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**Pro hac vice* applications forthcoming

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF IDAHO

MAYDAY HEALTH,

Plaintiff,

vs.

RAÚL R. LABRADOR, Attorney General of Idaho, in his official capacity,

Defendant.

Case No.

PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

Pursuant to Rule 65 of the Federal Rules of Civil Procedure, Plaintiff Mayday Health, by and through its undersigned counsel, hereby moves the Court for entry of a preliminary injunction against Defendant Attorney General Raúl Labrador, in his official capacity. This motion is based

on the accompanying memorandum and the Declarations of Leo Raisner and Adam S. Sieff.

For the reasons set forth in the accompanying memorandum, Plaintiff respectfully requests that the Court enter a preliminary injunction prohibiting Defendant Labrador from taking any action under any law—including Idaho Code §§ 18-603, 18-607, 18-622, 18-623, and 48-601—to penalize or threaten to penalize Mayday for displaying its mobile billboard in Idaho or for publishing its website to Idahoans.

Dated: May 29, 2026

By: /s/ Adam S. Sieff
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CERTIFICATE OF SERVICE

I hereby certify that on the date set forth below I served a true and correct copy of the foregoing **PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION** was served by electronic mail upon all registered CM/ECF users, and by United States Postal service upon all non-registered CM/ECF users in this case as indicated below:

Raúl R. Labrador
Office of the Attorney General
State of Idaho
700 W. Jefferson Street
P.O. Box 83720
Boise, ID 83720

Dated this 29th day of May, 2026.

/s/ Kelly O'Neill
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UNITED STATES DISTRICT COURT
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MAYDAY HEALTH,

Plaintiff,

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RAÚL R. LABRADOR, Attorney General of Idaho, in his official capacity,

Defendant.

Case No.

MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

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I. INTRODUCTION

Plaintiff Mayday Health is a 501(c)(3) non-profit public health education organization—not a medical provider that prescribes, handles, sells, arranges, or earns revenues from any healthcare service—dedicated to sharing accurate, evidence-based information about reproductive healthcare. After contracting to display a mobile billboard in Nampa, Idaho, reading "Pregnant? Don't want to be? Learn more at mayday.health," Mayday asked the Attorney General to disavow invoking the overbroad unconstitutional authority he has previously claimed to prosecute Mayday for engaging in this First Amendment-protected activity. The Attorney General—who disagrees with 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—refused to do so, both in open court in another proceeding and in response to multiple inquiries. Because the First Amendment shields Mayday from having to choose between coerced silence and fending off the unrenounced threat of unconstitutional penalties for engaging in protected speech, Mayday brings this motion to prevent further violation of its constitutional rights.

Mayday will likely prevail on the merits of its First Amendment claim because the First Amendment absolutely protects the publication of truthful information on an issue of public concern. The U.S. Food and Drug Administration (FDA) has approved abortion pills for safe and effective use and adopted official guidance that currently permits those drugs to be prescribed online and delivered through the mail. The Attorney General may not prevent Mayday from providing this information to Idahoans—or information involving the availability of legal abortion services generally—just because Idaho has made most abortions illegal and the Attorney General disagrees with the content and the viewpoint that leads Mayday to publish it.

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 enjoin the Attorney General from taking any action under any law—including Idaho Code §§ 18-603, 18-607, 18-622, 18-623, and 48-601—to penalize or threaten to penalize Mayday for displaying its mobile billboard in Idaho, or for publishing its website to Idahoans.

II. 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 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 at 1-2; Declaration of Leo Raisner ("Raisner Decl.") ¶ 2. It does not encourage or intend for any person to make any particular decision in response to the healthcare information it provides.

Mayday's website provides information about abortion, morning-after pills, birth control, and gender-affirming care. *See* Sieff Decl. Ex. 1; Raisner Decl. ¶¶ 2-3. 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. Raisner Decl. ¶¶ 3-4. Much of the linked information comes from clinicians, lawyers, and health experts. *Id*. If medically appropriate, some third-party clinics may provide access to abortion pills. *Id.* ¶ 4. The FDA has repeatedly and as recently as 2025 confirmed the safety of such medication, Sieff Decl. Exs. 4-7, as have independent and rigorous scientific studies published in peer-reviewed journals like the New England Journal of Medicine, *id.* Ex. 8.

Mayday does not sell, handle, or benefit financially from the sale of abortion pills, and operates independently from organizations that do. *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.*

Mayday's mission is nevertheless controversial. Attorneys General in Mississippi, Arkansas, and South Dakota have threatened or brought sham claims under their states' consumer protection laws in attempts to prevent Mayday from publishing in their states. *See, e.g.*, Sieff Decl. Exs. 10-12. These attorneys general have baselessly argued that the information Mayday publishes constitutes "deceptive" commercial advertising, or even aids, abets, or solicits criminal activity, and is thus unprotected. *See id.* None have prevailed on the merits of these claims.

B. Attorney General Labrador Threatens to Punish Abortion-Related Speech

After *Dobbs* enabled Idaho to outlaw most abortions, the Attorney General asserted sweeping powers to not only prohibit the practice of an abortion, but also information with even the slightest tendency to promote access to abortion care. The Attorney General claims these powers under several Idaho laws. Idaho Code §§ 18-622 and 18-8801 *et seq.*, for example, make it a crime to perform or attempt to perform an abortion in the state. Idaho Code § 18-603 further states that anyone who "wilfully publishes any notice or advertisement of any medicine or means for producing or facilitating a miscarriage or abortion" commits a felony. Idaho Code § 18-607 adds that anyone who "offers to sell," "advertises, or displays for sale anything specially designed to terminate a pregnancy" commits a misdemeanor. Idaho Code § 18-623 makes it a felony to "recruit" an Idaho minor to obtain an abortion without their parent's knowledge. And Idaho law also treats any persons who "aid and abet" or otherwise "advise[] and encourage[]" the commission of an Idaho crime as principal offenders. *Id.* § 18-204. A conviction for any of these crimes carries penalties including jail time and fines. *Id.* §§ 18-112, 18-113.

