding whether to require a REMS, including the benefits and risks of the drug, the duration of treatment, the number of expected users, and the background risk of adverse events in the population (see Box). Each REMS is customized to address the specific risks of a given drug. The REMS for clozapine, which is indicated for the treatment of schizophrenia, is illustrative: because the drug can cause severe neutropenia, its REMS requires, among other measures, that pharmacists verify that each patient has had a recent neutrophil count before dispensing the drug.[14] At this time, 74[12] of the approximately 1750 prescription drug and therapeutic biologic active ingredients that have been approved by FDA and marketed in the United States[15] have REMS programs.

The core of the Mifeprex REMS is three provisions designated as "elements to assure safe use."[16] First, the drug may be dispensed to patients only in clinics, medical offices, and hospitals by or under the supervision of a certified prescriber; it may not be sold in retail pharmacies. Second, to prescribe the drug, a health care provider must become "certified" by completing and sending a form to the drug distributor attesting that he or she can assess pregnancy duration, diagnose ectopic pregnancy, and provide surgical intervention if needed, either personally or by referral. Third, each woman taking Mifeprex must be given an FDA-approved medication guide and sign an FDA-approved patient agreement that summarizes the use instructions specified in the label and the potential risks of the drug. Whereas drug labels are generally not binding for individual clinicians[17] — misoprostol, for example, is approved for the prevention of gastric ulcers but is legally and widely used off-label for gynecologic purposes,

Excerpts from the Food, Drug, and Cosmetic Act Relevant to Risk Evaluation and Mitigation Strategies.*

a. Submission of proposed strategy

1. Initial approval

If the Secretary . . . determines that a risk evaluation and mitigation strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug, and informs the person who submits such application of such determination, then such person shall submit to the Secretary as part of such application a proposed risk evaluation and mitigation strategy. In making such a determination, the Secretary shall consider the following factors:

A. The estimated size of the population likely to use the drug involved.
B. The seriousness of the disease or condition that is to be treated with the drug.
C. The expected benefit of the drug with respect to such disease or condition.
D. The expected or actual duration of treatment with the drug.
E. The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug.
F. Whether the drug is a new molecular entity.
G. Assuring access and minimizing burden.

. . .

f. Providing safe access for patients to drugs with known serious risks that would otherwise be unavailable

1. Allowing safe access to drugs with known serious risks

The Secretary . . . may require that the risk evaluation and mitigation strategy for a drug include such elements as are necessary to assure safe use of the drug, because of its inherent toxicity or potential harmfulness, if the Secretary determines that —

A. the drug, which has been shown to be effective, but is associated with a serious adverse drug experience, can be approved only if, or would be withdrawn unless, such elements are required as part of such strategy to mitigate a specific serious risk listed in the labeling of the drug; and
B. for a drug initially approved without elements to assure safe use, other elements . . . are not sufficient to mitigate such serious risk.

2. Assuring access and minimizing burden

Such elements to assure safe use . . . shall:

A. be commensurate with the specific serious risk listed in the labeling of the drug;
B. within 30 days of the date on which any element . . . is imposed, be posted publicly by the Secretary [of Health] with an explanation of how such elements will mitigate the observed safety risk;
C. considering such risk, not be unduly burdensome on patient access to the drug, considering in particular —

i. patients with serious or life-threatening diseases or conditions; and
ii. patients who have difficulty accessing health care (such as patients in rural or medically underserved areas); and

D. to the extent practicable, so as to minimize the burden on the health care delivery system —

i. conform with elements to assure safe use for other drugs with similar, serious risks; and
ii. be designed to be compatible with established distribution, procurement, and dispensing systems for drugs.

* Information is quoted from the Food Drug and Cosmetic Act, Section 505-1, codified at 21 U.S.C. §355-1.

such as labor induction[18] — compliance with a REMS is mandatory and consequently has a nationwide effect.

When Mifeprex was first approved 16 years ago, documented experience with its use outside a research context was minimal, and the restrictions to minimize potential harm were perhaps understandable. Since then, however, its effectiveness and safety have been definitively established. To date, 19 deaths have been reported to the FDA among the more than 3 million women in the United States who have used Mifeprex (Long A, Danco Laboratories: personal communication); the estimated Mifeprex-associated mortality rate is thus 0.00063%. In contrast, the background risk of pregnancy-related death among pregnant women in the United States who do not have abortions and instead proceed to live birth is approximately 0.009%, which is 14 times higher.[19] Studies that together included more than 423,000 women around the world who had a medical abortion have reported that the rates of nonfatal serious adverse events after mifepristone use, such as hospital admission, blood transfusion, or serious infection, range from 0.01 to 0.7%, and these events are almost always treatable without permanent sequelae. Side effects such as bleeding, cramping, fever, and chills are typically minor and transient.[2] This reas-

suring safety record and the fact that each woman using Mifeprex receives only a single pill, which virtually eliminates the potential for substantial misuse, suggests that Mifeprex no longer fits the expected profile of a drug that requires a REMS.

Indeed, in our view, the Mifeprex REMS is inconsistent with the express requirements of the FDCA. The law states that a REMS may include the elements to assure safe use only if the "inherent toxicity or potential harmfulness" of the drug is such that no other means are available to mitigate a "specific serious risk" listed on the label. If included, the elements must be "commensurate" with this risk and must include an explanation of how the elements will mitigate this risk. In addition, the elements must not unduly burden either patient access to the drug — especially among patients with serious medical conditions and patients in medically underserved areas — or the health care system (see Box).

The Mifeprex elements do not meet these specifications. Mifepristone is not inherently toxic or harmful to the woman using it. The notion that the elements are essential to ensure that its benefits outweigh its risks has no basis in evidence; on the contrary, other countries that have not instituted regulations similar to the REMS have not encountered substantial safety problems. One or both of the two serious risks described on the Mifeprex label — atypical infection and prolonged heavy vaginal bleeding — also may occur after many other common obstetrical and gynecologic procedures, including vaginal delivery, medical and surgical management of miscarriage, and insertion of intrauterine devices. All these procedures are routinely performed without federally mandated provider certification, signed patient agreements, or venue limitations, and yet they are generally considered to be acceptably safe. In this context, a rationale for singling out Mifeprex as needing such measures to ensure safety is lacking, and the Mifeprex elements can hardly be justified as "commensurate" with the risks.

Similarly in conflict with the law, the Mifeprex REMS provides no explanation as to how the elements to assure safe use — in particular, the restriction on dispensing sites — could possibly have any effect on the risks of infection or bleeding. The new Mifeprex label permits a woman to take the drug after leaving the dispensing facility, and the pharmacologic effects do not begin for hours after ingestion. If a serious complication were to occur, the location where the woman had obtained the tablets would be entirely irrelevant to her clinical outcome. In fact, recent research has shown that allowing each woman who has a medical abortion to take the mifepristone in the place of her choosing is safe and is preferred by many women.[20-22]

The Mifeprex elements to assure safe use plainly impede women's access to the drug.[11] For example, the prohibition on sale at retail pharmacies and the provider certification requirement mean that a qualified clinician who has not completed the certification process and arranged to stock the drug in his or her office cannot provide timely medical abortion care to a woman who presents unexpectedly. Consequently, treatment of such a patient would be delayed, increasing cost and inconvenience and, if the delay is substantial, possibly even medical risk. The elements also complicate the provision of medical abortion through telemedicine,[23] which has proved valuable in improving access in rural areas.[24] More generally, the expense and hassle of maintaining drug inventories as well as reluctance to be included on a list of certified abortion providers — understandable, given the long history of harassment and violence[25] — may discourage some otherwise willing clinicians from offering medical abortion at all. Considering the severe shortage of abortion providers in many parts of the United States and the long distances that many women must travel to obtain abortion services,[26] we contend that any barrier to access that has no demonstrated benefit is excessive.

Finally, the Mifeprex elements to assure safe use violate the statutory requirement to minimize the burden on the health care delivery system. In particular, the elements are not compatible with established drug-distribution systems; instead, the Mifeprex distributor has had to set up an onerous and costly infrastructure, used only for this one drug, to enable clinicians to submit certification forms and order supplies. This process certainly does not conform to the distribution system for other drugs with similar serious risks. Anticoagulants can cause major bleeding at numerous anatomic sites, including the vagina,[27-29] and phosphodiesterase type 5 inhibitors for the treatment of erectile dysfunction are estimated to be associated with death in up to 0.004% of users,[30] and yet these drugs do not have REMS programs. Antibiotics, antihypertensive agents, and insulin also

can induce immediate serious or fatal reactions shortly after use, but most of these also are not restricted by REMS. In addition, the Mifeprex elements may impede the development of potentially cheaper, generic mifepristone products for abortion by requiring any generic developer either to negotiate a shared distribution system with the distributor of Mifeprex or to set up a separate, parallel system.

Given the data and experience that have been accumulated since the initial FDA approval, the Mifeprex REMS no longer makes clinical sense. The provider certification criteria can technically be met by any health care professional with the ability to read an ultrasound report and familiarity with emergency services, and thus the certification process itself — which is a self-certification without any validation component — is, in essence, an empty formality. Serious complications of mifepristone treatment are uncommon and are very familiar to clinicians who provide care to women of reproductive age; these risks should be manageable through routine labeling and standard clinical counseling. And abortion providers certainly can evaluate patients and prescribe mifepristone without having tablets physically present in their offices.

Medical abortion is a key component of women's health care because it enables effective, safe, private pregnancy termination when surgical abortion is unavailable, clinically contraindicated, or personally undesirable. Mifepristone is currently the only drug approved for medical abortion in the United States, and more than a third of women who present for abortion within the first 8 weeks of gestation now choose to use it. Some evidence suggests that access to this drug can reduce the demand for induced abortion in the second trimester.[31] The Mifeprex REMS impedes the provision of Mifeprex without offering any demonstrated or even reasonably likely advantage. We recommend that the REMS be expeditiously withdrawn.

Presented in part at the 2016 National Abortion Federation Annual Meeting, Austin, Texas, April 18–21, 2016.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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Exhibit 5

Gov. Rhoden Calls Attorney General to Investigate Abortion Advertising Campaign

Today, Governor Larry Rhoden urged Attorney General Marty Jackley to investigate a new abortion ad campaign, which appears to conflict with South Dakota's proud pro-life stance.

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FOR IMMEDIATE RELEASE
December 9, 2025
Contact: Josie Harms

Gov. Rhoden Calls Attorney General to Investigate Abortion Advertising Campaign

PIERRE, S.D. – Today, Governor Larry Rhoden urged Attorney General Marty Jackley to investigate a new abortion ad campaign, which appears to conflict with South Dakota's proud pro-life stance. He made this request in a letter, which you can find here. The Attorney General quickly agreed to pursue the investigation.

"South Dakota has the most pro-life laws in the nation – I am proud of that fact," wrote **Governor Larry Rhoden.** "This advertising campaign threatens the lives of children yet to be born in our state, and it also threatens the health of South Dakota mothers, as chemical abortions are four times as likely to cause a mother to end up in the emergency room."

According to KELOLAND News, Mayday Health is advertising abortion pills at 30 gas stations in 20 South Dakota cities. This campaign is potentially in violation of South Dakota's pro-life laws, including SDCL 22-17-5.1 and 36-4-8, or could even be a deceptive trade practice.

"All ad campaigns, no matter what the issue, need to follow state laws and fair trade practices," said **Attorney General Marty Jackley**. "We will review these ads and determine if any laws have been broken. If laws have been broken, we will take appropriate action."

"I thank you in advance for investigating this matter and defending both South Dakota moms and their babies. My team will continue working with yours to assess whether this issue needs to be addressed with further legislation," continued **Governor Rhoden**.

The Noem-Rhoden Administration banned chemical abortions via telemedicine with HB 1318 in 2022. Abortion became illegal in South Dakota, except to save the life of a pregnant mother, following the United States Supreme Court's *Dobbs* decision in 2022, and South Dakota voters ratified that law with the defeat of Amendment G in 2024.

###

Other Posts by this Agency

Governor Rhoden to Deliver State of the State Address

On Tuesday, Governor Larry Rhoden will deliver his 2026 State of the State Address to a joint session of the South Dakota Legislature.

Learn More

Gov. Rhoden Introduces Airport Expansion Bill

Today, Governor Larry Rhoden announced he pre-filed SB 76, which supports the expansion of the Sioux Falls and Rapid City airports by providing 0% interest loans of up to $15 million for each airport.

Learn More

Exhibit 6

STATE OF SOUTH DAKOTA

OFFICE OF THE GOVERNOR

LARRY RHODEN | GOVERNOR

December 9, 2025

The Honorable Marty Jackley
South Dakota Attorney General
1302 E. Hwy 14
Pierre, SD 57501

Dear General Jackley,

It has come to my attention that an out-of-state organization, Mayday Health, appears to be advertising an illegal service in the state of South Dakota. I urge you to investigate accordingly. According to *KELOLAND News*, this organization is advertising abortion pills at 30 gas stations in 20 South Dakota cities, potentially in violation of South Dakota's pro-life laws, including SDCL 22-17-5.1 and 36-4-8.

South Dakota has the most pro-life laws in the nation – I am proud of that fact. Our voters resoundingly supported those laws with the defeat of Amendment G in the last election. This advertising campaign threatens the lives of children yet to be born in our state, and it also threatens the health of South Dakota mothers, as chemical abortions are four times as likely to cause a mother to end up in the emergency room.

Mayday Health's website advertises several abortion pill providers that "Ship to all 50 states," which would presumably include South Dakota. Their own comments to *KELOLAND News* also make clear that they are facilitating the mailing of pills into our state, which would be illegal under the telemedicine abortion ban signed during the Noem-Rhoden Administration.

I thank you in advance for investigating this matter and defending both South Dakota moms and their babies. My team will continue working with yours to assess whether this issue needs to be addressed with further legislation.

Sincerely,

Larry Rhoden
Governor

Exhibit 7

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

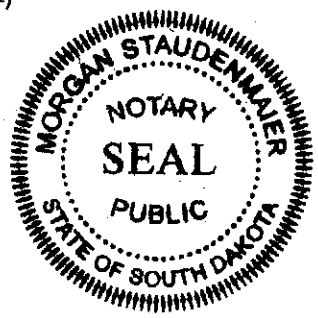
Dated this 22nd day of December, 2025.

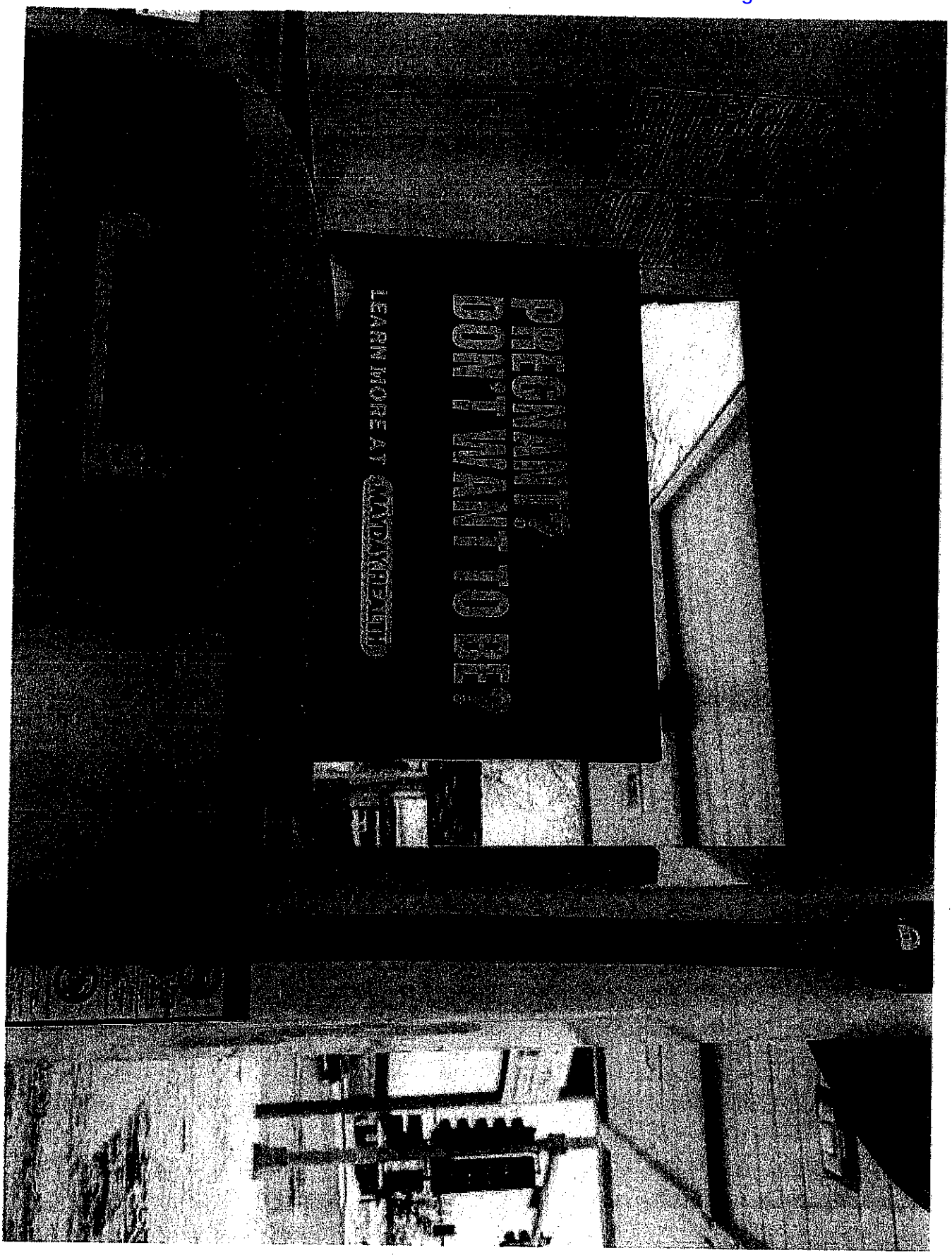
Kayla Klemann, Investigator
South Dakota Office of Attorney General
Consumer Protection Division

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

(Seal)

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





LIVE KELOLAND THIS MORNING KELOLAND News This Morning

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.