The Attorney General asserted the authority to suppress and punish the dissemination of abortion-related information under these authorities in an opinion letter to Idaho Representative Brent Crane on March 27, 2023. Sieff Decl. Ex. 13. The letter stresses the Attorney General's view that Idaho law not only empowers him to prosecute persons who provide abortion pills, but also any person generally involved in "the promotion of abortion pills to the public." *Id.* at 2. It makes no exception for speech, such as educational materials, public health information, or advocacy. Although the Attorney General withdrew the opinion letter for procedural reasons, he refused to disavow its substance at a hearing in another case in this District, and the Ninth Circuit has determined that his position stated in the letter thus continues to constitute an actionable threat. *See Planned Parenthood Great Nw., Haw., Alaska, Ind., Ky. v. Labrador*, 122 F.4th 825, 834–36,

845–50 (9th Cir. 2024).

The Attorney General has also taken a broad view of his power to prosecute speech that, in his view, intends to encourage or enable abortions. In defending his authority to prosecute "abortion trafficking" under Idaho Code § 18-623, for example, the Attorney General argued that "any speech" intended to enable minors to obtain an out-of-state abortion "is integral to criminal conduct" and thus unprotected and subject to penalties. Appellant's Reply Br., *Matsumoto v. Labrador*, No. 23-3787, ECF No. 43.1 at 11 (9th Cir. filed Feb 7, 2024). The Ninth Circuit rejected that position, affirming the relevant parts of a preliminary injunction because the Attorney General's view of what speech he is allowed to punish "goes well beyond" what the First Amendment allows, reaching speech that does not solicit, aid, or abet any criminal activity—especially when his position is considered in conjunction with Idaho's broad aiding-and-abetting statute. *Matsumoto v. Labrador*, 122 F.4th 787, 811, 813 (9th Cir. 2024). Undeterred, the Attorney General continues to press an expansive view of what abortion-related speech he is empowered to label criminal conduct and prosecute. *See* Def's Mem. in Supp. of Mot. for Summ. J., *Matsumoto v. Labrador*, Case No. 1:23-cv-0323-DKG, ECF No. 137-1 at 15-16 (D. Idaho filed April 16, 2026) (arguing that speech that tends to encourage minors to obtain abortion care, without regard for parental consent, is speech integral to criminal conduct punishable as a deceptive practice).

C. Mayday Contracts to Display A Mobile Billboard In Nampa, But Attorney General Labrador Refuses To Renounce Prosecuting Mayday For Displaying It.

To raise awareness about the availability of reproductive health services to communities across the country, Mayday publicizes its website through billboards, plane-pulled banners, art installations, apparel, and other tangible media. Raisner Decl. ¶ 5. As part of these efforts, on April 7, 2026, Mayday contracted with a sign-truck operator to display a mobile billboard displaying the message "Pregnant? Don't want to be? Learn more at www.mayday.health" in Nampa. *Id.* ¶ 7.

The billboard was to be displayed on a truck and driven around on April 20, 2026. Mayday made a non-refundable payment of $11,375 to secure the mobile billboard's placement. *Id*.

Mayday knew displaying the billboard in Nampa was likely to draw a negative reaction from Idaho state officials including the Attorney General. *Id.* ¶¶ 8-9. It was aware, for example, of the Attorney General's demonstrated hostility toward abortion, his assertion of broad authority to punish "the promotion of abortion pills," his refusal to disavow that position in open court, and his aggressive litigation positions taking an overbroad view of what types of abortion-related speech are putatively integral to criminal conduct. Given Mayday's own experiences fending off meritless threats from hostile state attorneys general in Mississippi, Arkansas, and South Dakota, Mayday sought to contact the Attorney General to avoid another needless dispute.

Mayday's counsel accordingly sent formal correspondence by email and FedEx to the Attorney General's office on April 8, 2026. *See* Sieff Decl. Ex. 14. The letter explained that Mayday's planned billboard campaign disseminated information and expressed a point of view fully protected by the First Amendment. Among other authorities, the letter cited decisions from a federal district court in the Southern District of New York temporarily enjoining the South Dakota Attorney General from penalizing Mayday for publishing an identical sign earlier this year, *Mayday Health v. Jackley*, 2026 WL 143372 (S.D.N.Y. Jan 17, 2026), and reaffirming that the First Amendment protects Mayday's speech, *Mayday Health v. Jackley*, No. 1:26-cv-00078-KPF, ECF 48 at 15:12-17:4 (S.D.N.Y. Feb. 17, 2026) (preliminary injunction warranted if Court had retained jurisdiction) (attached as Sieff Decl. Ex. 15 for ease of reference). The letter requested confirmation before April 15, 2026, that the Attorney General would take no action to prevent Mayday from displaying that billboard, nor penalize Mayday for doing so, under any state law.

After the requested deadline passed without a response from the Attorney General's office,

on the morning of April 17, 2026, Mayday's counsel sent an email forwarding its prior correspondence directly to deputy litigators in his office—James Craig, Aaron Green, and Kyle Grigsby—involved in defending the Attorney General's asserted authority to penalize abortion-related speech in both the *Matsumoto* and *Planned Parenthood* cases. Sieff Decl. Ex. 16. Receiving no response, Mayday's counsel, at around 11:00 a.m. Pacific Time that same day, called the Attorney General—including his general line, as well as the direct lines for Craig, Green, and Grigsby—and left individual voice messages with each of them requesting a conversation to discuss the same non-enforcement assurances. Sieff Decl. Ex. 17. The Attorney General's office did not return Mayday's calls. *Id*.

D. Mayday Self-Censors in Response to The Attorney General's Unrenounced Threat

Faced with the threat of impending and unrenounced prosecution for its speech—and potentially subject to imprisonment for up to five years, a fine of up to $50,000, or both—Mayday was forced to suspend its Nampa billboard campaign on April 17, 2026, and surrender its non-refundable payment, as it continued to seek assurances. Raisner Decl. ¶ 14. More than a week later, on April 27, 2026, a deputy in the Attorney General's office finally responded. Refusing to disavow bringing an enforcement action against Mayday, the deputy stated only that the "Attorney General does not provide legal advice to private parties." Sieff Decl. Ex. 18. Never mind that Mayday was not seeking legal advice. And never mind that attorneys general—including Attorney General Labrador—routinely enter into non-enforcement, stand-still, and similar agreements with potentially regulated parties.[1] The message from the Attorney General's office was clear: Mayday

[1] Attorney General Labrador often enters formal arrangements to that effect. *See* Consent Decree, *Planned Parenthood Great Northwest v. Labrador*, No. 1:23-cv-0142-BLW, ECF No. 193 (D. Idaho filed July 17, 2025); Consent Decree, *In re: Att'y Gen. Investigation of Kootenai Hosp. District*, No. CV25-24-0249 (Idaho Second Jud. Dist. Ct. filed May 10, 2024).

should stay silent, or else speak at its peril.

Although Mayday remains committed to its mission of providing truthful, evidence-based information to the public, the Attorney General's refusal to disavow legal action against Mayday has forced Mayday to weigh the risks and costs of defending legal actions against its desire to continue its educational efforts. Raisner Decl. ¶¶ 17-20. Already, Mayday has refrained from engaging in protected speech to avoid incurring future charges and legal costs defending that speech, including by suspending its Nampa billboard campaign. *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 media coverage. *Id.* ¶ 18.

E. Mayday Files This Action to Vindicate Its Constitutional Rights

Mayday filed this action on May 29, 2026, to prevent the Attorney General from silencing its protected speech. *See* Compl. (ECF No. 1).

III. LEGAL STANDARD

A preliminary injunction should issue where a movant demonstrates (1) a likelihood of success on the merits, (2) irreparable harm absent preliminary relief, and that (3) the balance of equities and (4) the public interest both support an injunction. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *Coffman v. Queen of Valley Med. Ctr.*, 895 F.3d 717, 725 (9th Cir. 2018). The last two factors merge when, as here, the government is the opposing party. *Hecox v. Little*, 104 F.4th 1061, 1073 (9th Cir. 2024) (citing *Nken v. Holder*, 556 U.S. 418, 435 (2009)).

IV. ARGUMENT

A. Mayday Is Likely To Prevail On The Merits

The reproductive health information Mayday publishes is both true and of great public

interest. The Attorney General's unrenounced threat to penalize Mayday for publishing that information—or to prevent Mayday from publishing it at all—is an unconstitutional prior restraint, as well as a content- and viewpoint-based restriction of First Amendment-protected speech that fails strict or any level of constitutional scrutiny.

1. 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). 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 billboards publicizing it to audiences offline—fall 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. 5 and 6 at 1 (attaching FDA's current official Risk Evaluation and Mitigation Strategy (REMS) guidance); *see also id.* Exs. 4, 7-9 (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. 3 at 1-2. Mayday does not provide legal advice or direct any action that would violate any state's laws. *Id.* Exs. 2-3; Raisner Decl. ¶ 5. Instead, Mayday links to third-party resources a reader can consult to make their own choices. Sieff Decl. Exs. 1-3;

Raisner Decl. ¶ 6.

Binding precedent, and decisions from federal courts across the country, leave no doubt that the First Amendment protects Mayday's speech. The Ninth Circuit has already explained to Attorney General Labrador that providing exactly this type of "information related to the availability of abortions, education on reproductive health care options, and instruction as to how to access an abortion legally" is speech the First Amendment "squarely protect[s]." *Matsumoto*, 122 F.4th at 812 (enjoining the Attorney General from making similar threats). And federal district courts have likewise held that the 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, *Welty v. Dunaway*, 791 F. Supp. 3d 818, 831 (M.D. Tenn. 2025) (Gibbons, J., sitting by designation), as well as "any speech connected to obtaining such care" generally since abortion "is not unlawful" everywhere in the United States, *Yellowhammer Fund v. Marshall*, 776 F. Supp. 3d 1071, 1108 (M.D. Ala. 2025) (M. Thompson, J.).

The Second Circuit's decision in *NIFLA v. James*, 160 F.4th 360, 379-80 (2d Cir. 2025)—which affirmed protections for mirror-image publishing activities *by abortion opponents*—underscores the First Amendment's application here. That case involved anti-abortion non-profits' First Amendment rights to disseminate "links and instructions for accessing" third-party providers of unregulated abortion *reversal* services "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 were "morally motivated," "receive no remuneration or financial benefit for engaging in" their speech, and "do not provide" the procedures, "but rather provide the public with information . . . and access to third-party providers," the Second Circuit affirmed that the First Amendment protected their websites. *Id.* at 375-76. So, too, Mayday's opposite viewpoint here.

It makes no difference that it is now illegal to provide most abortions in Idaho 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 in doing so here, either.