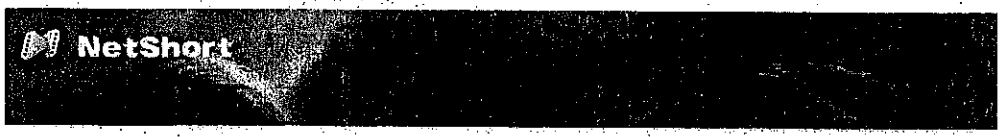


EXHIBIT tabbies 2

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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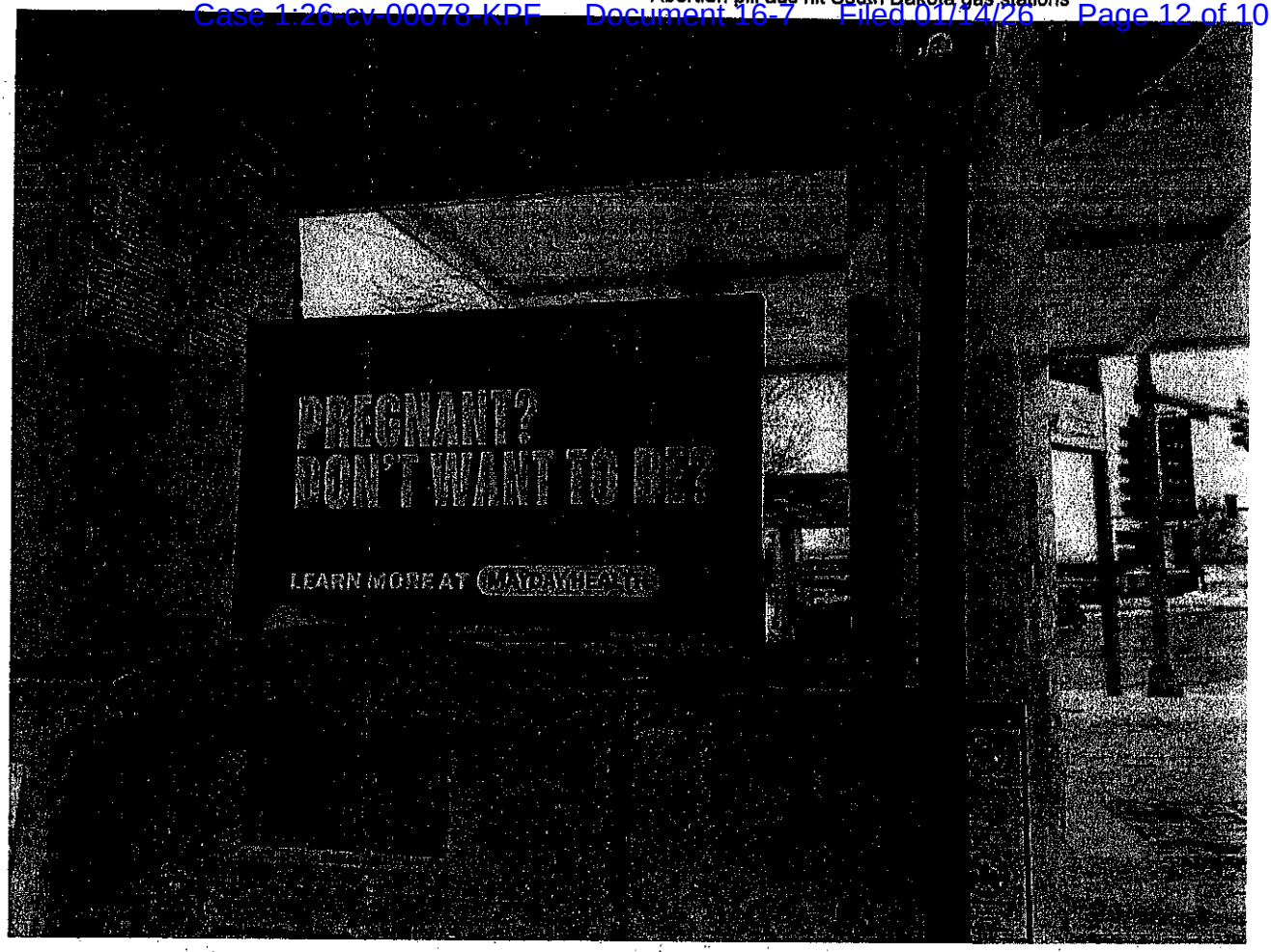
Cancel



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.

SFPD: 900 snowbird tickets issued after first snow alert ›

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 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.

"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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State medical board reprimands 2 M.D.s

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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.

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:

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

$70M revenue, H1 2025

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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.[1] 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
tabbies
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/wxhfswdf.

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. You may also use this email address to communicate any questions or concerns about this letter.

Sincerely,

Marty J. Jackley,
South Dakota Attorney General

Davis Wright Tremaine LLP

Adam S. Sieff
adamsieff@dwt.com
213.633.8618

Laura R. Handman
laurahandman@dwt.com
202.973.4224

Chelsea T. Kelly
chelseakelly@dwt.com
202.973.4250

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

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.[1] 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

[1] 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.

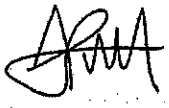
EXHIBIT 4

limited to mifepristone and misoprostol, which are approved by the U.S. Food and Drug Administration (FDA) for safe and effective use.[2] 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

[2] 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); Mifeprex REMS Study Group, *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, 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 9Th Ave SE; Ste. A
Watertown, SD 57201

FORMAL COMPLAINT AGAINST:

1. **MAYDAY HEALTH – Liv Raisner**

2. **MOMENTARA**
   16355 36th 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 tabbies

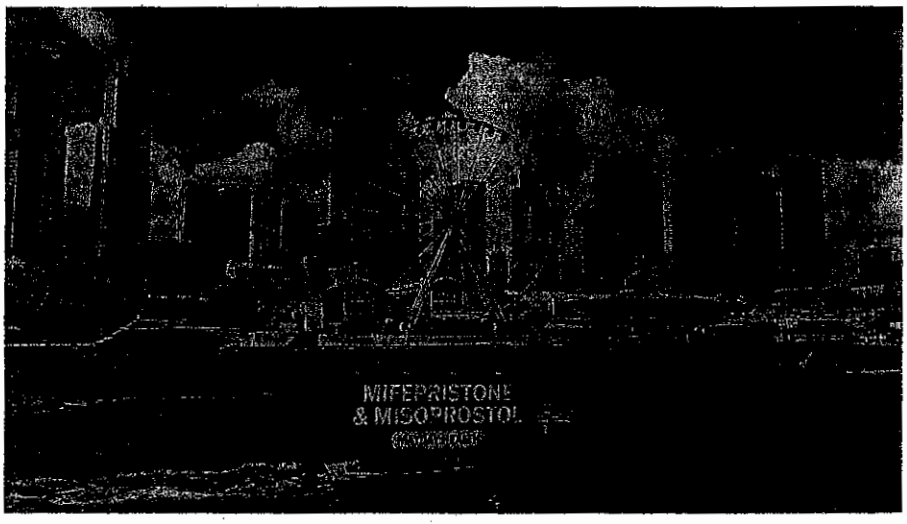
https://www.mayday.health/donate-today/

Does your employer use Benevity for corporate matching? If so, search for us there to ensure that your emplyer is supporting our work as well!

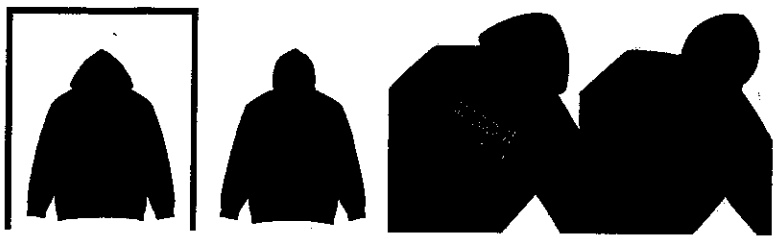
Mayday Health is a nonprofit that exists to provide information about how people can get mail-order abortion pills, birth control, emergency contraception, and gender affirming care in all 50 states, regardless of harmful state restrictions.

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).



"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

EXHIBIT 7

This site collects zero data that could identify a visitor.

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 tabbies 8

MAYDAY.HEALTH

How long has it been since your last period?

Less than 12 weeks

More than 12 weeks

I don't know

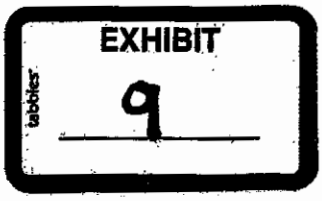
‹ ›

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.



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

Mifeprex (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 Mifeprex in 2000 and approved a generic version of Mifeprex, Mifepristone Tablets, 200 mg, in 2019.

Risk Evaluation and Mitigation Strategy (REMS) Information

Mifeprex 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.

Mifeprex was first approved in 2000 with restrictions to assure its safe use. Mifeprex 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 Mifeprex, 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 Mifeprex 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 outsi
drug supply chain; therefore, the FDA cannot ensure the safety, effectiveness, or quality of those medications.

To learn more about buying drugs safely, please see BeSafeRx: Your Source for Online Pharmacy Information (/drugs/buying-using-medicine-safely/besaferx-your-source-online-pharmacy-information)

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-mifeprex)
- 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 Mifeprex) (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

Mifeprex (mifepristone)

- Mifeprex Prescribing Information (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf)
- Mifeprex Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf#page=16)
- Mifeprex Patient Agreement Form (https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_Patient_Agreement_Form.pdf)
- Mifeprex Prescriber Agreement Form (https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_Prescriber_Agreement_Form_for_Danco_Laboratories_LLC.pdf
- Mifeprex Pharmacy Agreement Form (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)
- Mifepristone Tablets, 200 mg Prescriber Agreement Form (https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_Prescriber_Agreement_Form_for_GenBioPro_Inc..pdf)
- 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)

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U.S. FOOD & DRUG ADMINISTRATION

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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.

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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

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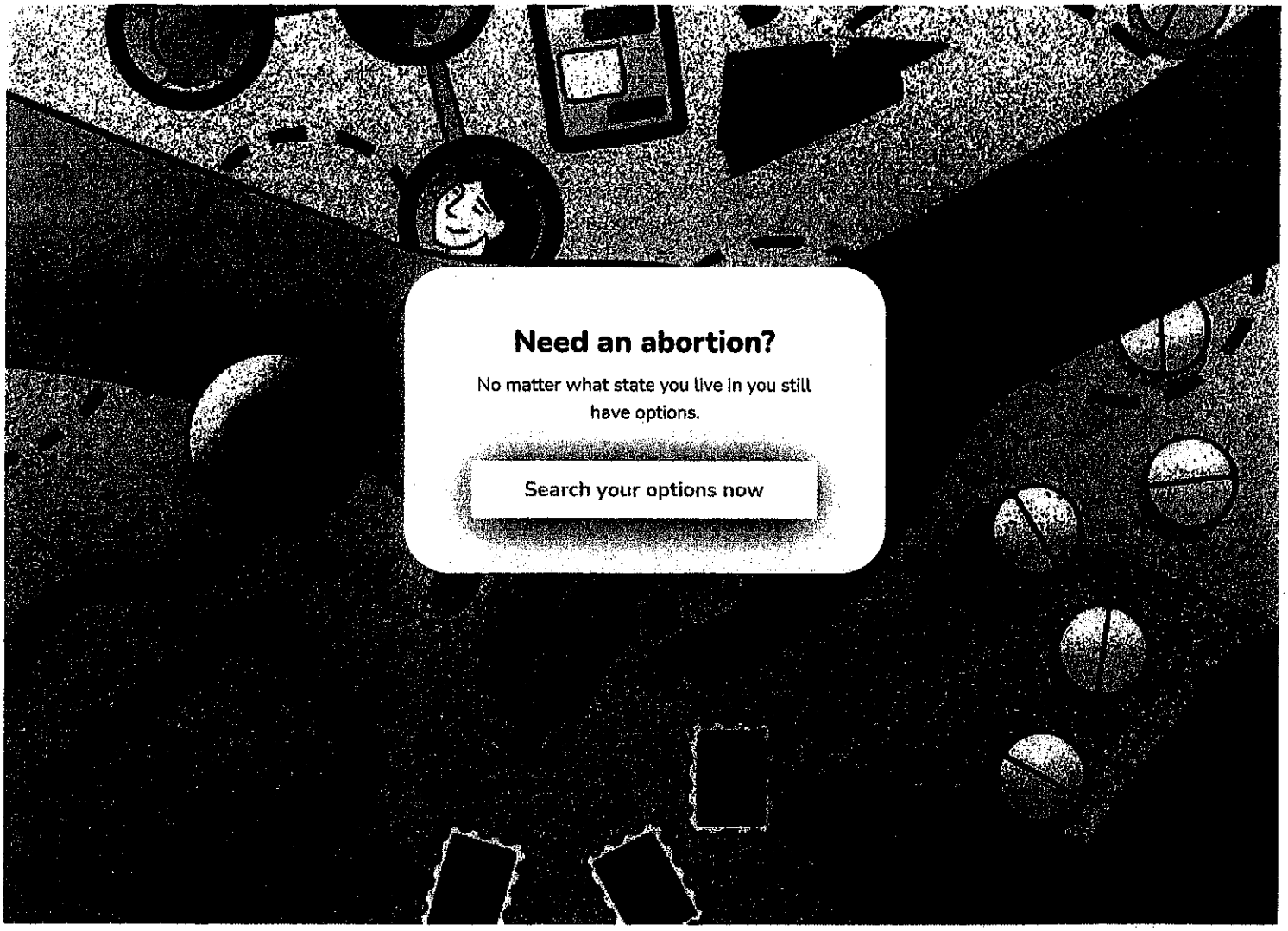
Using FDA's search feature

Understandability of the content

Overall Experience

Submit



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.

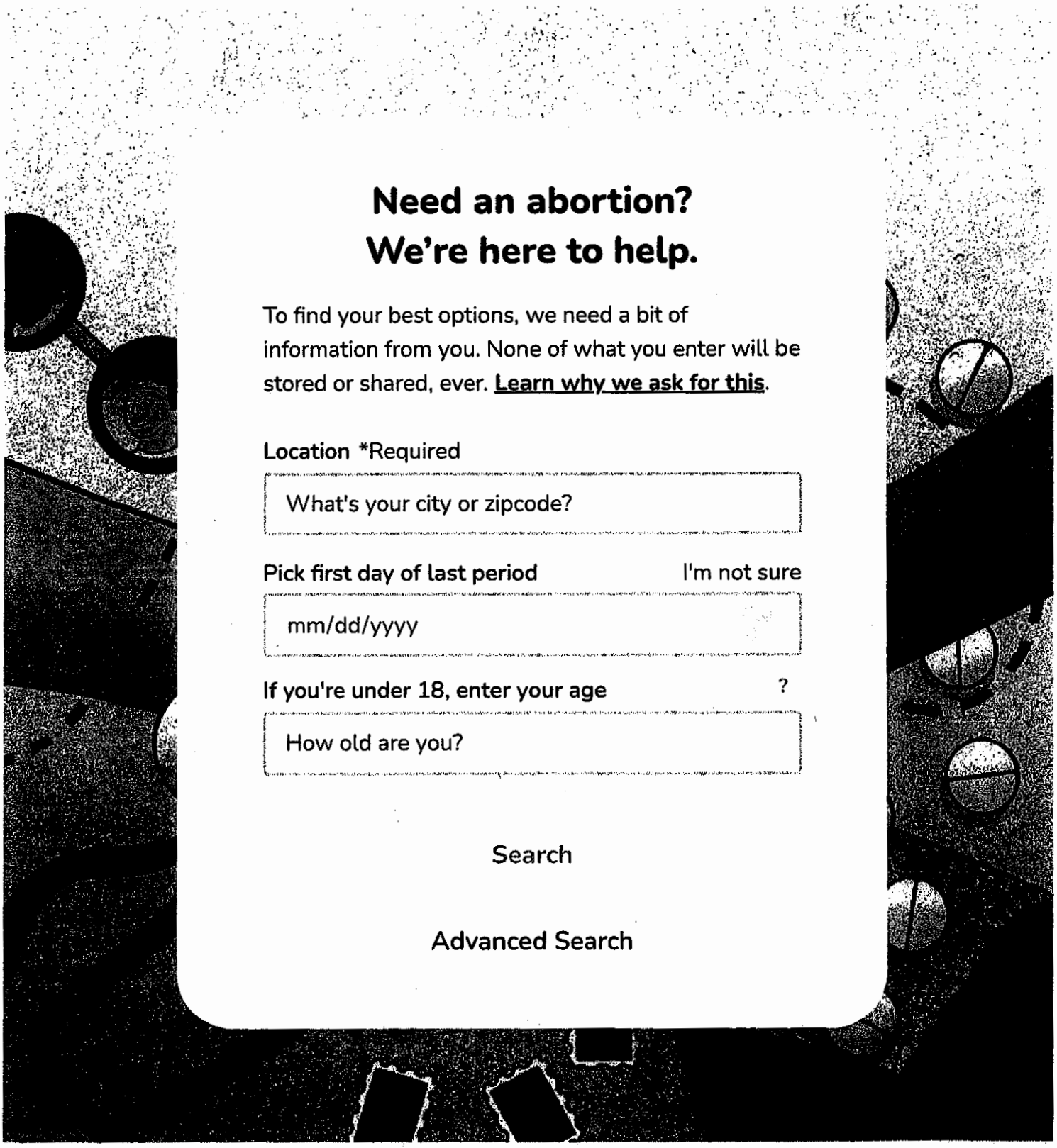
If you are using a shared device and trying to keep your information private, we recommend you remove this site from your browser history and in the future use "incognito" or "private" browsing to look up information.

Get more info on digital privacy

EXHIBIT
tabbies

i need an a.com

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

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?