2. The Attorney General's Unrenounced Threats Violate the First Amendment

The Attorney General's unrenounced threats to punish and prevent Mayday from publishing truthful speech of public concern are actionable because the Attorney General has refused repeated requests to disavow enforcing Idaho Code §§ 18-603, 18-607, 18-622, and 48-601 against Mayday's protected expression, and continues to argue in open court for such authority. *See Planned Parenthood Great Nw.*, 122 F.4th at 838-39 (finding the Attorney General's refusal to disavow the broad enforcement authority claimed in the March 27, 2023 opinion letter sufficient to establish a threat of enforcement); *Matsumoto*, 122 F.4th at 798-99 (similar refusal to disavow enforcement of Idaho Code § 18-623 created actionable injury in fact). These unrenounced threats effect not just a prior restraint, but a content- and viewpoint-based restriction of speech. The strictest constitutional scrutiny applies several times over, and the Attorney General cannot satisfy that standard.

"[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 scrutiny, it has confined those interests to the 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 unrenounced threat not only because he seeks 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 regulation 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 restrictions are subject to at least strict scrutiny, *Reed v. Town of Gilbert*, 576 U.S. 155, 168-69, 171 (2015), and may be unconstitutional per se. *See Junior Sports*

Mags. Inc. v. Bonta, 80 F.4th 1109, 1123-24 & 1124 n.1 (9th Cir. 2023) (Van Dyke, J., concurring) (explaining that the Supreme Court "has repeatedly emphasized the First Amendment's near-absolute prohibition on laws that restrict speech based on the viewpoint of the speaker"); *Cath. Charities v. Whitmer*, 162 F. 4th 686, 696 (6th Cir. 2025) (same).

The Attorney General could not justify his threats even assuming strict scrutiny—and not a per se rule—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 unconstitutional. *Reed*, 576 U.S. at 163. The government "bears the burden of proving" the suppression of speech is necessary to serve a compelling interest and is the least restrictive means of serving that interest. *United States v. Playboy Ent. Grp., Inc.*, 529 U.S. 803, 816 (2000). This means the government "must specifically identify an actual problem in need of solving, and the curtailment of free speech must be actually necessary to the solution." *Brown v. Ent. Merchants Ass'n*, 564 U.S. 786, 799 (2011).

Nothing justifies the Attorney General's unrenounced threat 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 statutes addressed in the Attorney General's March 27, 2023, opinion letter—including Idaho Code §18-622—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). Mayday is not a provider, and his failure to do so is dispositive.

The Attorney General's unrenounced threats thus violate the First Amendment for the same reasons a New York federal court determined that the South Dakota Attorney General's threat to prosecute Mayday for displaying the same billboard publicizing its website violated the First Amendment in *Mayday Health*, 2026 WL 143372 at *1, and *Mayday Health*, No. 1:26-cv-00078-KPF, ECF 48 at 15:12-17:4 (attached as Sieff Decl. Ex. 15). The same conclusion applies here.

B. Mayday Will Suffer Irreparable Harm Absent An Injunction

Mayday has already and will continue to suffer irreparable injury absent relief. Raisner Decl. ¶¶ 17-21. 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. *See Los Angeles Press Club v. Noem*, 171 F.4th 1179, 1190 (9th Cir. 2026).

Already, the Attorney General's refusal to disavow prosecution under Idaho law has had—and will continue to have—a chilling impact on Mayday's speech. 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. ¶¶ 17-21. It has cancelled its mobile billboard campaign and refrained from posting any new signs in Idaho. *Id.* ¶¶ 14, 18. Those changes in Mayday's behavior are more than enough to establish a chilling effect. *See Cuviello v. City of Vallejo*, 944 F.3d 816, 833 (9th Cir. 2019) (a "chill" on First Amendment rights is irreparable harm "even if it results from a threat of enforcement rather than actual enforcement").

C. Mayday Satisfies The Remaining Preliminary Injunction Factors.

The remaining factors—the balance of equities and the public interest—merge because the government is the defendant. *Hecox*, 104 F.4th at 1073. They favor a preliminary injunction here.

Absent relief, Mayday will suffer a loss of its First Amendment rights or substantial penalties for exercising those rights. Raisner Decl. ¶¶ 17-21. Equity and the public interest favor plaintiffs "whose First Amendment rights are being chilled" by government action, as it is "always in the public interest to prevent the violation of a party's constitutional rights." *Imperial Sovereign Ct. of Montana v. Knudsen*, 170 F.4th 820, 876 (9th Cir. 2026) (quotations omitted). In contrast, the Attorney General has no interest in unconstitutional threats. *Zepeda v. I.N.S.,* 753 F.2d 719, 727 (9th Cir. 1983).

V. CONCLUSION

Mayday respectfully requests an order preliminarily enjoining the Attorney General from taking any action under any law—including Idaho Code §§ 18-603, 18-607, 18-622, 18-623, and 48-601—to penalize or threaten to penalize Mayday for displaying its mobile billboard in Idaho, or for publishing its website to Idahoans.

Dated: May 29, 2026

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

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**Pro hac vice* applications forthcoming

CERTIFICATE OF SERVICE

I hereby certify that on the date set forth below I served a true and correct copy of the foregoing **MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION** was served by electronic mail upon all registered CM/ECF users, and by United States Postal service upon all non-registered CM/ECF users in this case as indicated below:

Raúl R. Labrador
Office of the Attorney General
State of Idaho
700 W. Jefferson Street
P.O. Box 83720
Boise, ID 83720

Dated this 29th day of May, 2026.

/s/ Kelly O'Neill
Kelly O'Neill

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF IDAHO

MAYDAY HEALTH, Plaintiff, vs. **RAÚL R. LABRADOR**, Attorney General of Idaho, in his official capacity, Defendant.	Case No.

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

I, Adam S. 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 May 27, 2026, available at https://www.mayday.health/.

3. Attached hereto as **Exhibit 2** is a true and correct copy of Mayday Health's Frequently Asked Questions web page, captured May 27, 2026, available at https://www.mayday.health/faq/.

4. Attached hereto as **Exhibit 3** is a true and correct copy of Mayday Health's Options page of external links, captured May 27, 2026, available at https://www.mayday.health/options-2/.

5. Attached hereto as **Exhibit 4** 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.

6. Attached hereto as **Exhibit 5** 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.

7. Attached hereto as **Exhibit 6** 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.

8. Attached hereto as **Exhibit 7** 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.

9. Attached hereto as **Exhibit 8** 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.

10. Attached hereto as **Exhibit 9** 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.

11. Attached as **Exhibit 10** is a true and correct copy of an Administrative Subpoena issued to Mayday Health by the Office of the Attorney General of Mississippi to Mayday Health, in or around July 2022.

12. Attached as **Exhibit 11** is a true and correct copy of a cease and desist letter from Arkansas Attorney General Tim Griffin to Mayday Health, dated July 29, 2025.

13. Attached as **Exhibit 12** is a true and correct copy of a cease and desist letter from South Dakota Attorney Marty Jackely to Mayday Health, dated December 10, 2025.

14. Attached as **Exhibit 13** is a true and correct copy of an opinion letter from Attorney General Raúl R. Labrador to Idaho Representative Brent Crane, dated March 27, 2023.

15. Attached hereto as **Exhibit 14** is a true and correct copy of a letter from Adam S. Sieff to Attorney General Labrador, dated April 8, 2026.

16. Attached hereto as **Exhibit 15** is a true and correct copy of the decision by the United States District Court for the Southern District of New York in *Mayday Health v. Jackley*, No. 1:26-cv-00078-KPF, ECF 48 at 15:12-17:4 (S.D.N.Y. Feb. 17, 2026). Although the District Court—having previously granted a temporary restraining order—was required to deny Mayday's motion for a preliminary injunction on abstention grounds (*id.* at 14), it concluded that "absent *Younger* abstention, this Court would be granting plaintiff's motion for injunctive relief," and provided detailed analysis explaining that conclusion. *Id.* at 16.

17. Attached as **Exhibit 16** is a true and correct copy of my email to deputy litigators in Attorney General Labrador's office, James Craig, Aaron Green, and Kyle Grigsby, dated April 17, 2026.

18. Attached as **Exhibit 17 is** a true and correct copy of a call log reflecting phone calls I placed to Attorney General Labrador's general line, as well as the direct lines for Craig, Green, and Grigsby, on April 17, 2026, which were not returned.

19. Attached as **Exhibit 18** is a true and correct copy of an email from a deputy litigator in the Attorney General's office, Jim Craig, to my co-counsel, Wendy Heipt, dated April 27, 2026.

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

Los Angeles, California
May 29, 2026

By: _____
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

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. 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.

Additional Resources

Links to trusted organizations.

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

Abortion decision support

All-Options

Abortion pill FAQs

Plan C

What to expect

HowToUse

We Testify: Self-managed abortion

We Testify: Abortion 101

Reprocare

Financial support

National Network of Abortion Funds

Women's Reproductive Rights Assistance Project

Questions on logistics/delivery times/support while waiting

r/abortion

Reprocare

I Need an A: Abortion stories

We Testify: Abortion stories

Online/phone medical support

M+A Hotline

r/abortion

In-person medical support

Will medical staff know if I've used abortion pills?

Abortion Finder

I Need an A

Emotional support

Reprocare

Exhale Pro-Voice

Legal support

If/When/How Repro Legal Helpline

Pregnancy Justice

Privacy support

Digital Defense Fund

Reproductive Justice

SisterSong

State-by-state guide to pills

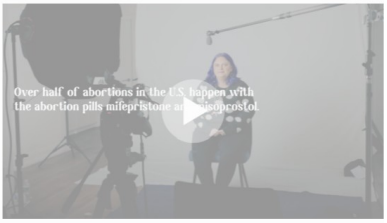
Plan C

Donate or Share

Donate Today

Share Us on Social

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

Mayday Medicines, Inc. 767 Broadway #1555 New York, New York 10003

For media inquiries only:
media@mayday.health

Exhibit 2

This site collects zero data that could identify a visitor.

Quick Exit ES MAYDAY.HEALTH Donate Merch Resources

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.

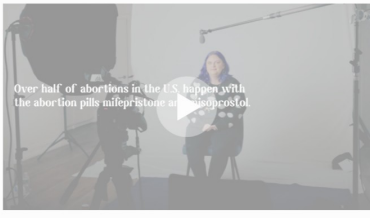
Are abortion pills safe?

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.

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.

Mayday Videos



Mayday Featured

The New York Times · TIME · The Atlantic · AP · MPB Mississippi Public Broadcasting

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media@mayday.health

Exhibit 3

This site collects zero data that could identify a visitor.

Quick Exit ES MAYDAY.HEALTH Donate Merch Resources

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

Order from:

Abuzz

- 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

Aid Access*

Aid Access is experiencing longer delivery times than usual

- SHIPS TO ALL 50 STATES
- COST: SLIDING SCALE
- DELIVERY WITHIN 5 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.