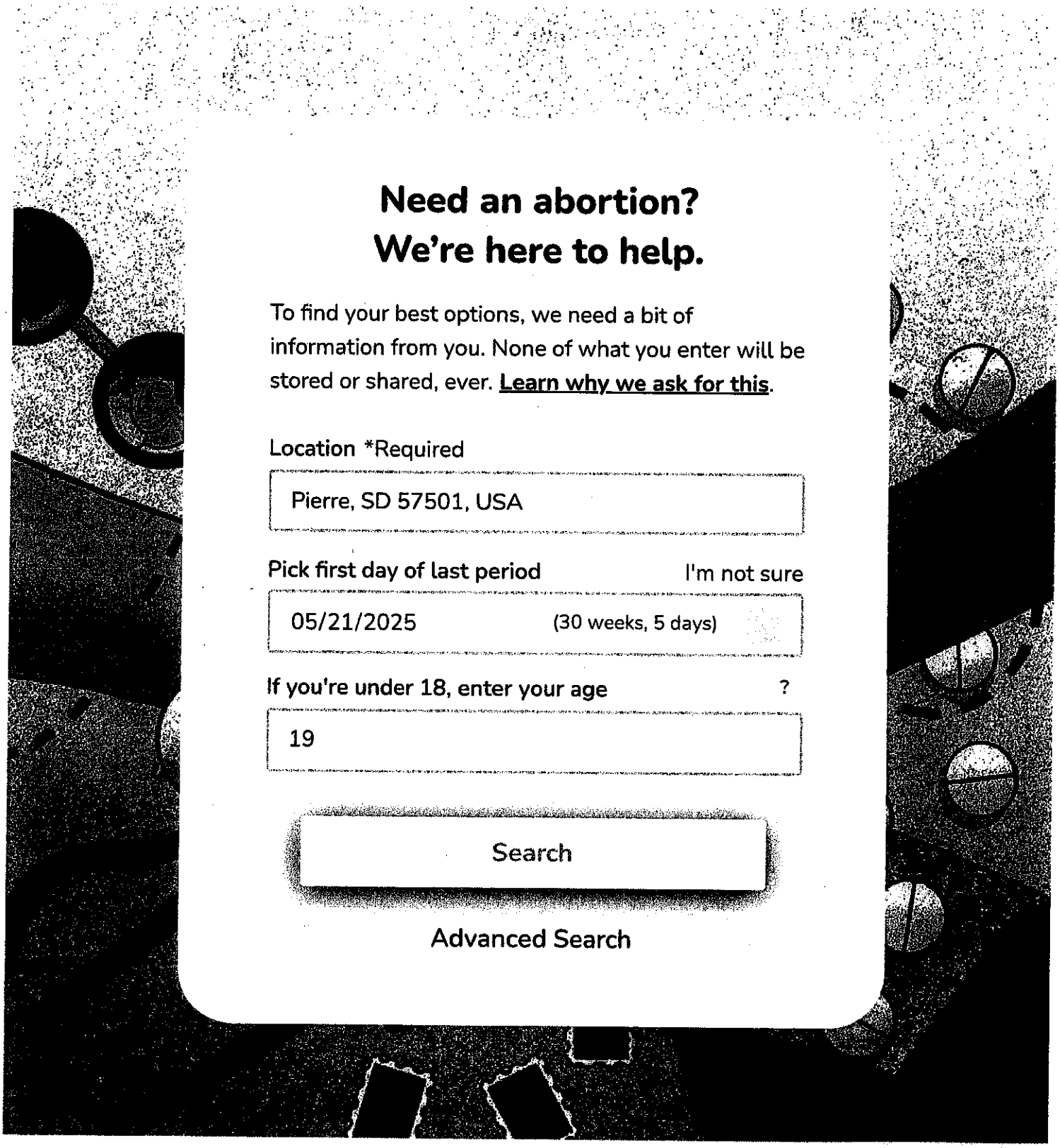
Search

Advanced Search

EXHIBIT 12

i need an a.com

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 I'm not sure

05/21/2025 (30 weeks, 5 days)

If you're under 18, enter your age ?

19

Search

Advanced Search

!

EXHIBIT
tabbies
13

Abortion is banned in South Dakota, but you've still got options.

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

Go to website (303) 418-8660

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.

Pills By Mail

Go to website

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

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 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

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

Video length 50:00

Watch here

video written +9

Trans people build families and have abortions, too.

Video length 4:40

Watch @ WeTestify

video certain +6

Shout Your Abortion Stories Volume 3

Video length 1:41

Watch @ Shout Your Abortion

See more stories

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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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Telehealth Providers	Support Organizations
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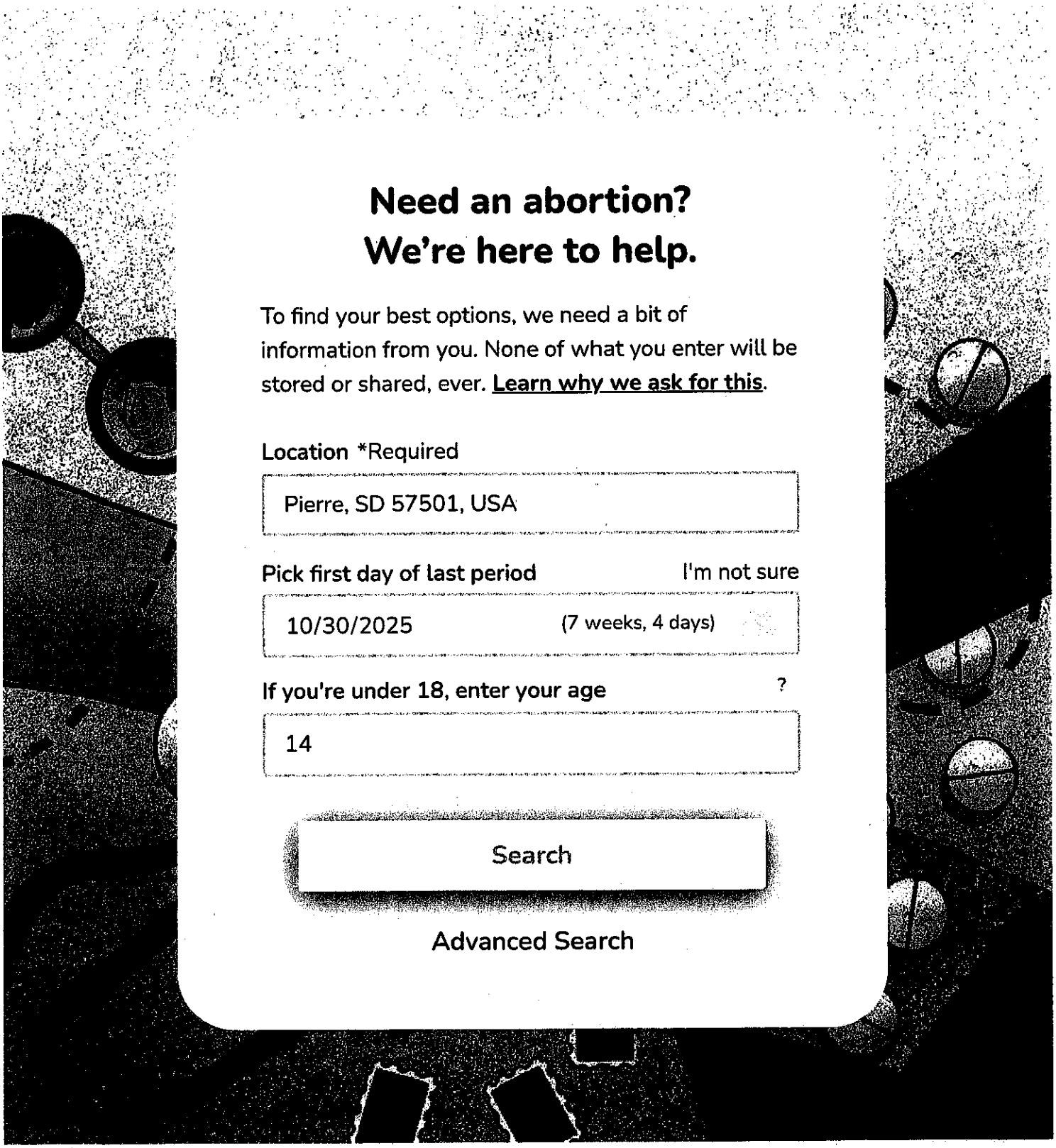
Find all your abortion options

Providers, laws, costs, and support updated daily

Search now

i need an a.com

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 I'm not sure

10/30/2025 (7 weeks, 4 days)

If you're under 18, enter your age ?

14

Search

Advanced Search

!

EXHIBIT 14

Abortion is banned in South Dakota, but you've still got options.

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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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

Trans people build families and have abortions, too.

Video length 4:40

Watch @ WeTestify

video certain +6

Shout Your Abortion Stories Volume 3

Video length 1:41

Watch @ Shout Your Abortion

See more stories

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Learn more about us | Get involved | Donate

About

Get involved

Blog

Donate

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**.

destination state in the above table, you can call the Repro Legal Helpline at 844-868-2812 for help.

There are also two other options to consider on where to have an abortion:

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 judges' permission.

   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 D.C.

   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 doctor. Talk to the clinic for more details.

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.

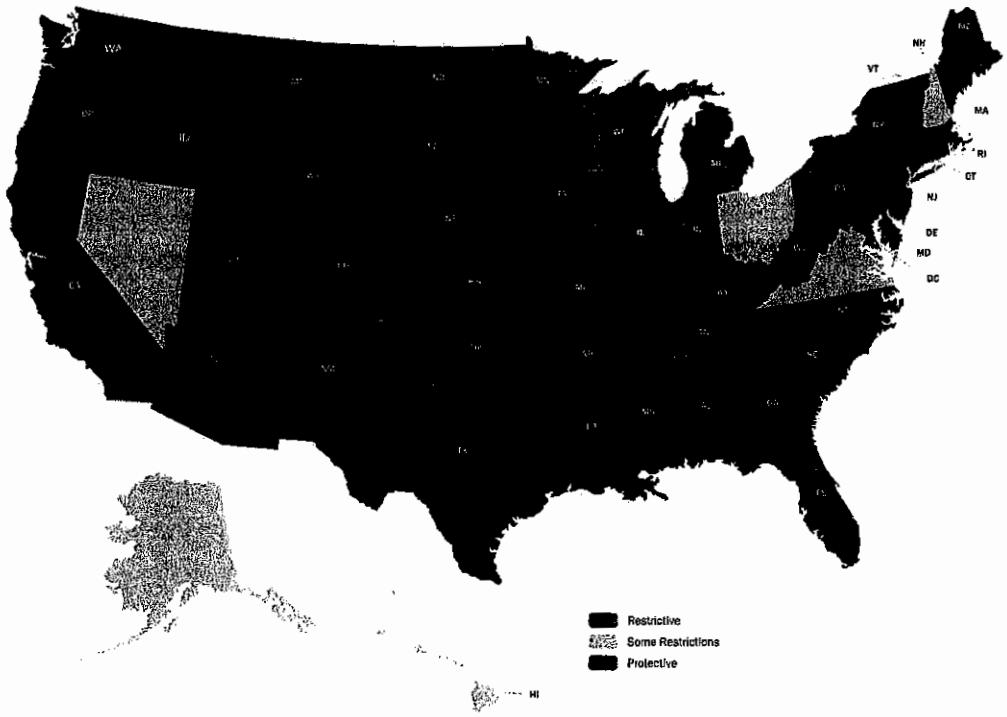
Yes

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 tabbies



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

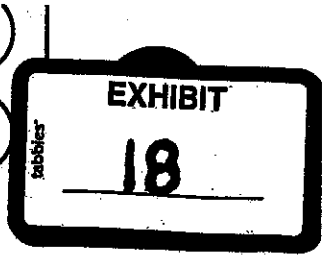
DELIVERY WITHIN 5 DAYS

Abuzz

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.

SHIPS TO SELECT STATES

COST: SLIDING SCALE



DELIVERY WITHIN 5 DAYS

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

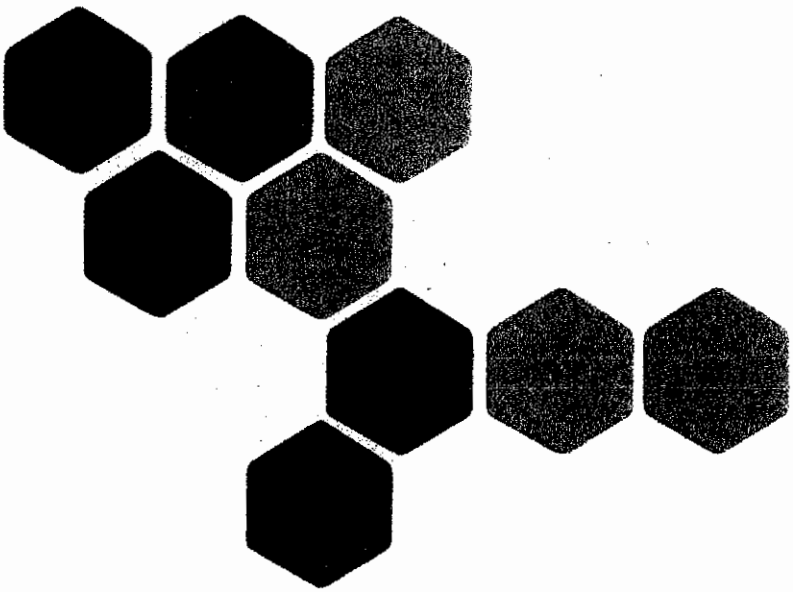
FAQs

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.

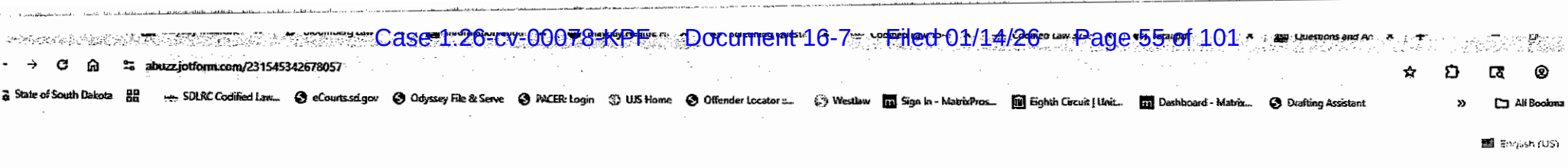
You must be less than 13 weeks pregnant to access abortion through Abuzz. Remember that pregnancy is measured from the first day of your last menstrual period, which is around two weeks before conception.

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.

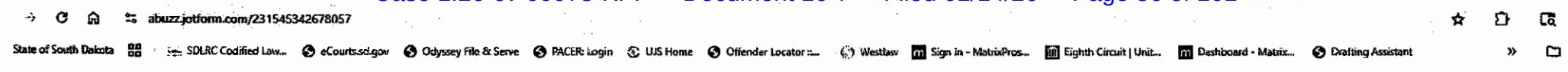
EXHIBIT
tabbies
19



Please select your state.*

South Dakota

← PREVIOUS NEXT →

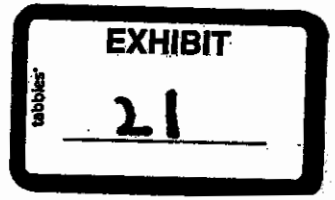


Important Information

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.**

← PREVIOUS NEXT →



How people get abortion pills online in every state

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

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 22

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

Abortion pills

Search by state

FAQ

Pills in advance

Missed period pills

Support & resources

Abortion pill instructions

Blogs

Get involved

Community action

Stickers & flyers

Plan C road trip

Social media toolkit

Plan C merch

Partner with us

For medical professionals

Work with Plan C

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About

About Plan C

Press

Research & learning

Plan C: The documentary

2024 Annual Report

Media inquiries

Contact us

Privacy & terms

This is not legal or medical advice and does not substitute for the representation of an attorney or the advice of a doctor. No attorney client relationship has been formed by reviewing this material. In this website when we use the term "Guide," we refer to a health information resource that aggregates publicly-available services, hotlines and data.

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

EXHIBIT 23

(844) 868-2812

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

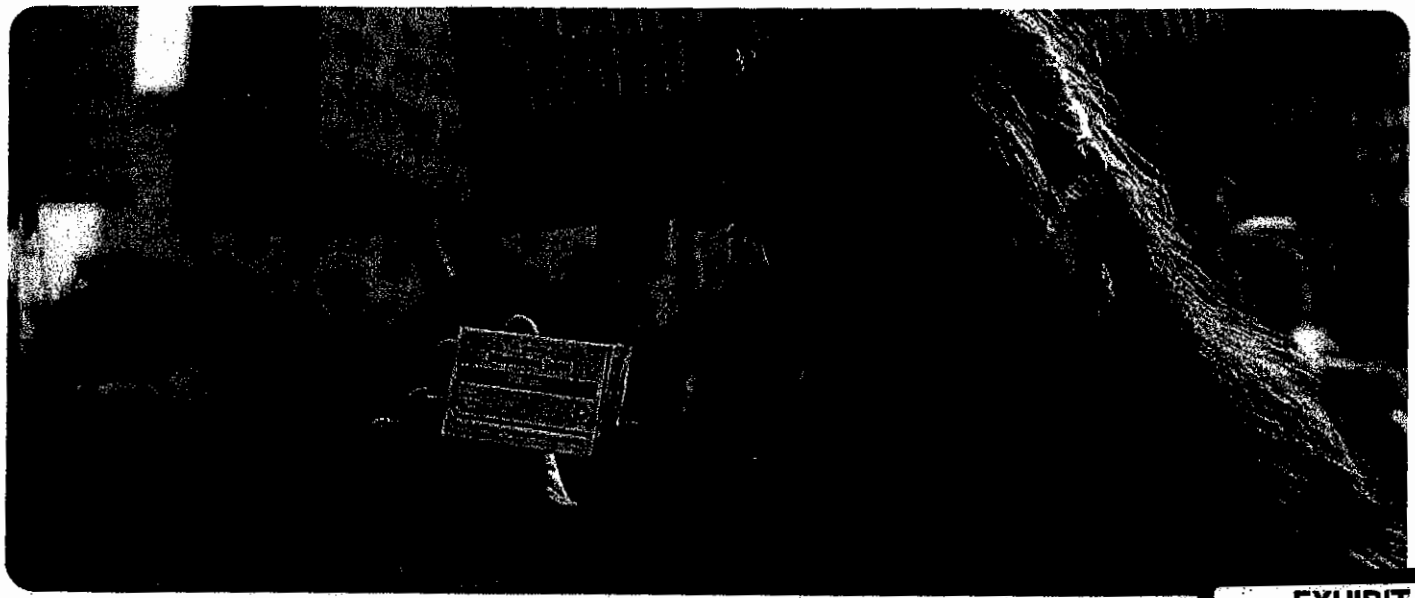

EXHIBIT
24

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

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

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)(l) of the FD&C Act (21 U.S.C. § 352(f)(l)) 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)(l) of the FD&C Act (21 U.S.C. § 353(b)(l)], 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)(l)(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)(l) 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)(l) 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 reviewin& 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)].