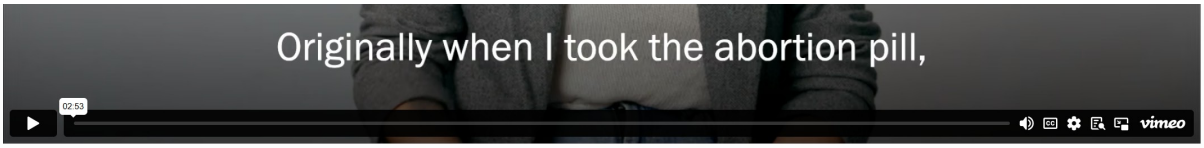
Want more information and other ways to get pills?

Visit Plan C's state by state guide.

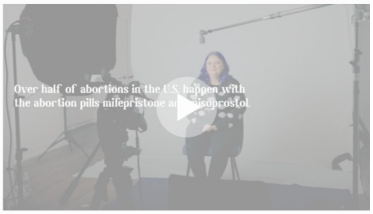
Visit Red State Access for info on community support networks (volunteers who provide pills for free).

Info on digital privacy, legal concerns, and medical questions

Privacy Guide **Medical Hotline** **Legal Helpline**



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 · IndyStar. · AXIOS · COSMOPOLITAN · NOW THIS

MAYDAY.HEALTH

Mayday Medicines, Inc. 767 Broadway #1555 New York, New York 10003

For media inquiries only:
media@mayday.health

Exhibit 4

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.

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 5

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

Content current as of:
01/17/2025

Regulated Product(s)
Drugs

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

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 6

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 7

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 8

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.

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

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Exhibit 09

JAMA | Special Communication | WOMEN'S HEALTH

The US Food and Drug Administration's Regulation of Mifepristone

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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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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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Exhibit 10

STATE OF MISSISSIPPI

ADMINISTRATIVE SUBPOENA

STATE OF MISSISSIPPI
OFFICE OF THE ATTORNEY GENERAL

IN THE MATTER OF: MAYDAY.HEALTH ("MAYDAY")

TO: **OLIVIA MORRELL RAISNER**
Individually, and in her capacity as
Co-Founder of Mayday.Health ("MAYDAY")
1825 7TH Street NW, Apt. 412
Washington, DC 20001-3196

MAYDAY.HEALTH ("MAYDAY")
1825 7TH Street NW, Apt. 412
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Pursuant to Miss. Code Ann. Section 75-24-27, and by the authority vested in the Attorney General, you are hereby required to deliver copies of the documents specified to James Rankin, Special Assistant Attorney General, Post Office Box 220, Jackson, MS 39205, james.rankin@ago.ms.gov, no later than August 15, 2022.

DEFINITIONS

1. **"AGENT"** refers to any person empowered to represent or act on another's behalf, including, but not limited to, all employees, contractors, consultants, lobbyists, volunteers, or board members.
2. **"ALL"** shall be construed to include the collective as well as the singular and shall mean "each," "any," and "every."
3. **"YOU" or "YOUR"** refers to the entity to which this Administrative Subpoena is intended, including all owners, officers, agents and employees thereof, and any predecessor, successor, parent company, subsidiary, d/b/a, and affiliated companies or other entities.
4. **"ANY"** shall be construed to mean "any and all."
5. **"COMMUNICATIONS," "COMMUNICATED,"** or **"COMMUNICATING"** shall refer to any and all methods of giving and/or exchanging information by verbal expression, gesture, writings, electronic, and/or any other means of conveying information and/or requests for information by such means, including, without limitation, the transmission or receipt of information in person or by telephone, electronically, email and/or through correspondence. "Communications" shall include, without limitation, copies of correspondence, emails and like that are provided to you by others.
6. **"DOCUMENT(S)"** and **"DOCUMENTATION"** mean any writing or any other tangible thing, whether printed, recorded (in audio, video or by any other means), reproduced by any process, or written or produced by hand, including, but not limited to, letters, memoranda, notes, opinions, books, reports, studies, agreements, statements,

communications (including inter-company and intra-company communications), correspondence, telegrams, logs, bookkeeping entries, summaries or records of personal conversations, diaries, calendars, telephone messages and logs, forecasts, photographs, tape recordings, models, statistical statements, graphs, laboratory and engineering reports, notebooks, charts, plans, drawings, minutes, bylaws, resolutions, records of conferences, expressions or statements of policy, lists of persons attending meetings or conferences, lists of clients or customers or suppliers, reports or summaries of interviews, opinions or reports of negotiations, brochures, pamphlets, advertisements, circulars, trade letters, press releases, drafts of any document and revisions of drafts of any document, and any other similar paper or record. The term "document" also includes a copy of a document where the copy is not exactly the same as the original. The term "document" also includes emails and other documents made or stored in electronic form, whether kept on computers, computer tapes, disks or drives of any type, or other media upon which information may be recorded.

7. **"INCLUDING"** is used merely to emphasize certain types of documents requested and should not be construed as limiting the request in any way.

INSTRUCTIONS

1. When providing your responses, indicate the Request to which each document or answer responds.
2. For each document that you produce, produce the current version together with all earlier editions or predecessor documents during the relevant time period, even though the title of earlier documents may differ from current versions.

3. Each page of a produced document shall have a legible, unique page identifier ("Bates Number") branded onto the image at a location that does not obliterate, conceal, or interfere with any information from the source document.
4. To the extent that such documents exist in Excel or some other spreadsheet, produce the document in Excel.
5. You may, in lieu of producing original documents, produce photographic reproductions of documents, provided that the reproductions are accurate and legible, and provided that you retain the originals from which the reproductions were made until the final disposition of the matter.
6. Produce all described documents in your possession, custody, or control without regard to the person or persons by whom or for whom the documents were prepared (e.g., your employees, distributors or dealers, competitors or others).
7. If, after exercising due diligence to secure the answer, you cannot answer a question in full, state your answer to the fullest extent possible and state why you are unable to answer the question fully. If the question does not apply to you, indicate that it is not applicable and state why it is not applicable.
8. If any responsive document was, but no longer is, in your possession, custody or control, produce a description of each such document. The description shall include the following:

a. the name of each author, sender, creator, and initiator of such document;

b. the name of each recipient, addressee, or party for whom such document was intended;

c. the date the document was created;

d. the date(s) the document was in use;

e. the title of the document;

f. a detailed description of the content of the document;

g. the reason it is no longer in your possession, custody or control; and

h. the document's present whereabouts and custodian thereof.

9. In the event a document that is responsive to these requests is not in your possession but you have a right to obtain the document or a copy of the document from a third party, you must obtain it (or a copy) and produce it in response to these requests.

10. If the document is no longer in existence, in addition to providing the information indicated above, state on whose instructions the document was destroyed or otherwise disposed of, and the date and manner of the disposal.

11. Produce the entire document; do not mask any portion of any document. Produce all attachments to responsive documents attached to the responsive documents.

12. Provide a key to all abbreviations used in documents and attach the key to the appropriate documents.

13. You have an affirmative duty to supplement your responses with any new and or different information and/or documents that become available to you.

14. Any documents that are withheld in whole or in part from production based on a claim of privilege shall be assigned document control numbers (with unique consecutive numbers for each page of each document). For purposes of this instruction, each attachment to a document shall be treated as a separate document and separately logged, if withheld, and cross referenced, if produced. You shall also provide a statement of the claim of privilege and all facts relied upon in support of the decision

to withhold each document. For each document identified on the Company's privilege log, state:

a. the document's control numbers;

b. all authors, writers, senders, creators, or initiators of the document;

c. all addressees of the document;

d. all recipients of the document or of any copies of the document, to the extent not included among the documents' addressees;

e. the date of the document and whether it is a draft or final;

f. a description of the subject matter of the document;

g. the nature, type, and grounds of the privilege that the Company is asserting for the document (e.g., attorney-client privilege or work product privilege);

h. the identity of any attorney or attorneys who are acting in their attorney capacity in connection with said document and whether the document a) directly requests that attorney to provide legal advice; b) whether the document is providing legal advice by the attorney; or c) the document contains or refers to specific identifiable legal advice provided by the attorney; if the communication falls neither in subparagraph a) or b), additionally state the following:

   i. the lines on which the allegedly privileged communication is contained; and

   ii. whether the alleged privileged communication has been redacted with the balance of the document produced.

i. the Specification(s) of this Request to which the document is responsive;

j. whether the document has been produced in redacted form;

k. if an email that is part of a chain, identify all other reproductions of the chain email and cross reference.

DOCUMENT REQUESTS

REQUEST NO. 1: Provide all contact information for Mayday.Health, or any entity doing business as Mayday.Health, and for any of its agents or employees, including, but not limited to, names of all individuals, physical addresses, mailing addresses, telephone numbers, and email addresses.

REQUEST NO. 2: Provide a copy of all articles of incorporation, applications for licenses, certificates, and/or registrations, and/or any other filing on behalf of Mayday.Health, or any entity doing business as Mayday.Health, with any state or federal governmental entity.

REQUEST NO. 3: Provide a copy of all documents, advertisements in any form, or other representations that you have made and/or caused to be distributed in the State of Mississippi.

REQUEST NO. 4: Provide the number of billboards you previously used and/or are currently using for Mayday.Health in the State of Mississippi, including the exact location of each billboard and the company providing the service.

REQUEST NO. 5: With respect to each billboard you identified in Request No. 4, provide the entire content of the billboard, including all information displayed, dates of display, and all documents and information related to payments you made for any billboard or other forms of advertising in the State of Mississippi. This request also includes, but is not limited to, payments you have made for billboard services provided to Mayday.Health by Trailhead Media, LLC.

REQUEST NO. 6: Provide all contact information for Aid Access, and any of its agents or employees, including, but not limited to, names of all individuals, all physical addresses, all mailing addresses, telephone numbers, and email addresses.

Exhibit 11

TIM GRIFFIN
ATTORNEY GENERAL

July 29, 2025

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

Re: Notice of Cease and Desist

Dear Ms. Raisner:

The Office of the Arkansas Attorney General ("OAG") is the State's chief consumer advocate and law enforcement officer. To fulfill these duties, the OAG is empowered to investigate business practices and to enforce consumer protection laws where violations exist.

Recently, the OAG received information that Mayday Medicines Inc. d/b/a Mayday Health is advertising that certain medical pills that induce abortions may be obtained in all States, including Arkansas. The OAG independently reviewed Mayday's website and verified this allegation.

Abortions are prohibited in Arkansas pursuant to Ark. Code Ann. § 20-16-1304 *et seq.*, except for specific, extenuating circumstances. Moreover, Ark. Code Ann. § 20-16-1504 specifically makes it a crime "to provide any abortion-inducing drug via courier, delivery, or mail service." Consequently, abortion pills may not legally be shipped to Arkansas.

Furthermore, Mayday's website states that "[a]bortion pills are safe and effective." A recent study, however, 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.

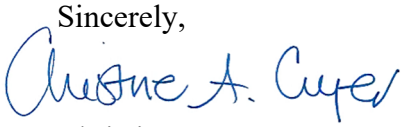
Based on this information, it appears that some of your business practices may constitute false, deceptive, and unconscionable trade practices under the Arkansas Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101 *et seq* ("ADTPA"). The Attorney General of Arkansas demands that you **IMMEDIATELY CEASE AND DESIST** from conducting any advertising related to the delivery of abortion drugs into the State of Arkansas. If you refuse to comply, a formal investigation will be opened. Additionally, the Attorney General may bring a lawsuit against you for violations of the ADTPA. If successful, you may face civil penalties up to $10,000 per violation.