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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 FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov (mailto:FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov).

Sincerely,

/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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FDA U.S. FOOD & DRUG ADMINISTRATION

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
Submit

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:

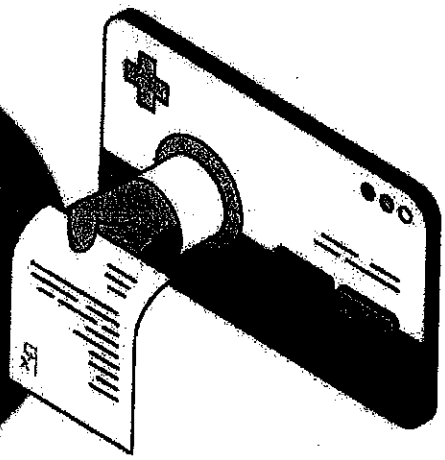
- South Dakota abortion pill online orders costs $150 USD
- Reliable abortion pill shipping to South Dakota in 1-5 days
- Tracking numbers provided when the pills are mailed
- Help desk support available in English and Spanish

How to get an abortion pill in South Dakota

Submit our online consultation form

1

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



Our doctors will review your order

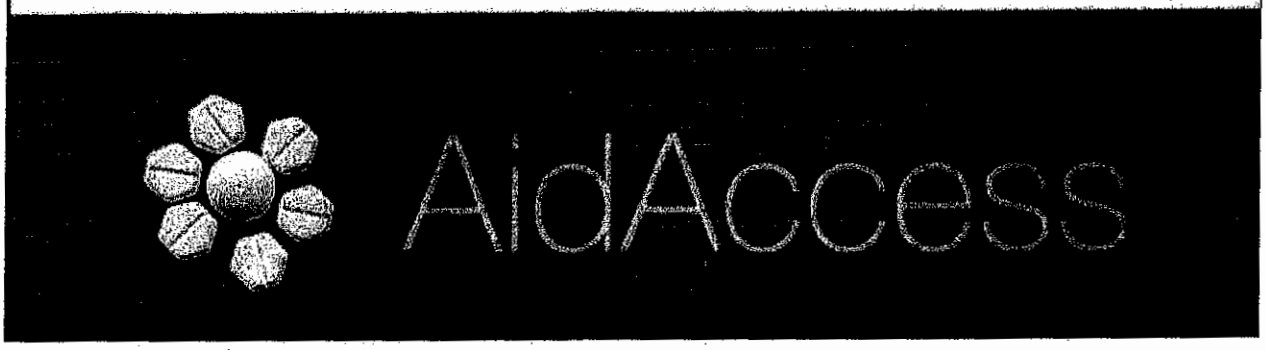
2

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

Receive pills by mail in 1-5 days

3

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



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:

1 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.

2 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.

3 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 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.

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;

7. The Convention on the Rights of Persons with Disabilities: Article 25 in 2006.

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."[2]

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."[3]

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."[4]

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."[5]

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/

[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 28

Additional Resources

Links to trusted organizations.

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

- **Abortion decision support** >
- **Abortion pill FAQs** >
- **What to expect** >
- **Financial support** >
- **Questions on logistics/delivery times/support while waiting** >
- **Online/phone medical support** >
- **In-person medical support** >
- **Emotional support** >
- **Legal support** >
- **Privacy support** >
- **Reproductive Justice** >

EXHIBIT 29

This site collects zero data that could identify a visitor.

MAYDAY.HEALTH

Frequently Asked Questions

What if I'm concerned about the cost? >

What is my legal risk? >

Are abortion pills safe? >

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

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 or FDA at 1-800-FDA-1088 or *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*

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

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.

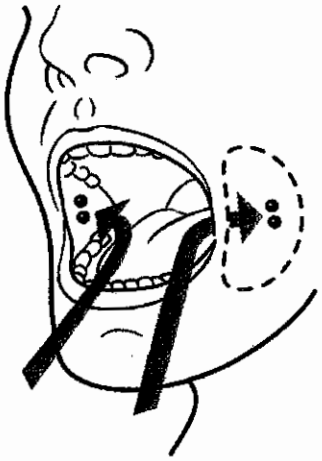
Remove any intrauterine device ("IUD") before treatment with MIFEPREX begins [*see Contraindications (4)*].

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 uterotonics, 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
Nausea	3	1,248	51-75%	70 days
Weakness	2	630	55-58%	63 days
Fever/chills	1	414	48%	63 days
Vomiting	3	1,248	37-48%	70 days
Headache	2	630	41-44%	63 days
Diarrhea	3	1,248	18-43%	70 days
Dizziness	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 (%)
Transfusion	4	17,774	0.03-0.5%	3	12,134	0-0.1%
Sepsis	1	629	0.2%	1	11,155	<0.01%*
ER visit	2	1,043	2.9-4.6%	1	95	0
Hospitalization Related to Medical Abortion	3	14,339	0.04-0.6%	3	1,286	0-0.7%
Infection without sepsis	1	216	0	1	11,155	0.2%
Hemorrhage	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 MIFEPREX in a regimen with misoprostol.

8.4 Pediatric Use

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

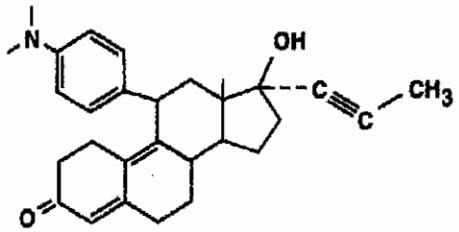
10 OVERDOSAGE

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 (ninefold 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

MIFEPREX 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 11ß-[*p*-(Dimethylamino)phenyl]-17ß-hydroxy-17-(1-propynyl)estra-4,9-dien-3-one. Its empirical formula is $C_{29}H_{35}NO_2$. 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 ± 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 ± 0.7 mg/L occurring approximately 45 minutes after ingestion. Mean $AUC_{0-\infty}$ was 25.8 ± 6.2 mg*hr/L.

Distribution

Mifepristone is 98% bound to plasma proteins, albumin, and α_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 11ß; 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 pompe* 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
Complete Medical Abortion	97.4%	96.2%
Surgical Intervention*	2.6%	3.8%
Ongoing Pregnancy**	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.

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 to14 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
New York, NY 10185
1-877-4 Early Option (1-877-432-7596)
www.earlyoptionpill.com

03/2023

MEDICATION GUIDE

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

Read this information carefully before taking Mifeprex 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 Mifeprex?

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 Mifeprex 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 Mifeprex 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 Mifeprex, you should read this Medication Guide and you and your healthcare provider should discuss the benefits and risks of your using Mifeprex.

What is Mifeprex?

Mifeprex 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. Mifeprex is not approved for ending pregnancies that are further along. Mifeprex blocks a hormone needed for your pregnancy to continue. When you use Mifeprex on Day 1, you also need to take another medicine called misoprostol 24 to 48 hours after you take Mifeprex, 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 Mifeprex 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 Mifeprex will need a surgical procedure because the pregnancy did not completely pass from the uterus or to stop bleeding.

Who should not take Mifeprex?

Some patients should not take Mifeprex. Do not take Mifeprex 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 Mifeprex.
- 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 Mifeprex.

What should I tell my healthcare provider before taking Mifeprex?

Before you take Mifeprex, tell your healthcare provider if you:

- cannot follow-up within approximately 7 to 14 days of your first visit
- are breastfeeding. Mifeprex can pass into your breast milk. The effect of the Mifeprex 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.
  Mifeprex 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.

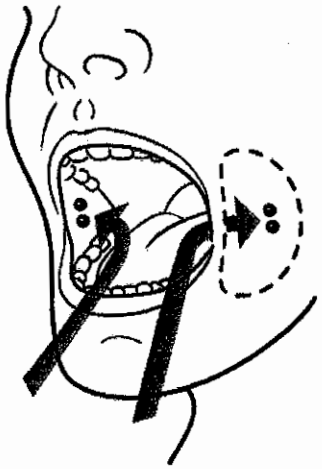


Figure A (2 tablets between your left cheek and gum and 2 tablets between your right cheek and gum).

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 to16 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 or call 1-877-4 Early Option (1-877-432-7596).

Manufactured for: *Danco Laboratories, LLC*
P.O. Box 4816
New York, NY 10185
1-877-4 Early Option (1-877-432-7596) www.earlyoptionpill.com

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

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

Drugs@FDA: FDA-Approved Drugs

Home (index.cfm) | Previous Page

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)

- Medication Guide (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)
- 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/Mifeprex_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
MIFEPREX	MIFEPRISTONE	200MG	TABLET;ORAL	Prescription	AB	Yes	Yes

Showing 1 to 1 of 1 entries

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	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s026
01/03/2023	SUPPL-25	REMS - MODIFIED - D-N-A	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025
04/11/2019	SUPPL-22	REMS-Modified	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020687s022lbl.pd
03/29/2016	SUPPL-20	Efficacy-New Dosing Regimen	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pd
06/08/2011	SUPPL-14	REMS-Proposal	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020687s014lbl.pd
06/08/2011	SUPPL-14	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020687s014lbl.pd
04/24/2009	SUPPL-15	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020687s015lbl.pd
07/19/2005	SUPPL-13	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020687s013lbl.pd
11/15/2004	SUPPL-10	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/02068 lbl.pdf)
09/28/2000	ORIG-1	Approval	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687

Showing 1 to 10 of 10 entries

Therapeutic Equivalents for NDA 020687

Exhibit 8

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.[1] 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."

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/wxhfswdf.

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. You may also use this email address to communicate any questions or concerns about this letter.

Sincerely,

Marty J. Jackley

Marty J. Jackley,
South Dakota Attorney General

Exhibit 9

Davis Wright Tremaine LLP

Adam S. Sieff
adamsieff@dwt.com
213.633.8618

Laura R. Handman
laurahandman@dwt.com
202.973.4224

Chelsea T. Kelly
chelseakelly@dwt.com
202.973.4250

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

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.[1] 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

[1] 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.

limited to mifepristone and misoprostol, which are approved by the U.S. Food and Drug Administration (FDA) for safe and effective use.[2] 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

[2] 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); Mifeprex REMS Study Group, *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, 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").

Exhibit 10

STATE OF SOUTH DAKOTA) SS: COUNTY OF HUGHES	)	IN CIRCUIT COURT SIXTH JUDICIAL CIRCUIT
STATE OF SOUTH DAKOTA, Plaintiff, vs. MAYDAY MEDICINES INC. d/b/a MAYDAY HEALTH, and ALLOVER, LLC, d/b/a MOMENTARA, Defendants.	)	32 CIV -____ PLAINTIFF'S MOTION FOR A PRELIMINARY AND PERMANENT INJUNCTION PURSUANT TO SDCL 37-24-23

COMES NOW, the above-named Plaintiff, State of South Dakota, by and through the undersigned counsel, Jacob R. Dempsey, Assistant Attorney General, and hereby moves this Court for an Order granting either a preliminary or permanent injunction, pursuant to SDCL 37-24-23, enjoining Defendants Mayday Medicines Inc., d/b/a Mayday Health (Mayday Health) and AllOver Media, LLC, d/b/a Momentara (Momentara), from engaging in the deceptive advertisement of abortion-inducing pills and abortion services.

BACKGROUND

At the request of the Governor of the State of South Dakota, the South Dakota Attorney General's Office commenced an investigation into advertisements appearing at multiple gas stations throughout the state that read, in prominent letters, "PREGNANT? DON'T WANT TO BE?" *See* Affidavit of Klemann; Exhibit 1. Below the main tagline of the ad was a prompt for consumers to "LEARN MORE AT MAYDAY.HEALTH." *Id.*

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* Affidavit of Klemann; Exhibit 2. 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* Affidavit of Klemann; Exhibit 2. During the press interview, Olivia Raisner (Raisner), Executive Director of Mayday Health, further stated, "[w]e just want people to have the right information so they can make informed decisions about their own bodies." *Id.* Raisner, who oversees the New York based pro-abortion corporation, said that she specifically targeted South Dakota "due to the state's strict abortion laws." *Id.*

An investigation into Mayday Health's advertisements uncovered a plethora of deceptive acts and practices, false pretense, false promises, or misrepresentations, and the concealment, suppression, or omission of material facts in connection with the advertisement of abortion-inducing pills and abortion services; the sale of abortion related merchandise; and in the solicitation of contributions for charitable purposes, in violation of SDCL 37-24-6. *See* Affidavit of Klemann. Upon these findings, the South Dakota Attorney General issued a Cease-and-Desist Letter to Mayday Health, demanding they remove the illegal advertisements by December 19, 2025. Exhibit 3. On December 19, 2025, Mayday Health issued a response refusing to remove the illegal advertisements. Exhibit 4.

Many of the South Dakota gas stations initially targeted for Mayday Health's advertisements voluntarily removed them upon learning what they were. *See* Affidavit of Klemann; Exhibit 2. Indeed, some business owners had refused to permit the advertisements from the outset, but their wishes were not respected, and the ads were posted at their businesses without their consent. *See* Affidavit of Klemann; Exhibit 5. At the time of this writing, illegal advertisements remain at only two locations – Schoon's Pump N' Pak, 202 Main Ave. South, Brookings, SD; and Pump N' Pak, 629 Stanford Street, Vermillion, SD. *See* Affidavit of Kollars.

The State is respectfully requesting the Court to enter either a preliminary or permanent injunction, pursuant to SDCL 37-24-23, enjoining Mayday Health and Momentara from engaging in the deceptive advertising of abortion-inducing pills and abortion services in this state. Immediate and irreparable injury, loss, or damage will result to South Dakota consumers who are misled by the deceptive advertisements. *See* Affidavit of Klemann.

The injury, loss, or damage suffered by South Dakota consumers include, but are not limited to, loss of life or injury to teenage children who were instructed by the website how to surreptitiously obtain medical or surgical abortions without their parents knowledge or consent, leaving the parents unable to monitor their teenage children for adverse reactions, side effects, hemorrhaging, or infections resulting from the abortion procedure; suggesting to women that they should keep their abortions secret and not seek follow-up medical care relating to abortion procedures for fear they might "get

in trouble," thereby reducing the chances that women will seek medical care for adverse reactions, side effects, hemorrhaging, or infections; and failing to provide South Dakota consumers with accurate information about medical and surgical abortions, as well as the risks and side effects associated with medical and surgical abortion procedures. *Id.*

The South Dakota Attorney General provided notice to Mayday Health of these violations in a Cease-and-Desist letter dated December 10, 2025. Exhibit 3. Mayday Health refused to comply, resulting in the instant action. Exhibit 4. Accordingly, no additional notice should be required.

JURISDICTION AND VENUE

This Court has subject matter jurisdiction over this matter pursuant to Article V, Section 5, of the South Dakota State Constitution. This Court has personal jurisdiction over the parties pursuant to SDCL 15-7-2. The proper venue for this action is Hughes County, SD, pursuant to SDCL 37-24-25.[1]

PARTIES

Attorney General Marty Jackley is charged with enforcing the laws of the State of South Dakota. He is specifically authorized to bring this action in the public interest pursuant to SDCL 37-24-23.

Mayday Health is a pro-abortion non-profit corporation organized under the laws of Delaware and headquartered in New York, New York. Its self-proclaimed mission is "to empower people to make their own informed

[1] South Dakota agrees not to seek more than $40,000 in attorney's fees and costs in the entirety of this action.

decisions about their own bodies" and claims it "just want[s] people to know their options." Mayday Health advertises the availability of abortion pills "in all 50 states," which is inherently misleading, in addition to suction curettage abortion services. *See infra*, at 5-8. The corporation also solicits charitable donations from consumers and sells merchandise with a misleading statement regarding the availability of abortion pills "in all 50 states." *See* Affidavit of Klemann, Exhibit 6 and 7.

Momentara is a tech-enabled marketing company that "leverages situational context, allowing messages to more successfully influence customer choices and thinking." Momentara is a limited liability company organized under the laws of Minnesota, with its principal place of business in Minneapolis Minnesota and an operational facility in Katy, Texas.

FACTS

Mayday Health, along with the facilitation of Momentara, launched a targeted assault of deceptive abortion advertisements on South Dakota beginning December 8, 2025. *See* Affidavit of Klemann; Exhibit 2. The advertisements direct South Dakota consumers to Mayday Health's website. When a consumer follows the prompt to visit the Mayday Health website, the large headline on the main page reads, "What do you need?" *See* Affidavit of Klemann, Exhibit 8. There are four clickable links to choose from on the main page: abortion, morning after pills, birth control, and gender-affirming care. *Id.* If the consumer selects "abortion," they are asked how long it has been since their last period. *See* Affidavit of Klemann, Exhibit 9. This screen starts a

decision tree that leads to the suggestion of different abortion options depending on the woman's current length of pregnancy. This is likely because abortions performed over twelve weeks since the consumer's last period necessarily implicate an in-clinic physical procedure to abort the baby. *See* 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); Exhibit 10. Indeed, the U.S. Food and Drug Administration (FDA), has only approved abortion-inducing pills for pregnant women "through ten weeks gestation." *Id.* The in-clinic physical abortion procedure performed on women more than ten weeks pregnant will hereinafter be referred to as a "suction curettage abortion" or "surgical abortion." The at-home abortion procedure accomplished through abortion-inducing pills for women that are ten weeks pregnant or less will hereinafter be referred to as a "medical abortion."

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, which ostensibly means "I need an abortion." *See* Affidavit of Klemann, Exhibit 11. Once a South Dakota consumer has disclosed on the website that they are more than twelve weeks pregnant, they are shown a screen that reads, "Need an Abortion? No matter what state you live in you still have options." *Id.* A clickable link follows, that prompts the consumer to, "Search your options

now." *Id.* 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* Affidavit of Klemann, Exhibit 12. 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* Affidavit of Klemann, Exhibit 13.

The only exception to the options offered to consumers, regardless of the information they enter on the website, is when a consumer identifies as a minor. The minor 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* Affidavit of Klemann, Exhibit 14.

The deceptive information provided to children in the guide for teens, as well as the omissions of material fact, deserve further treatment here. In the guide for teens, children are advised, "[a]bortion is safe, normal, and any reason to have one is a good reason." *See* Affidavit of Klemann, Exhibit 15. 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 judges' permission." *See* Affidavit of Klemann, Exhibit 16.

Navigating back to the fork of the decision tree on Mayday Health's main website for abortion services, if "[l]ess than 12 weeks" is selected since the consumer's last period, 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* Affidavit of Klemann, Exhibit 17. South Dakota is identified as a "red state." *Id.* Once the "red state" option is selected, the consumer is directed to a page that lists five separate abortion-inducing pill providers. *See* Affidavit of Klemann, Exhibit 18. Four out of the five abortion-inducing pill providers specifically state that their company "SHIPS TO ALL 50 STATES." *Id.* At no point is there a large disclaimer at the top of the page, as there was for surgical abortions, that medical abortions are illegal in the State of South Dakota. *Compare* Exhibit 13 *with* Exhibit 18.

It is illegal to mail abortion-inducing pills into the State of South Dakota under SDCL 22-17-5.1, which provides that "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, unless there is appropriate and reasonable medical judgment that performance of an abortion is necessary to preserve the life of the pregnant female, is guilty of a Class 6 felony."

If a consumer clicks on a link for an abortion-inducing pill provider, even more deceptive information and omissions of material fact are uncovered. For

example, 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* Affidavit of Klemann, Exhibit 19. Or, in other words, 91 days since the first day of their last period. However, the FDA only approved the use of Mifepristone for medical abortion "through ten weeks gestation (70 days or less since the first day of a patient's last menstrual period." Exhibit 10.

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* Affidavit of Klemann, Exhibit 20. 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* Affidavit of Klemann, Exhibit 21. 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. *See* Affidavit of Klemann, Exhibit 22. Once here, consumers receive more deceptive "information" on abortion issues. *Id.* For example, if a consumer navigates to the "Legal and safety considerations" portion of the website, they can click on a link stating, "Is this legal? Can someone get in trouble for using abortion pills?" *Id.* at 4. Instead of advising consumers that it is illegal to mail abortion-inducing pills into the State of South Dakota, consumers are told:

> Research shows that hundreds of thousands of people have

> received and used pills by mail over the past few years with no legal problems.

Similarly misleading, 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 Affidavit of Klemann, Exhibit 23.

The other abortion-inducing pill providers Mayday Health advertises make equally misleading claims regarding abortion-inducing pills and abortion services. 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* Affidavit of Klemann, Exhibit 24. Again, the FDA has only approved the use of Mifepristone for medical abortion "through ten weeks gestation." Exhibit 10.

Further, the FDA has already previously issued warning letters to Aid Access for selling unapproved and misbranded abortion-inducing pills (Mifepristone and Misoprostol) over the internet. Warning Letter Issued to Aidacess.org from the United State Food and Drug Administration, Exhibit 25. However, consumers are not provided this information. 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* Affidavit of

Klemann, Exhibit 26. Instead, on their "legal" FAQs, the website directs consumers to declarations made by the World Health Organization, which is has no bearing on whether abortion-inducing pills are legal in the State of South Dakota. *See* Affidavit of Klemann, Exhibit 27.

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* Affidavit of Klemann, Exhibit 28. Directly following this representation, Mayday Health provides links to several "trusted organizations" it has approved for legal and medical advice. *See* Affidavit of Klemann, Exhibit 29. This is further reiterated in Mayday Health's FAQs where it vouches 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* Affidavit of Klemann, Exhibit 30.

As for the Mayday Health website itself, it 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* Affidavit of Klemann, Exhibit 9. However, 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)." U.S. Food and Drug Administration, Labeling Information for Mifepristone, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf#page=16 (last visited December 21, 2025); Exhibit 31 at 16.

Moreover, FDA issued warnings and precautions regarding abortion-inducing drugs include:

- Cases of serious bacterial infection, including very rare cases of fatal septic shock;
- Uterine bleeding occurs in almost all patients during a medical abortion:
  - Prolonged heavy bleeding 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;
  - Excessive uterine bleeding usually requires treatment by uterotonics, vasoconstrictor drugs, surgical uterine evacuation, administration of saline infusions, and/or blood transfusions.
- The drug is "available only through a restricted program . . . because of the risks of serious complications."

Id. at 5-6. Abortion-inducing drugs also have the following adverse side effects reported by the FDA:

- Nausea
- Weakness
- Fever/Chills
- Vomiting
- Headache
- Diarrhea
- Dizziness
- 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.

Id. at 7-8. But neither the FDA's warnings and precautions, nor the adverse effects of these drugs are contained on Mayday Health's website. A website that advertises its self-proclaimed mission is "to empower people to make their own informed decisions about their own bodies" and claims it "just want[s] people to know their options" omitted several important health advisements from the FDA.

Additional adverse events caused by abortion-inducing pills that are not contained on Mayday Health's website include:

- Ongoing Pregnancy - 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 (last visited December 21, 2025);
- 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 (last visited December 21, 2025).

Based on these facts, it is the State's position that Mayday Health, facilitated by Momentara, has engaged in deceptive trade practices and acts in violation of SDCL 37-24-6.

ARGUMENT

Pursuant to SDCL 37-24-23, the attorney general may bring an action for injunction for violations of the state's Deceptive Trade Practices Act if he reasonably believes it would be in the public's interest. The attorney general has determined that enjoining deceptive advertisements regarding abortion-

inducing pills and abortion services is in the public interest.

"Granting or denying an injunction rests in the sound discretion of the trial court." *Halls v. White*, 2006 S.D. 47, ¶ 4, 715 N.W.2d 577, 579. The Court should consider the following factors in determining whether to grant injunctive relief:

> (1) Did the party to be enjoined cause the damage? (2) Would irreparable harm result without the injunction because of lack of an adequate and complete remedy at law? (3) Is the party to be enjoined acting in bad faith or is the injury-causing behavior an innocent mistake? (4) In balancing the equities, is the hardship to be suffered by the enjoined party . . . disproportionate to the . . . benefit to be gained by the injured party?

Duerre v. Hepler, 2017 S.D. 8, ¶ 35, 892 N.W.2d 209, 221–22. Here, all factors weigh in favor of the granting of an injunction. First, Mayday Health and Momentara caused the damage by affirmatively engaging in the deceptive advertisement of abortion-inducing pills and abortion services. It is completely within Mayday Health's control what and where they choose to advertise. It is also completely within Momentara's control as to what advertisers they desire to accept as clients.

Second, irreparable harm will result without the injunction due to the lack of an adequate and complete remedy at law. It is the attorney general's responsibility to protect South Dakota consumers and enforce the Deceptive Trade Practice Act. Mayday Health has misrepresented to South Dakota consumers that elective abortion is legal in this state and that abortion-inducing pills can be legally mailed into the state. The attorney general cannot simply sit idle while an advertiser continues to promote illegal services within

the state.

Further, South Dakota consumers face immediate and dire consequences that could result from the deceptive advertisement of abortion-inducing pills and abortion services. The injury, loss, or damage suffered by South Dakota consumers include, but are not limited to, loss of life or injury to teenage children who were instructed by the Mayday advertisement how to surreptitiously obtain medical or surgical abortions without their parents knowledge or consent, leaving the parents unable to monitor their teenage children for adverse reactions, side effects, hemorrhaging, or infections resulting from the abortion procedure; Mayday's advertisement suggesting to women that they should keep their abortions secret and not seek follow-up medical care relating to abortion procedures for fear they might "get in trouble," thereby reducing the chances that women will seek medical care for adverse reactions, side effects, hemorrhaging, or infections; and Maydays failure to provide South Dakota consumers with accurate information about medical and surgical abortions, as well as the risks and side effects associated with medical and surgical abortion procedures.

Third, Mayday Health has acted in bad faith. In a press statement Raisner, the Executive Director of Mayday Health, admitted that she specifically targeted South Dakota "due to the state's strict abortion laws." She knew that abortion-inducing pills and abortion services were illegal in South Dakota when she began running advertisements for them, and she was put on notice through the Cease and Desist letter issued by the attorney general. Yet

in a perplexing response to the letter, Mayday Health refused to stop running the illegal ads and claimed protection of the safe harbor provision, which provides:

> Nothing in this chapter shall apply to publishers, broadcasters, printers, or other persons in so far as an unlawful act or practice as defined in § 37-24-6 involves information that has been disseminated or reproduced on behalf of others *without knowledge that it is an unlawful act or practice.*

SDCL 37-24-11 (emphasis added). Mayday Health not only knew that their actions were illegal in the State of South Dakota, they specifically sought out advertising here for that very reason. Mayday Health does not have clean hands.

Finally, in a balancing the equities, the hardship suffered by Mayday Health is not disproportionate to the benefit gained by South Dakota consumers with the grant of the injunction. Mayday Health has alleged that this is an issue of free speech. However, it has long been the rule that "there can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 563, 100 S. Ct. 2343, 2350, 65 L. Ed. 2d 341 (1980). Indeed, the state "may ban forms of communication more likely to deceive the public than to inform it, or commercial speech related to illegal activity." *Id.* at 564. Mayday Health's advertisements check both of those unprotected boxes.

The advertisements are deceptive in that they 1) claim medical abortion is safe, yet link to several websites that provide abortion-inducing pills well

beyond the FDA recommended timeframe; 2) instruct children how to obtain abortion inducing pills without warning them that the pills are illegal in this state; 3) instruct children how to leave the state and obtain an abortion without their parent's knowledge or consent; 4) inform children that abortions are "safe, normal, and any reason to have one is a good reason" without warning of any of the risks associated with abortion procedures; 5) suggest to women that they should keep their abortions secret and not seek follow-up medical care relating to abortion procedures for fear they might "get in trouble," thereby reducing the chances that women will seek medical care for adverse reactions, side effects, hemorrhaging, or infections; 6) completely omit any of the FDA's warnings and precautions and adverse effects from their advertisement, 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."

More importantly, the abortion-inducing pills and abortion services Mayday health is advertising in South Dakota is illegal in this state. Yet their ads and the merchandise they sell indicates that consumers "can still get abortion pills in all 50 states."

On the other hand, the benefit to be gained by the State and South Dakota consumers is boundless. Halting the deceptive advertisements protects South Dakota consumers from any potential injury or death that may result from the misleading information. For example, a teenage child could be saved who may have otherwise followed Mayday Health's instructions and surreptitiously perform an at-home medical abortion without informing their

parents and then dies of septic shock because their parents were not aware of the abortion-inducing drugs their child had ingested. The same goes for the woman encouraged not to seek follow-up medical care for fear of "getting in trouble" according to the advice given by Mayday Health's "trusted websites and partners." And finally, it benefits the state to simply shut down bad actors who are knowingly advertising illegal services.

Mayday Health's advertisements are not protected speech. They do not accurately inform the public of a lawful activity, and for the most part, they promote illegal activity within the state.

CONCLUSION

The Plaintiff respectfully requests that this Court enter an Order granting its Motion for a Preliminary or Permanent Injunction. Mayday Health intentionally inserted itself into the state to cause this damage, the damage cannot be remedied without the injunction because the deceptive advertisements have created a health and safety risk to South Dakota consumers, Mayday Health acted in bad faith by inserting itself into the state and advertising abortion-inducing pills and abortion service that it knew to be illegal along with other misinformation, and in balancing the equities, the hardship suffered by Mayday Health is slight compared to the benefit gained by the state and south Dakota consumers. Mayday Health's advertisements are not protected speech, and they create a public safety and health risk to South Dakota consumers.

Dated this 22nd day of December, 2025.

/s/ Jacob R. Dempsey
Jacob R. Dempsey
Assistant Attorney General
1302 E. S.D. Highway 1889, Suite #1
Pierre, South Dakota 57501
Telephone: (605) 773-3215
Email: jacob.dempsey@state.sd.us

Exhibit 11

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

Postmarket Drug Safety Information for Patients and Providers

Index to Drug-Specific Information

Mifeprex (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 Mifeprex in 2000 and approved a generic version of Mifeprex, Mifepristone Tablets, 200 mg, in 2019.

Risk Evaluation and Mitigation Strategy (REMS) Information

Mifeprex 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.

Mifeprex was first approved in 2000 with restrictions to assure its safe use. Mifeprex 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 Mifeprex, 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 Mifeprex 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.

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

Content current as of:
01/17/2025

Regulated Product(s)
Drugs

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 legitimate U.S. drug supply chain; therefore, the FDA cannot ensure the safety, effectiveness, or quality of those medications.

To learn more about buying drugs safely, please see BeSafeRx: Your Source for Online Pharmacy Information

Related Information

- Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation
- Previous REMS
  - REMS Approved in 2011
  - REMS Approved in 2016
  - REMS Approved in 2019
  - REMS Approved in 2021
- Historical Information on Mifepristone (marketed as Mifeprex)

Labeling and Other Important Information

Mifeprex (mifepristone)

- Mifeprex Prescribing Information
- Mifeprex Medication Guide
- Mifeprex Patient Agreement Form
- Mifeprex Prescriber Agreement Form
- Mifeprex Pharmacy Agreement Form

Mifepristone Tablets, 200 mg

- Mifepristone Tablets, 200 mg Prescribing Information
- Mifepristone Tablets, 200 mg Medication Guide
- Mifepristone Tablets, 200 mg Patient Agreement Form
- Mifepristone Tablets, 200 mg Prescriber Agreement Form
- Mifepristone Tablets, 200 mg Pharmacy Agreement Form

Exhibit 12

Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation

Postmarket Drug Safety Information for Patients and Providers

Index to Drug-Specific Information

On this page:

Content current as of:
02/11/2025

General Information

1. **What is mifepristone and how does it work?**

   Mifepristone is a drug that blocks a hormone called progesterone that is needed for a pregnancy to continue. Mifepristone, when used together with another medicine called misoprostol, is used to end an intrauterine pregnancy through ten weeks gestation (70 days or less since the first day of the last menstrual period). The approved mifepristone dosing regimen is:

   - On day one: 200 mg of mifepristone taken by mouth
   - 24 to 48 hours after taking mifepristone: 800 mcg of misoprostol taken buccally (in the cheek pouch), at a location appropriate for the patient
   - About seven to fourteen days after taking mifepristone: follow-up with the health care provider

2. **When did the FDA approve mifepristone for medical termination of pregnancy?**

   The FDA first approved Mifeprex (mifepristone) in September 2000 for medical termination of pregnancy through seven weeks gestation, and this was extended to ten weeks gestation in 2016. FDA approved a generic version of Mifeprex, Mifepristone Tablets, 200 mg, in April 2019. The agency's approval of this generic reflects the FDA's determination that Mifepristone Tablets, 200 mg, is therapeutically equivalent to Mifeprex and can be safely substituted for Mifeprex. Like Mifeprex, the approved generic product is indicated for the medical termination of an intrauterine pregnancy through 70 days gestation. The labeling for the approved generic version of Mifeprex is consistent with the labeling for Mifeprex.

3. **Who should not take mifepristone, in a regimen with misoprostol, for medical termination of pregnancy?**

   An individual should not take mifepristone, in a regimen with misoprostol, for medical termination of pregnancy if it has been more than 70 days since the first day of their last menstrual period, or if they:

   - have an ectopic pregnancy (a pregnancy outside of the uterus)
   - have problems with the adrenal glands (the glands near the kidneys)
   - are currently being treated with long-term corticosteroid therapy
   - have had an allergic reaction to mifepristone, misoprostol or similar drugs
   - have bleeding problems or are taking anticoagulant (blood thinning) drug products
   - have inherited porphyria (a rare disorder that can affect the liver and other organs)
   - have an intrauterine device (IUD) in place (it must be removed before taking mifepristone)

4. **Is it safe to use mifepristone?**

   Yes. Mifepristone is safe when used as indicated and directed and consistent with the Mifepristone Risk Evaluation and Mitigation Strategy (REMS) Program. The FDA approved Mifeprex more than 20 years ago based on a thorough and comprehensive review of the scientific evidence presented and determined that it was safe and effective for its indicated use. As of 2016, it is approved for use for medical termination of pregnancy up to 70 days of gestation. The FDA's periodic reviews of the postmarketing data for Mifeprex and its approved generic have not identified any new safety concerns with the use of mifepristone for medical termination of pregnancy through 70 days gestation. As with all drugs, the FDA continues to closely monitor the postmarketing safety data on mifepristone for the medical termination of pregnancy.

5. **What are the possible side effects of using mifepristone for medical termination of pregnancy through ten weeks gestation?**

   The possible side effects are described in the labeling and in the Medication Guide for mifepristone.

6. **What serious adverse events have been reported after the use of mifepristone for medical termination of pregnancy through ten weeks gestation?**

   As with all approved drugs, when the FDA receives new information regarding adverse events, the agency reviews the new information and, as appropriate, takes necessary action. This could include, for example, providing updates to health care providers and their patients so that they have information on how to use a drug safely.

   It is common for the FDA to receive reports of serious adverse events for prescription drugs after they are approved. Many drugs are associated with serious adverse events that are known at the time of approval and considered when the FDA makes its approval decision. The FDA continuously reviews reports of adverse events to, among other things, determine whether they are known risks or whether they are signals of emerging safety concerns.

   The FDA has received reports of serious adverse events in patients who took mifepristone. As of December 31, 2024, there were 36 reports of deaths in patients associated with mifepristone since the product was approved in September 2000, including two cases of ectopic pregnancy (a pregnancy located outside the womb, such as in the fallopian tubes) resulting in death, and several fatal cases of severe systemic infection (also called sepsis). The adverse events cannot with certainty be causally attributed to mifepristone because of concurrent use of other drugs, other medical or surgical treatments, co-existing medical conditions, and information gaps about patient health status and clinical management of the patient. A summary report of adverse events that reflects data through December 31, 2024, is here. The FDA has reviewed this information and did not identify any new safety signals. The FDA intends to update this summary report as appropriate.

7. **What should health care providers watch for in patients who have taken mifepristone for medical termination of pregnancy through ten weeks gestation?**

   Health care providers should review the approved labeling for Mifeprex and the approved generic, Mifepristone Tablets, 200 mg. The signs and symptoms they should watch for are included in the labeling, available here.

8. **What is an ectopic pregnancy?**

   An ectopic pregnancy is a non-viable pregnancy that develops outside of the womb. It occurs in approximately two percent of all pregnancies. An ectopic pregnancy is usually located in one of the fallopian tubes. As the fetus grows, the tube cannot hold it, causing the tube to rupture (burst) and bleed. Unless they are discovered and treated early, almost 40 percent of ectopic pregnancies rupture suddenly, causing pain and bleeding in the abdominal cavity. The other 60 percent usually cause slow bleeding in the abdomen. Ruptured ectopic pregnancies can be fatal. The approved labeling for Mifeprex and the approved generic, Mifepristone Tablets, 200 mg, states that the use of mifepristone, in a regimen with misoprostol, for the medical termination of pregnancy through ten weeks gestation is contraindicated in patients with a confirmed or suspected ectopic pregnancy.

9. **Does the FDA endorse this drug product?**

   The FDA does not endorse any drug product. The agency evaluates all drug applications submitted by applicants to determine whether the data and information in an application support the approval of the application. The same standards are applied to the drug applications for Mifeprex and the approved generic Mifepristone Tablets, 200 mg, as are applied to all drug applications.

The Mifepristone REMS Program

10. **Why is there a REMS for this product?**

    The FDA's determination as to whether a REMS is necessary for a particular drug is a drug-specific evaluation. The agency considers whether (based on premarketing or postmarketing risk assessments) there is a particular risk or risks associated with the use of the drug that, on balance, outweigh its benefits and whether additional risk mitigation measures beyond the FDA-approved labeling are necessary to ensure that the drug's benefits outweigh its risks.

    The Mifepristone REMS Program is intended to mitigate the risk of serious complications associated with mifepristone when used for medical termination of pregnancy through ten weeks gestation by, among other things, requiring that prescribers have the necessary qualifications to assess whether patients are appropriate candidates for the drug and to provide necessary intervention in case of complications (or have made plans to provide such care through others), ensuring that mifepristone is only dispensed by certified pharmacies or by or under the supervision of certified prescribers, and requiring that patients be informed of the risks of the treatment regimen.

11. **What are the restrictions on prescribing and dispensing mifepristone for medical termination of pregnancy through ten weeks gestation?**

    When the agency reviewed and approved the original new drug application for Mifeprex (mifepristone) in 2000, it concluded that certain restrictions were necessary to ensure the safe use of the drug. These restrictions were approved as a risk evaluation and mitigation strategy (REMS) in 2011 and have been modified since then.

    These REMS requirements also apply to the approved generic version of Mifeprex. Mifeprex and the approved generic version of Mifeprex are subject to a single, shared system REMS, known as the Mifepristone REMS Program. This program sets the requirements that must be followed to ensure safe use of both Mifeprex and the approved generic version of Mifeprex.

    Under the Mifepristone REMS Program, these requirements include, 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 prescribing mifepristone.
    - The patient must be provided with a copy of the Patient Agreement Form and the 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.

    Each REMS is required to have a plan for periodic assessments by the applicants, which are reviewed by the agency to determine whether the REMS is meeting its goals or whether certain goals or elements of the REMS must be modified. The FDA may require applicants to modify a REMS if the agency determines that an element is no longer necessary to ensure that the benefits of the drug outweigh the risks or to minimize the burden on the health care delivery system.

12. **How does the Mifepristone REMS Program ensure safe use of the drug?**

    The Mifepristone REMS Program requires that in order for patients to receive mifepristone, it must be prescribed by a certified prescriber who has certain qualifications and agrees to follow certain guidelines for use. Under the Mifepristone REMS Program, mifepristone 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. The Mifepristone REMS Program is a closed system, meaning prescribers, pharmacies, and distributors are certified or authorized and verified under the REMS prior to distribution or dispensing of the drug. The Mifepristone REMS Program ensures that mifepristone is only distributed to health care providers and pharmacies that have agreed to the REMS requirements.

13. **How does the Mifepristone REMS Program as modified in January 2023 differ from the previous REMS requirements?**

    Prior to the modifications to the Mifepristone REMS Program approved in January 2023, the Mifepristone REMS Program required mifepristone to be dispensed in person in a clinic, medical office, or hospital. The requirement to dispense in person in one of these settings was referred to as the “in-person dispensing requirement.” There were periods when the in-person dispensing requirement was not being enforced. First, from July 13, 2020, until January 12, 2021, the FDA was enjoined from enforcing the in-person dispensing requirement by an injunction issued in the ACOG v. FDA litigation, which was filed in the U.S. District Court for the District of Maryland. On April 12, 2021, the agency stated its intent to exercise enforcement discretion with respect to the in-person dispensing requirement during the COVID-19 public health emergency.

    In 2021, after conducting a comprehensive review of the Mifepristone REMS Program, the FDA determined, based on the available data and information, that the REMS must be modified to reduce burden on the health care delivery system and to ensure the benefits of the product outweigh the risks. On December 16, 2021, the FDA announced that the modifications to the Mifepristone REMS Program would consist of:

    - Removing the “in-person dispensing requirement”
    - Adding a requirement that pharmacies that dispense the drug be certified

Consistent with the typical process for REMS modifications, the FDA sent REMS Modification Notification letters to the applicants for Mifeprex and the approved generic, Mifepristone Tablets, 200 mg. Following receipt of these letters, the applicants prepared a proposed REMS modification and submitted it to their respective applications. After reviewing the applicants' submissions, the FDA approved the REMS modification on January 3, 2023. The REMS document and materials are available at:

- Find information on Mifeprex (mifepristone) here
- Find information on generic mifepristone here

Where can patients get mifepristone for medical termination of pregnancy through ten weeks gestation?

Mifepristone must be prescribed by a certified prescriber who meets certain qualifications and agrees to follow certain guidelines for use. Under the Mifepristone REMS Program, mifepristone can be dispensed by or under the supervision of a certified prescriber or by a certified pharmacy on a prescription issued by a certified prescriber.

14. **What qualifications must health care providers have to become certified to prescribe mifepristone for medical termination of pregnancy through ten weeks gestation?**

    Health care providers who would like to become certified to prescribe mifepristone must review the Prescribing Information for mifepristone and must have the ability to date pregnancies accurately and the ability to diagnose ectopic pregnancies. Health care providers must also be able to provide any necessary surgical intervention or have made arrangements for others to provide for such care. Health care providers must be able to ensure that patients 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.

    Some states allow health care providers other than physicians to prescribe medications. Health care providers should check their individual state laws.

15. **Under the Mifepristone REMS Program, are patients required to see a health care provider in person before obtaining mifepristone for medical termination of pregnancy through ten weeks gestation?**

    The Mifepristone REMS Program does not require patients to see a health care provider in person before obtaining mifepristone for medical termination of pregnancy through ten weeks gestation. Mifeprex and the approved generic, Mifepristone Tablets, 200 mg, are indicated, in a regimen with misoprostol, for the medical termination of an intrauterine pregnancy through 70 days gestation and are contraindicated for certain patients, including those with an ectopic pregnancy. The FDA has determined that it is not necessary for the REMS to mandate how providers clinically assess patients for duration of pregnancy and for ectopic pregnancy. The prescription labeling for Mifeprex and the approved generic provide guidance to prescribers regarding how they can confirm the gestational age of the pregnancy and confirm that the pregnancy is located in the uterus. Aspects of a patient's medical history that may constitute contraindications to medical termination of pregnancy may be elicited without direct physical contact with the certified prescriber and can be done in different types of health care settings, thus certified prescribers are not necessarily required to be physically present with the patient when they prescribe mifepristone. As explained above (Question 15), health care providers certified under the Mifepristone REMS Program must also be able to provide any necessary surgical intervention or have made arrangements for others to provide for such care and must be able to ensure that patients have access to medical facilities for emergency care.

16. **What information did the FDA consider when it reviewed the Mifepristone REMS Program in 2021?**

    To determine whether a modification to the Mifepristone REMS Program was warranted, the FDA conducted a comprehensive review of the published literature, other relevant safety and adverse event data, and information provided by advocacy groups, individuals, and the applicants related to the modifications that were under consideration. Our review also included an examination of literature references provided by plaintiffs in the *Purcell v. Becerra* (previously *Chelius v. Becerra*) litigation.

17. **Prior to the FDA's action in January 2023, how was mifepristone dispensed to patients?**

    Prior to the FDA's action on the REMS modification applications submitted by the applicants for Mifeprex and the approved generic, Mifepristone Tablets, 200 mg, in 2022, the Mifepristone REMS Program required that mifepristone be dispensed in person in a clinic, medical office, or hospital. The requirement to dispense in person in one of these settings was referred to as the "in-person dispensing requirement."

    There were periods when the in-person dispensing requirement was not being enforced. First, from July 13, 2020, until January 12, 2021, the FDA was enjoined from enforcing the in-person dispensing requirement by an injunction issued in a

lawsuit, *ACOG v. FDA* filed in the U.S. District Court for the District of Maryland. On April 12, 2021, the agency stated its intent to exercise enforcement discretion with respect to the in-person dispensing requirement during the COVID-19 public health emergency.

During the periods when the in-person dispensing requirement was not being enforced, the applicants for Mifeprex and the approved generic, Mifepristone Tablets, 200 mg, used mail order pharmacies to receive and hold mifepristone on behalf of the certified prescribers who purchased the product. Pursuant to a prescription for Mifeprex or its approved generic, the mail order pharmacy would ship the product to a named patient.

18. **What is the FDA's role in overseeing the Mifepristone REMS Program?**

    As with all REMS, the FDA monitors the applicants' compliance with the Mifepristone REMS Program, including by reviewing periodic assessment information from the applicants and conducting on-site inspections, and takes action as appropriate.

19. **What is pharmacy certification and why is it a requirement of the Mifepristone REMS Program?**

    The Mifepristone REMS Program requires all pharmacies that dispense mifepristone to be specially certified. The pharmacy certification requirement incorporates pharmacies into the REMS, ensures that pharmacies are aware of and agree to follow applicable REMS requirements, and ensures that mifepristone is only dispensed pursuant to prescriptions that are written by certified prescribers. Any pharmacy that meets the requirements of the Mifepristone REMS Program is eligible to be certified.

20. **What steps are required for pharmacy certification?**

    The pharmacy certification requirement ensures that pharmacies are aware of and agree to follow applicable REMS requirements and ensures that mifepristone is only dispensed pursuant to prescriptions that are written by certified prescribers.

    To become certified to dispense mifepristone, pharmacies must: (1) be able to receive Prescriber Agreement Forms by email and fax; (2) be able to ship mifepristone using a shipping service that provides tracking information; (3) designate an authorized representative to carry out the certification process on behalf of the pharmacy; and (4) ensure the authorized representative oversees implementation and compliance with the Mifepristone REMS Program, which includes, among other requirements, the completion of a Pharmacy Agreement Form.

21. **Is mifepristone available at retail pharmacies?**

    The January 2023 modification to the Mifepristone REMS Program removed the restriction that did not allow mifepristone to be dispensed by retail pharmacies. While pharmacy certification is required, any pharmacy that meets the requirements of the Mifepristone REMS Program is eligible for certification.

22. **Is mifepristone available for over-the-counter use?**

    No. Mifepristone for medical termination of a pregnancy through ten weeks gestation is only available by prescription. An applicant seeking to switch mifepristone for medical termination of pregnancy through ten weeks gestation from prescription to nonprescription (also referred to as over-the-counter) status would need to submit this information to the FDA for evaluation. In order for a drug product to be approved for nonprescription use (including switching a prescription drug product to nonprescription marketing), the applicant must provide sufficient information demonstrating that the drug can be used safely and effectively by consumers without the supervision of a health care provider.

23. **What would be required to remove the REMS?**

    The FDA may release a REMS or remove certain components of a REMS if, after review of REMS assessments or other information, the agency determines that the REMS or certain components of the REMS are no longer necessary to ensure a medication's benefits outweigh its risks.

Additional Information

25. **Is it possible for an individual to become pregnant again after taking mifepristone for medical termination of pregnancy through ten weeks gestation?**

    It is possible for an individual to become pregnant again soon after a pregnancy ends. A patient should consult with their health care provider regarding any specific questions they may have.

26. **Is mifepristone approved in any other countries for medical termination of pregnancy?**

    Mifepristone for medical termination of pregnancy has been approved in France since 1988, and also is approved in the United Kingdom, Sweden, and approximately 100 other countries.

27. **Does the FDA set the price of mifepristone and is the drug reimbursed by health insurance providers?**

The FDA does not have the authority to regulate the prices of drug products in the United States. Manufacturers, distributors, and retailers establish the prices. Additionally, the FDA does not have input into or legal control over whether an insurance company does or does not cover the cost of a drug. Insurance coverage is a decision made by an insurance provider. Individuals should contact their insurance provider if they have questions about whether a particular insurance provider will cover the cost of the drug.

28. **Has FDA ever taken action regarding the sale of mifepristone online?**

    The FDA has sent warning letters to websites selling unapproved and misbranded mifepristone and misoprostol over the internet, including AidAccess and Rablon.

    There have also been several criminal cases related to the online sale of mifepristone for medical termination of pregnancy. We are aware of three cases about which the Agency can speak publicly. The first is *United States v. O'Neil*, in the U.S. District Court for the District of Maryland. Information about two more individual prosecutions are available here: March 28, 2017: Former Atlantic County, New Jersey, Man Charged with Smuggling and Dispensing Misbranded Drugs | FDA and here: New York Woman Sentenced for Selling Abortion-Inducing Pills Illegally Smuggled Into US | USAO-WDWI | Department of Justice. The FDA also issued a Final Debarment Order for Ursula Wing, debarring her for a period of five years from importing or offering for import any drug into the United States. This debarment was based on her felony conviction related to her importation and distribution of unapproved and misbranded mifepristone and misoprostol over the internet.

The January 2023 REMS Modification

29. **What action did the FDA take on the Mifepristone REMS Program in January 2023?**

    In response to the REMS Modification Notification letters sent on December 16, 2021, to the applicants for Mifeprex and the approved generic Mifepristone Tablets, 200 mg, the applicants submitted supplemental applications to modify the Mifepristone REMS Program to remove the in-person dispensing requirement and add pharmacy certification. The FDA reviewed the applicants' supplemental applications and approved a modification to the Mifepristone REMS Program. Under the Mifepristone REMS Program, as modified, Mifeprex and its approved generic can be dispensed by or under the supervision of a certified prescriber or by a certified pharmacy on a prescription issued by a certified prescriber.

    The Mifepristone REMS Program continues to require the Patient Agreement Form and certification of health care providers who prescribe mifepristone.

30. **What was the process for approving the current REMS modification?**

    In 2021, in order to determine whether a modification to the Mifepristone REMS Program was warranted, the FDA conducted a comprehensive review of the published literature, other relevant safety and adverse event data, and information provided by advocacy groups, individuals, and the applicants related to the modifications that were under consideration. After conducting this review, the FDA determined that the REMS must be modified to remove the in-person dispensing requirement and add pharmacy certification. In accordance with the typical process for REMS modifications, the FDA sent REMS Modification Notification letters to the applicants for Mifeprex and the approved generic, Mifepristone Tablets, 200 mg. Following receipt of these letters, the applicants prepared a proposed REMS modification and submitted it to their respective applications.

31. **Why did the FDA conduct a review of the Mifepristone REMS Program in 2021?**

    The agency's comprehensive review of the Mifepristone REMS Program, which led to the agency's December 16, 2021, decision that a modification was required, was related to the litigation in *Purcell v. Becerra* (previously *Chelius v. Becerra*). On May 7, 2021, the FDA and the plaintiffs in *Purcell* filed a joint motion to stay that litigation, which involves the single, shared system REMS for Mifeprex and its approved generic, Mifepristone Tablets, 200 mg. The court granted the stay on May 7, 2021. The *Purcell* case was reopened on February 28, 2023, and the plaintiffs now challenge the modified Mifepristone REMS Program. The agency generally does not comment on pending litigation.

32. **Was there a change in the reported adverse events during the pandemic when the in-person dispensing requirement was not enforced?**

    No. There were periods when the in-person dispensing requirement was not being enforced. First, from July 13, 2020, until January 12, 2021, the FDA was enjoined from enforcing the in-person dispensing requirement by an injunction issued in the *ACOG v. FDA* litigation, which was filed in the U.S. District Court for the District of Maryland. On April 12, 2021, the agency stated its intent to exercise enforcement discretion with respect to the in-person dispensing requirement during the COVID-19 public health emergency. The FDA analyzed postmarketing data to determine if there was a difference in adverse events between periods when in-person dispensing was and was not enforced. Based on this review, the agency concluded that there did not appear to be a difference in adverse events between periods when in-

person dispensing was and was not enforced

Litigation and Other Legal Issues

33. **Was the Mifepristone REMS Program modified in 2023 in response to the Supreme Court's 2022 decision in *Dobbs v. Jackson Women's Health Organization*?**

    No. The agency's comprehensive review of the Mifepristone REMS Program, which led to the 2021 decision that a modification was required, is related to the litigation in *Purcell v. Becerra* (previously *Chelius v. Becerra)*. In accordance with the typical process for REMS modifications, the FDA sent REMS Modification Notification letters to the applicants for Mifeprex and the approved generic, Mifepristone Tablets, 200 mg. Following receipt of these letters, the applicants prepared a proposed REMS modification and submitted it to their respective applications. The FDA reviewed the REMS modification supplements submitted by the applicants in the Mifepristone REMS Program and approved a REMS modification that removes the in-person dispensing requirement and adds pharmacy certification.

34. **Was the Mifepristone REMS Program modified in 2023 in response to state abortion laws?**

    No. See response to Question 33.

35. **What happens if a state refuses to allow mifepristone to be prescribed for medical termination of pregnancy?**

    Any questions regarding the application of state law should be directed to the Department of Justice.

36. **What is the status of the *Alliance for Hippocratic Medicine* lawsuit about the approval of mifepristone?**

    On November 18, 2022, the FDA and HHS were sued in the U.S. District Court for the Northern District of Texas by the Alliance for Hippocratic Medicine and other plaintiffs. In June 2024, the Supreme Court held that the original plaintiffs lack standing to challenge FDA's actions, and the original plaintiffs voluntarily dismissed their claims in November 2024. Several states (Missouri, Idaho, and Kansas) intervened in the case before the Supreme Court's ruling. The agency generally does not comment on pending litigation.

Exhibit 13

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Frequently Asked Questions

What if I'm concerned about the cost?

Many providers offer financial assistance. Let them know if you need this. They can also connect you to abortion funds, which can pay for your care.

What is my legal risk?

Mayday does not provide legal advice. We are not aware of any successful criminal prosecution for self-managing a first trimester abortion after the overturn of Roe v. Wade, but this does not predict future risk. For more info you can call the Repro Legal Helpline for free advice at (844) 868-2812 or by visiting their website here.

Are abortion pills safe?

According to the World Health Organization, abortion pills are safe and effective in the first 12 weeks of pregnancy. If you are 12 weeks more pregnant we link to ineedana, a trusted source which has information on abortion procedures and care after 12 weeks.

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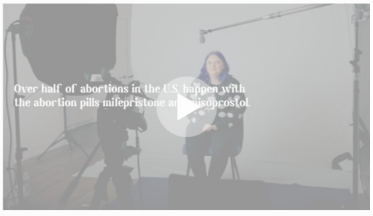

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- COST: SLIDING SCALE
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- DELIVERY WITHIN 5 DAYS

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

How are health care providers able to get me pills?

Shield laws offer protection for doctors, nurses and other practitioners in abortion-friendly states who prescribe and send abortion pills to people living in other states that ban or severely restrict abortion. In many states, these laws protect prescribers and patient data, helping patients in other states access abortion pills online from the prescribers. For more information on shield law prescribers, visit the Abortion Coalition for Telemedicine.

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

Check out our FAQ.

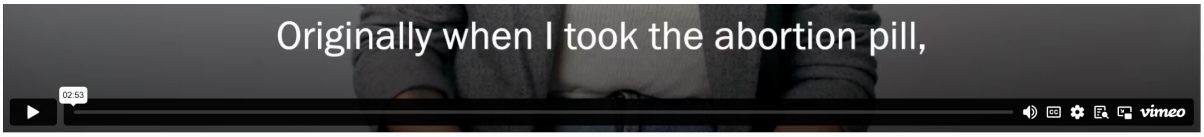
Want more information and other ways to get pills?

Visit Plan C's state by state guide.

Visit Red State Access for info on community support networks (volunteers who provide pills for free).

Info on digital privacy, legal concerns, and medical questions

Privacy Guide | Medical Hotline | Legal Helpline



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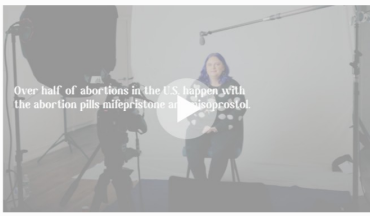

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Exhibit 15

JAMA | Special Communication | WOMEN'S HEALTH

The US Food and Drug Administration's Regulation of Mifepristone

Sophie Dilek, MPH; Joanne Rosen, JD, MA; Anna Levashkevich, MSPH; Joshua M. Sharfstein, MD; G. Caleb Alexander, MD, MS

IMPORTANCE Mifepristone, used with misoprostol, is the most common abortion regimen in the US. It is also a focal point of reproductive health policy and politics, with controversy over its legal status and regulation by the US Food and Drug Administration (FDA).

OBJECTIVE To characterize the FDA's decision-making with respect to the regulation of mifepristone, with a particular interest in the agency's rationale for establishing, maintaining, or modifying key components of its regulatory approach over time.

EVIDENCE REVIEW Qualitative analysis of 5239 pages of FDA documents obtained through a Freedom of Information Act request, including sponsors' Risk Evaluation and Mitigation Strategy (REMS) assessment reports, FDA review of these reports, internal memos, and regulatory correspondence (2011-2023), supplemented by a review of publicly available information. Review focused on FDA justifications for implementing, maintaining, or modifying postapproval safety measures and the supporting evidence cited.

FINDINGS Five key moments in the FDA's regulation of mifepristone that have led to the current state of oversight were identified: (1) conversion to the REMS framework in June 2011; (2) reevaluation of REMS necessity in October 2013; (3) a sponsor-requested label change in May 2015; (4) the response to the COVID-19 pandemic in 2020 and 2021; and (5) a comprehensive reassessment of the REMS in November 2021. Key themes across this period were consistent findings on safety, lack of ideological bias in staff scientists' recommendations, and the limited impact of political interference—to date—on the agency's oversight. Even as litigation, the COVID-19 public health emergency, and evolving practice standards changed the context of mifepristone regulation, the agency generally followed the policy approach favored by scientists at the agency.

CONCLUSIONS AND RELEVANCE FDA oversight of mifepristone, developed during key moments from 2011 to 2023, has been shaped by scientific evidence and a cautious regulatory approach led by scientists at the agency.

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Author Affiliations: Center for Drug Safety and Effectiveness, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland (Dilek, Alexander); Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland (Rosen, Sharfstein); Department of Population, Family, and Reproductive Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland (Levashkevich); Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland (Alexander); Division of General Internal Medicine, Johns Hopkins Medicine, Baltimore, Maryland (Alexander).

Corresponding Author: G. Caleb Alexander, MD, MS, Johns Hopkins Bloomberg School of Public Health, 615 N Wolfe St, W6035, Baltimore, MD 21205 (galexan9@jhmi.edu).

Mifepristone is a progesterone receptor antagonist with antiglucocorticoid activity. In combination with misoprostol, it is the most widely used abortion regimen in the US.[1] Mifepristone is also approved by the US Food and Drug Administration (FDA) for the control of hyperglycemia in adults with endogenous Cushing syndrome who are not candidates for curative surgery. First approved by the FDA in 2000 for pregnancy termination through 49 days' gestation, mifepristone had already been subject to controversy for more than a decade and has remained under intense scrutiny by parties across the spectrum of the abortion debate. There is consensus among leading US and international professional associations and regulatory authorities that mifepristone is effective for pregnancy termination and that serious complications, such as heavy bleeding or sepsis, are very rare.[2,3]

The FDA has imposed special restrictions on mifepristone to support its safe use. Initially, these conditions were part of 21 CFR Part 314 Subpart H, a regulatory pathway that permitted the FDA to require specific safety-related measures for drugs with serious safety concerns or potential for significant risk.[4] The final plan accompanying the 2000 FDA approval of mifepristone included prescriber qualifications, dispensation limited to certain settings, signed patient agreement forms, provision of a patient medication guide, and mandatory reporting of adverse events.[5]

With the passage of the Food and Drug Administration Amendments Act (FDAAA) in 2007, oversight transitioned to a new statutory framework. Under the FDAAA, the agency was authorized to require a formal program known as a Risk Evaluation and Mitigation Strategy (REMS) for both newly approved drugs and previously approved drugs with known serious risks. REMS could include specific measures, known as Elements to Assure Safe Use (ETASU), for products whose safety varies markedly depending on the context of their use. Per the FDAAA, ETASUs must be commensurate with specific serious risks listed in the labeling of the drug and

should not be unduly burdensome on patient access. Additionally, the FDA is required to periodically review and reassess whether regulatory elements continue to be necessary to assure safe use. Mifepristone was among the drugs the FDA deemed to require a REMS based on existing restrictions governing its use. The official REMS for mifepristone was formally approved in 2011.

Substantial debate has surrounded the mifepristone REMS program. Some organizations and politicians, including those opposed to abortion, have argued that availability of the drug should be restricted fully or substantially to avoid adverse events.[6] Others, including researchers and professional associations, have argued that the continuation of additional safety precautions is unnecessary.[7] This debate surfaced again on October 1, 2025, when the FDA approved a new generic version of mifepristone.[8]

These competing perspectives are also reflected in litigation. In cases such as *US Food and Drug Administration v Alliance for Hippocratic Medicine*, parties have argued that the FDA improperly applied the US Food, Drug, and Cosmetic Act in its initial approval of and subsequent decisions regarding mifepristone.[9] Conversely, in cases such as *Purcell v Kennedy* (formerly *Chelius v Becerra*), parties have argued that the continuation of the mifepristone REMS program is unnecessary.[10] These cases, together with the *Dobbs v Jackson Women's Health Organization* decision overturning *Roe v Wade*, have set the stage for renewed federal review of mifepristone, as well as state-level efforts to limit, ban, or protect access to mifepristone.

Despite extensive public discussion and litigation, to date, there has been no review of FDA documents to shed light on how regulatory decisions about mifepristone have been made.

Document Review and Analysis

Study Design and FOIA History

In May 2019, we submitted a Freedom of Information Act (FOIA) request to the FDA regarding the design, conduct, and evaluation of FDA postapproval safety programs for 6 products, including mifepristone.[11] Based on similar prior work examining postapproval opioid regulation,[12,13] we requested a variety of documents relevant to each program, including the sponsors' REMS assessment reports, FDA reviews of these reports, internal memos, and regulatory correspondence.

Over 4 productions between March and September 2023, the FDA provided 1977 pages of documents regarding mifepristone. We reviewed and indexed these documents and then used the peer-reviewed literature on mifepristone safety and effectiveness, publicly available policy briefs, FDA-published archives, and the initially provided documents to identify additional documents of interest. We requested these documents from the FDA, yielding an additional 3262 pages of materials. The FDA redacted some documents based on exceptions for "confidential commercial information" (5 USC §552 [b][4]) and/or "personal privacy" (5 USC §552 [b][6]).[14] We appealed some redactions, resulting in the deredaction of 1 document. Our final analysis included 264 documents representing 5239 pages covering the FDA's safety program for mifepristone from June 2011 to January 2023 (eTable in the Supplement).

Document Coding and Analysis

Two authors (A.L., S.D.) performed primary document review, with oversight from a third (G.C.A.), followed by primary analysis and discussion among all authors. Each source document was reviewed and indexed to track the document subject, document type, creation date, length, and the presence of redacted material. Our primary focus was the FDA's rationale for the initial establishment of the mifepristone safety program and the agency's subsequent decisions to maintain, modify, or remove specific regulatory elements over time. We sought to identify key moments in this regulatory history, as well as key themes of the FDA's actions. Our analytic approach centered on a close reading of internal FDA review documents and other materials relevant to the agency's oversight of the mifepristone REMS program. Within each REMS review document, we extracted content related to the agency's stated rationale for maintaining or modifying specific ETASUs and evidence cited in support of regulatory decisions.

History of the FDA's Mifepristone REMS Program

Our review of documents identified 5 key moments related to the regulation of mifepristone over time: (1) conversion to the REMS framework in June 2011; (2) reevaluation of REMS necessity in October 2013; (3) a sponsor-requested label change in May 2015; (4) response to the COVID-19 pandemic in 2020 and 2021; and (5) a comprehensive reassessment of the REMS in November 2021 (**Table**).

Key Moment 1: Conversion to REMS Framework (June 2011)

The sunsetting of Subpart H following the passage of the FDAAA presented the FDA with a key opportunity to consider whether to require a formal REMS for mifepristone and to make substantive changes to its postapproval regulation.

Documents suggest there was substantial communication between the FDA and sponsor Danco over the initial use of the REMS authority for mifepristone. However, the FDA extensively redacted documents describing the agency's internal deliberations regarding specific regulatory requirements under the REMS, and the details of this exchange are not available.

The final approved REMS closely mirrored the Subpart H requirements. Under the REMS, these restrictions were formalized as ETASUs: certification of prescribers with specialized training or experience; restricted distribution to clinics, medical offices, and hospitals under the supervision of a certified prescriber; and documentation of safe-use conditions (FDA Review of Risk Evaluation and Mitigation Strategy for Mifepristone, June 2011 [Reference ID FDACDER006118-FDACDER006144]).

The FDA adopted an implementation system to monitor adherence and required the manufacturer to submit assessment reports to the FDA 1 year following approval and every 3 years thereafter, as well as in response to specific regulatory events, such as safety-related label changes (FDA Review of Risk Evaluation and Mitigation Strategy for Mifepristone, June 2011 [Reference ID FDACDER006118-FDACDER006144]).

Key Moment 2: Reevaluation of the Need for the REMS (October 2013)

In October 2012, the director of the Center for Drug Evaluation and Research (CDER), Janet Woodcock, requested a reevaluation

Table. Evolution of Mifepristone Regulatory Elements Over Time

Requirement	Pre-REMS, Sept 2000-June 2011	Key moment 1: Conversion to REMS Framework, June 2011	2: Reevaluation of REMS necessity, October 2013	3: Sponsor-requested label change, March 2016	4: COVID-19 pandemic, July 2020-April 2021	5: Comprehensive reassessment of REMS, November 2021
Certification of prescribers: Prescribers required to have specific training or experience	Prescribers required to meet specific qualifications as part of approval under 21 CFR Part 314 Subpart H	Requirement maintained under the REMS framework as ETASU	No change	No change	No change	No change
Certification of dispensing setting: Dispensing health care settings, such as pharmacies, must be specially certified	No requirement for pharmacy certification as part of approval under 21 CFR Part 314 Subpart H	No change	No change	No change	No change	Pharmacy certification was recommended for approval in November 2021 as ETASU B but change not formally implemented until January 2023 following approval of regulatory materials reflecting updated REMS elements
Restricted distribution: Dispensing restricted to certain health care settings	Distribution limited to clinics, medical offices, and hospitals under supervision of a certified prescriber as part of approval under 21 CFR Part 314 Subpart H	Requirement maintained under REMS framework as ETASU	No change	No change	In response to litigation, enforcement discretion exercised with respect to this requirement between July 2020 and January 2021 In April 2021, agency announced formal policy of enforcement discretion	In-person dispensation requirement recommended for removal in November 2021 but change not formally implemented until January 2023 following approval of regulatory materials reflecting updated REMS elements
Documentation of safe use conditions: Drug can only be dispensed to patients with documentation of safe-use conditions	Prescribers required to provide the patient agreement form and Medication guide, obtain patient signature on agreement form, and place in medical record as part of approval under 21 CFR Part 314 Subpart H	Requirement maintained under REMS framework as ETASU	No change	Patient agreement form recommended for removal by staff scientists, though maintained per commissioner's request Medication guide was removed from the REMS but maintained under labeling requirements	No change	No change

Abbreviations: CFR, Code of Federal Regulations; ETASU, Elements to Assure Safe Use; REMS, Risk Evaluation and Mitigation Strategies.

of mifepristone to determine whether the REMS continued to be necessary, prompting a review that was completed the following year (Key Document 1 in the Supplement). As part of this assessment, FDA staff scientists reviewed safety data and reported that the "overall safety profile of Mifeprex has not changed over the last 6-7 years and is consistent with current product labeling."

The scientists reviewed each ETASU in turn. After assessing the impact of removing or retaining each element, the scientists explicitly outlined the pros and cons of maintaining the REMS. In support of REMS elimination, they cited the stable safety profile and data indicating that safe-use practices were already embedded in most sites. In support of REMS maintenance, they argued that there was a relative lack of familiarity with medical abortion among clinicians given limited training opportunities. Scientists also noted controversies over the medication in considering changes to restricted distribution, writing "Concerns regarding protests or targeting may deter retail pharmacies from stocking Mifeprex." Ultimately, they concluded that the REMS should be maintained.

Key Moment 3: Sponsor-Requested Label Change (May 2015)

In May 2015, mifepristone's sponsor submitted an efficacy supplement proposing substantial changes to the drug's labeling, including extending the approved gestational age from 49 days to 70 days; reducing the dose of mifepristone; modifying the dosing regimen and the interval between mifepristone and misoprostol; changing the route of misoprostol administration; and broadening the qualifications for certified prescribers. Because these labeling changes affected the conditions for safe use, they triggered the need for a formal REMS modification. Consequently, the FDA reviewed the efficacy supplement and the REMS in parallel, issuing coordinated decisions on March 29, 2016 (Key Document 2 in the Supplement).[15]

In undertaking this review, the FDA conducted a comprehensive assessment of available evidence, including published studies reflecting clinical practice, 16 years of accumulated postmarketing safety data, and the most recent sponsor-submitted

REMS assessment report. Collectively, these sources demonstrated that the revised dosing regimen, route of administration, and expanded clinician qualifications were appropriate.[15] Consistent with these findings, the FDA concluded that "Overall, the rate of deaths and SARs [Serious Adverse Reactions] is acceptably low and data for the proposed regimen do not suggest a safety profile that deviates from that of the originally approved regimen."[15] The agency also revised the assessment plan by eliminating certain adverse event metrics from the sponsor's required reports because this information was already being provided to the FDA through other pathways, including spontaneous adverse event reporting (Key Document 2 in the Supplement).

Two additional considerations arose during this regulatory review that do not appear to have been raised by the company. The first related to the medication guide, a handout given to all patients with information about mifepristone. Because of a broader shift in REMS regulation, the FDA removed the medication guide from the REMS program but still required its distribution to patients under patient labeling provisions.

The second consideration was the patient agreement form, which patients were required to sign under the existing REMS. In the review document, FDA scientists argued that this form was "duplicative of the informed consent and counseling processes that take place in the US, consistent with medical standard of care and current clinical practice guidelines for abortion providers," as well as the medication guide (Key Document 2 in the Supplement).

The FDA commissioner at the time, Dr Robert Califf, overrode this decision. In a memo, CDER director Janet Woodcock wrote, "After being briefed on the planned changes to the [New Drug Application] that the Center was considering, the Commissioner concluded that continuing the REMS requirement for a signed patient agreement form would not interfere with access and would provide additional assurance that the patient is aware of the nature of the procedure, its risks, and the need for appropriate follow-up care" (Key Document 3 in the Supplement).

Key Moment 4: The COVID-19 Pandemic (2020-2021)

The COVID-19 pandemic created a challenging moment for mifepristone regulation. The FDA faced the key question of whether to modify REMS provisions governing the medication, as the FDA had done with 2 other drugs that were under an in-person dispensation requirement.[16]

In May 2020, the American College of Obstetricians and Gynecologists (ACOG) sued the FDA to challenge the enforcement of the in-person dispensation and signature requirements for mifepristone during the pandemic. The FDA opposed this action, arguing that these requirements were necessary to mitigate serious risks associated with the medication.[16] The court found that ACOG's action was likely to succeed and issued a preliminary injunction in July 2020 enjoining the FDA from enforcing these requirements while the litigation continued.

Our review of documents found that the FDA's position in the ACOG litigation was contrary to the views of scientists in the FDA's review division. On June 10, 2020—the same day that the FDA filed its brief in the litigation—an office within CDER wrote a memo to the center director reviewing the various mifepristone REMS requirements (Key Document 4 in the Supplement). The staff scientists acknowledged that "the public, including patients seeking medical abortion, have been advised to practice social distancing and avoidance of public places, to minimize their risk of exposure to the novel coronavirus." They highlighted the intended purpose of the in-person dispensing requirement—to ensure that patients receive counseling at the time of dispensation and to facilitate completion of the patient agreement form—before stating that these benefits could be achieved through telemedicine. The scientists concluded that if other REMS requirements were met, then "the in-person dispensing of mifepristone for medical termination of early pregnancy may present additional COVID-related risks to patients and healthcare personnel…Accordingly, it would be appropriate to exercise enforcement discretion with respect to this element of the Mifepristone REMS Program during the COVID-19 [public health emergency]." This internal memo, however, did not change the FDA's position in the litigation.

In January 2021, the Supreme Court reinstated the in-person requirements. Soon after, the FDA initiated a new review of these requirements. In an April 2021 memo from FDA staff to the CDER director, scientists cited 4 published studies finding no evidence of an increase in serious safety concerns occurring with medical abortion as a result of modifying the in-person dispensation requirement between June 2020 and January 2021 (Key Document 5 in the Supplement). The CDER director endorsed this conclusion (Memorandum to Acting Commissioner Regarding In-Person Dispensing Requirement in Mifepristone REMS Program During the COVID-19 Public Health Emergency, April 2021 [Reference ID FDACDER006897-FDACDER006898]). Later that month, the FDA adopted a formal policy of enforcement discretion, meaning it would not enforce the in-person dispensation requirement.

Key Moment 5: Comprehensive Reassessment of the REMS (November 2021)

In November 2021, the FDA undertook a comprehensive reassessment of the REMS program, creating another opportunity for significant changes to mifepristone's postapproval regulation. The agency considered a range of options, from resuming enforcement of the in-person dispensation requirement to eliminating the REMS program altogether.

The comprehensive reassessment was conducted by an internal FDA team. Findings were shared at a meeting in November 2021 (Key Document 6 in the Supplement). The team relied primarily on a scoping literature review spanning 2016-2021 and safety data collected since the initiation of the COVID-19 public health emergency. Evidence was evaluated in relation to the necessity of each ETASU. FDA scientists once again affirmed the safety of the medication, writing that the agency "routinely monitors adverse events reported to FAERS [FDA Adverse Event Reporting System] and published in the medical literature with mifepristone for medical termination of pregnancy…to date, no new safety concerns have been identified."

On prescriber certification, agency scientists identified no new data demonstrating a continued need for certification; however, in the view of agency scientists, the literature also did not support removing the certification. On the patient agreement form, the team referenced 2 studies indicating a potential increase in the number of new prescribers, which they argued warranted a greater need for standardized patient education (Key Document 6 in the Supplement).

On the in-person dispensation requirement, the FDA team cited results from 16 publications documenting the absence of significant concerns associated with various mifepristone delivery models. They also referenced as supporting evidence the absence of new safety concerns during the public health emergency when enforcement discretion was exercised and mifepristone was available without in-person dispensation (Key Document 6 in the Supplement).

To meet the agency's obligation to ensure REMS are not unduly burdensome, the reviewers concluded that the in-person dispensation requirement should be removed and replaced with a pharmacy certification system (Review of the One Year [1st] Single Shared System REMS Assessment Report for Mifepristone, December 2021 [Reference ID FDACDER006331-FDACDER006354]). Under this approach, pharmacies would be required to obtain certification, which typically involves agreeing to specified dispensing and recordkeeping requirements. Documents detailing the specific operationalization of the pharmacy certification system were not included in our analysis. The final recommendations from the internal FDA team also included retaining the patient agreement form. The agency announced these changes in December 2021 but did not formally implement them until January 2023, following the sponsors' submission and the FDA's approval of regulatory materials reflecting the updated REMS elements.

Key Themes

Internal FDA documents offer a rare opportunity to examine how the agency made decisions over time about mifepristone, a medicine that has been the subject of intense debate. At key moments, agency scientists reviewed extensive evidence about the agency's controls on mifepristone access and made decisions regarding whether to maintain stricter requirements for mifepristone than for most other medicines, whether to expand the condition of use, whether to adapt to the pandemic, and whether to lift certain provisions as clinical experience accumulated. Three key themes emerged from our analysis.

Consistent Findings on Safety

The FDA has monitored mifepristone's safety through multiple complementary mechanisms, including spontaneous adverse event reports, clinical studies, published literature, and information submitted by professional organizations and advocacy groups (Letter from Select Health Care Practitioners, March 2021 [Reference ID FDACDER006463-FDACDER006750]; Letter from the American College of Obstetricians and Gynecologists and Society for Maternal Fetal Medicine, April 2020 [Reference ID FDACDER006391-FDACDER006445]). From the drug's original approval in 2000 through 2016, the REMS assessment plan required the sponsor to provide summaries of spontaneous adverse event reports and updates on any postapproval studies. In 2016, the agency continued to obtain these data through annual reports, routine pharmacovigilance, and other mechanisms.

The documents we examined underscore the repeated regulatory finding by FDA scientists that mifepristone's safety is well-characterized, serious adverse events have rarely occurred, and best-practice guidelines address major risks.

Lack of Ideological Bias in Staff Scientists' Recommendations

Staff scientists at the FDA based their recommendations on comprehensive reviews of evidence, making decisions that were not consistently on one side or the other of the debate taking place outside the agency regarding mifepristone regulation.

For example, FDA scientists supported removing the in-person dispensation requirement, first in June 2020 during the pandemic, then again in April 2021, and again, following a comprehensive review, in November 2021. These decisions have drawn criticism from abortion opponents, who have pressed for a return to more restrictive regulation.

At the same time, FDA scientists continued to endorse multiple elements to support safe use, including provisions requiring prescriber certification and completion of the patient agreement form. In each case, the agency cited the need for additional data to justify any reconsideration of these provisions. These determinations have been criticized by ACOG and other professional groups, who have called for them to sunset.

The Question of Political Interference

In our document review, we identified 2 moments of potential intervention from FDA political appointees on decisions that ran contrary to the perspective of agency scientists on appropriate evidence-based regulation. In 2016, the FDA commissioner decided, over the apparent objections of the review division, to maintain a requirement for a patient agreement form. The commissioner justified this decision on the grounds that it would promote understanding without interfering with access. Several years later, FDA scientists would endorse continuing with this requirement to best ensure patient understanding of the risks of the product.

In June 2020, the scientific team's conclusion that in-person dispensation was not required during the COVID-19 pandemic was not adopted as the agency's position in response to a court challenge by ACOG against the continuation of this requirement during the pandemic. On the same day that a memo from the scientific team concluded that the in-person dispensation requirement was not needed, the agency filed a brief opposing the challenge. We did not identify documents to explain the timing of these decisions or their provenance.

What might have been a moment of interference with the scientific team's approach was forestalled by the court's action to block the in-person requirement from July 2020 to January 2021. With the exception of the period from January 2021, when the Supreme Court reinstated the in-person requirement, until April 2021, when the FDA chose not to enforce it, we found no documentary evidence of political intervention that substantially affected access to the medication.

Looking Ahead

Litigation on mifepristone access continues to generate uncertainty. Several active cases seek the removal of the REMS requirements altogether. Other cases have been directed at restricting or revoking FDA approval of the drug—most notably, *Alliance for Hippocratic Medicine v FDA*.[17] Although the Supreme Court unanimously dismissed the case in June 2024 on procedural grounds, its decision left the door open for future plaintiffs to revisit similar arguments. Three states are currently challenging the FDA's approval

of mifepristone.[18] These cases are occurring alongside broader campaigns targeting abortion providers and access, state efforts to restrict mifepristone availability, mounting pressures on the health care system, and deepening disparities in reproductive care.[19]

On September 19, 2025, Department of Health and Human Services Secretary Robert F. Kennedy Jr and FDA Commissioner Martin Makary indicated that the FDA is undertaking a new evaluation of mifepristone's safety and effectiveness.[20] Kennedy has said that key decisions would be up to the president himself.[21] A reversal of FDA policy on mifepristone by political leaders or appointees would represent a significant break from the last quarter century of mifepristone oversight.

Limitations

Our analysis has several limitations. Documents that we received through our FOIA request included redactions that limited our ability to fully understand the factors the FDA considered and its internal deliberations with regard to those factors. In some instances, entire pages were redacted, preventing us from understanding regulatory decision-making and presenting gaps in our review. Additionally, there may be documents that were not provided to us or internal discussion related to mifepristone regulation that was not captured in the written documents. Our interpretation of the documents necessarily reflects judgments about the weight and meaning of regulatory actions over time. Consequently, our analysis may not fully capture the complexity of agency decision-making or the influence of external pressures, including political or legal considerations, that are not explicitly documented. Moreover, our study was not designed to be comparative, and we did not evaluate how the mifepristone REMS compares with REMS programs for other drugs.

Conclusions

Mifepristone's regulatory trajectory offers an instructive case study of how the FDA has conducted drug safety oversight in a politicized environment: cautiously and with the support of evidence and regulatory judgment. Our analysis of internal agency documents spanning more than a decade shows that while the FDA has consistently affirmed mifepristone's safety, changes to its REMS were often made conservatively, incrementally, and in response to external events such as the COVID-19 pandemic. While the FDA considered more radical changes at several key moments, it opted against them to better balance various considerations. As the FDA prepares to review the safety data again, as legal challenges are expected to continue, and as state policies diverge, mifepristone will likely remain a flashpoint in reproductive health policy. Maintaining integrity in this process will require a continued commitment to scientific evidence and an avoidance of political interference.[22]

ARTICLE INFORMATION

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Conflict of Interest Disclosures: Dr Sharfstein reported serving as principal deputy commissioner of the US Food and Drug Administration (FDA) from March 2009 to January 2011. Dr Alexander reported that he is past chair of the FDA's Peripheral and Central Nervous System Advisory Committee and a cofounding principal and equity holder in Stage Analytics. These arrangements have been reviewed and approved by Johns Hopkins University in accordance with its conflict of interest policies. No other disclosures were reported.

Data Sharing Statement: Researchers interested in accessing specific documents may contact G. Caleb Alexander (galexan9@jhmi.edu). Please include the applicable reference numbers for the requested materials and the basis for the request.

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MAYDAY HEALTH, Plaintiff, v. MARTY J. JACKLEY, Attorney General of South Dakota, in his official capacity, Defendants.	Case No. 1:26-cv-00078-KPF

DECLARATION OF LIV RAISNER IN SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

I, Liv Raisner, declare as follows:

1. I am the Founder and Executive Director of Mayday Health ("Mayday"), a reproductive health education nonprofit. I co-founded Mayday in May 2022 in the wake of the U.S. Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022)—responding to the widespread confusion, fear, and misinformation that followed the elimination of the federal constitutional right to abortion, particularly regarding the safety, legality, and availability of abortion pills. As Executive Director, I am responsible for setting Mayday's strategic vision, overseeing our day-to-day operations, and supervising content development and press outreach. I make this declaration from personal knowledge and could competently attest to all facts in this declaration.

Mayday's Mission and Website

2. Mayday's mission is to share accurate information about abortion pills, birth control, and gender-affirming care in any state, and empower people to make their own informed decisions

about their own bodies. To this end, we own and operate a globally accessible website (https://mayday.health) that publishes truthful information about reproductive healthcare, including the safe and effective use of FDA-approved abortion pills such as mifepristone and misoprostol.

3. The front page of our website asks the visitor what category of information they are interested in: abortion, morning-after pills, birth control, or gender-affirming care. For each category, it then provides a series of links to third-party organizations that may provide access to such medical care or other resources. *See id.* For the abortion category, Mayday provides links to well-established third-party websites including Aid Access, Cambridge Reproductive Health Consultants, A Safe Choice, Abuzz, and We Take Care of Us. *See id.* Mayday also links to organizations offering supporting services, including the Digital Defense Fund's privacy guide, the Miscarriage and Abortion Hotline, and the If/When/How Repro Legal Helpline. *See id.*

4. Much of the information that Mayday's website links to is from clinicians, legal organizations, and health experts. We independently research that information to ensure our resources are accurate. If medically appropriate, some of these third-parties may choose to prescribe and provide access to abortion pills, such as mifepristone and misoprostol.

5. To raise awareness about the availability of reproductive health services to communities across the country, we publicize our website through social media platforms like TikTok and Instagram, as well as through billboards, plane-pulled banners, art installations, apparel, and other tangible media. Mayday itself does not sell, handle, provide, offer for sale, or distribute any medications. It also does not provide any medical or legal advice, charge any fee, collect any revenue related to the provision of medical or legal services, or obtain any other

valuable consideration in exchange for disseminating its message. It does not benefit from the sale of abortion medication, and has no customers. Nor does it monetize its users' data.

6. Rather, Mayday is a donor-funded information clearinghouse—an educational resource with links to third-party websites—that provides people with the information they need to make informed reproductive healthcare choices, including (if they want) to terminate pregnancies lawfully and safely despite residing in places that have burdened or outlawed abortion. This information is provided as free of charge to users—as an expression of Mayday's values and beliefs. We believe this work is essential to ensuring that individuals, regardless of their location, can make informed decisions about their health and well-being.

Mayday's Signs in South Dakota and the State's Response

7. To this end, on December 8, 2025, we placed signs at gas stations around South Dakota. The signs read: "Pregnant? Don't want to be?" with a prompt for consumers to "Learn more" by visiting Mayday's website, as shown below.

8. The next day, December 9, 2025, South Dakota Governor Larry Rhoden issued a press release announcing he was urging South Dakota Attorney General Marty Jackley to investigate Mayday.

9. The Attorney General then commenced an investigation into us for possible violations of the South Dakota Deceptive Trade Practices and Consumer Protection Act, SDCL § 37-24-6.

10. On December 10, 2025, the Attorney General sent us a letter to an address in New York (as well as by e-mail) demanding that we immediately desist from publishing information that could be used to facilitate "the delivery of abortion drugs to the State of South Dakota." Failure to comply, he threatened, exposed us to "felony criminal consequences or civil penalties up to $5,000 per violation."

11. The Attorney General's letter falsely accuses us of "urging women not to seek medical care after taking abortion pills" and claims, among other things, that Mayday had engaged in "deceptive act[s] or practice[s]" by republishing official FDA and other medical findings that abortion pills are safe and effective. But beyond that, the Attorney General's allegations refer almost entirely to information published by and on linked third-party websites, not by Mayday.

12. Mayday responded on December 19, 2025. Objecting to the Attorney General's demand in its entirety, we explained that we are non-profit information resource that does not sell, handle, provide, offer for sale, or benefit from the sale of abortion medication, and are accordingly not subject to South Dakota deceptive trade practices law.

13. We also made clear in the letter that our publications and resources are truthful, constitutionally protected speech on a matter of public concern, and thus, any legal action against us on the basis of that speech cannot be sustained under the First Amendment.

14. Mayday received no further communication from the Attorney General.

15. On December 22, 2025, we learned from news reports and social media posts that the Attorney General filed a motion in South Dakota state court purporting to seek an injunction against us and against the company that placed our signs at gas stations in South Dakota.

16. As of the time of this filing, Mayday has not received a copy of this motion at its current address.

17. The Attorney General's motion seeks to require us to remove existing content and links from our New York-based website, and also seeks to ban us from posting signs at gas stations publicizing our website to audiences in South Dakota.

The Repercussions of the State's Action on Mayday's Speech

18. Mayday remains committed to our mission of providing truthful, evidence-based information to the public. But the Attorney General's actions have forced us to weigh the risks and costs of defending bad faith legal actions against that commitment.

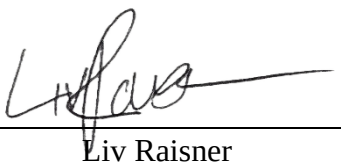
19. We have already refrained from publishing resources to avoid prosecution and legal fees. While we would like to publish more information into South Dakota in future, our plans are on hold in light of the Attorney General's threats. We are also refraining from publishing content on social media featuring South Dakota residents describing their healthcare challenges. These shuttered posts would have reached audiences around the world.

20. Mayday is also more closely vetting press requests, and our leadership, including myself, is now limiting and second-guessing the tone and content of statements we make on behalf of Mayday, lest our speech—though protected—cause some controversy that exposes us to litigation. This is a significant injury for a non-profit like us whose mission is to raise awareness through earned media like newspapers, radio, and television stations.

21. In short, the threat that the South Dakota Attorney General will eventually file an actual legal action against Mayday—with threatened penalties including "felony criminal consequences or civil penalties up to $5,000 per violation"—has forced us to restrict our publication activities and will continue to affect how, where, and what we say in the future unless this court enters an order preventing the Attorney General from taking actions that would pressure or force us to restrict our speech. Without relief, Mayday will continue to be restricted from reaching the people who we believe need the information we publish the most.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: New York, New York
January 14, 2026

By: 
Liv Raisner