To avoid further action, please notify the OAG of the steps you have taken to remedy this situation within 14 days of the date of this letter. Your response should be in writing and addressed to:

Office of the Arkansas Attorney General
c/o Christine Cryer
101 West Capitol Avenue
Little Rock, AR 72201

Alternatively, you may provide your response by email to Christine.Cryer@ArkansasAG.gov. You may also use this email address to communicate any questions or concerns about this letter.

Sincerely,



Christine Cryer
Deputy Attorney General

Exhibit 12

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,
South Dakota Attorney General

Exhibit 13

STATE OF IDAHO
OFFICE OF THE ATTORNEY GENERAL
RAÚL R. LABRADOR

March 27, 2023

BY HAND DELIVERY

The Honorable Brent Crane
Idaho House of Representatives
Idaho State Capitol
700 W. Jefferson Street, Rm. EW46
Boise, Idaho 83702

Re: Request for AG Analysis

Dear Representative Crane:

This letter is in response to your recent inquiry regarding Idaho's criminal prohibitions on abortion. Specifically, you asked whether Idaho's abortion prohibitions preclude 1) the provision of abortion pills, 2) the promotion of abortion pills, and 3) referring women across state lines to obtain abortion services or prescribing abortion pills that will be picked up across state lines. Idaho law prohibits each of these activities.

1) Idaho's criminal prohibition on performing an abortion includes providing abortion pills. Idaho's criminal law defines abortion to mean "the use of *any means* to intentionally terminate the clinically diagnosable pregnancy of a woman with knowledge that the termination by those means will, with reasonable likelihood, cause the death of the unborn child." Idaho Code § 18-604(1) (emphasis added). The criminal abortion statute, to which the statutory definition of "abortion" applies, does not distinguish between an abortion carried out as a medical procedure and an abortion carried out by pills or chemicals; the use of *any means* to carry out an abortion is prohibited. *See* Idaho Code § 18-622.

2) Two Idaho criminal statutes prohibit promoting abortion pills to the public. Idaho Code section 18-603 prohibits the promotion of abortion pills, unless the promoter is a licensed physician: "Every person, except licensed physicians . . ., who willfully publishes any notice or advertisement of any medicine or means for

EXECUTIVE OFFICE
P.O. BOX 83720, BOISE, IDAHO 83720-0010
TELEPHONE: (208) 334-2400, FAX: (208) 854-8071
LOCATED AT 700 W. JEFFERSON STREET, SUITE 210

producing or facilitating a miscarriage or abortion . . . is guilty of a felony." Idaho Code § 18-603. Similarly, under Idaho Code section 18-607, "[a] person who . . . offers to sell, . . . advertises, or displays for sale anything specially designed to terminate a pregnancy, or held out by the actor for that purpose, commits a misdemeanor." The statute has several exceptions, but none of them apply to the promotion of abortion pills to the public.

3) Idaho law prohibits an Idaho medical provider from either referring a woman across state lines to access abortion services or prescribing abortion pills for the woman to pick up across state lines. Idaho law requires the suspension of a health care professional's license when he or she "*assists* in performing or attempting to perform an abortion." Idaho Code § 18-622(2) (emphasis added). The plain meaning of assist is to give support or aid. An Idaho health care professional who refers a woman across state lines to an abortion provider or who prescribes abortion pills for the woman across state lines has given support or aid to the woman in performing or attempting to perform an abortion and has thus violated the statute.

Please let me know if you have any additional questions.

Sincerely,

Raúl R. Labrador

RAÚL R. LABRADOR
Attorney General

RRL:kw

Exhibit 14

Davis Wright Tremaine LLP

27th Floor
350 South Grand Avenue
Los Angeles, California 90071

Adam S. Sieff
adamsieff@dwt.com
213.633.8618

April 8, 2026

VIA EMAIL

Hon. Raul R. Labrador
Idaho Attorney General
700 West Jefferson Street, Suite 210
P.O. Box 83720
Boise, Idaho 83720-0010
AGLabrador@ag.idaho.gov

Re: Mayday Health Planned Campaign

Dear Mr. Labrador:

This firm represents Mayday Health, a 501(c)(3) non-profit public health education organization that publishes factual information about reproductive healthcare. Mayday Health is not a medical provider and does not prescribe, handle, sell, or earn revenue from any healthcare product or service. Mayday has contracted to display a mobile billboard in Nampa, Idaho on April 20, 2026, stating: "*Pregnant? Don't want to be? Learn more at mayday.health.*" A copy of the billboard is attached. This letter seeks confirmation that your office will take no action to prevent Mayday from displaying that billboard, or penalize Mayday for doing so, under any state law.

Truthful speech about matters of public concern receives virtually absolute protection under the First Amendment. *See Bartnicki v. Vopper*, 532 U.S. 514, 527, 535 (2001); *Garrison v. Louisiana*, 379 U.S. 64, 74 (1964). The government accordingly may not punish or prevent the publication of truthful information about reproductive healthcare, even in states like Idaho that have made most abortions illegal. *See Bigelow v. Virginia*, 421 U.S. 809, 815 n.5 (1975). *Bigelow* is on point. The case held that a Virginia law criminalizing the dissemination of information that allegedly "encourage[d] or prompt[ed] the procuring of an abortion" infringed a Virginia newspaper's 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. The Supreme Court held Virginia had no valid "interest in shielding its citizens" from this information. *Id.* at 827-28.

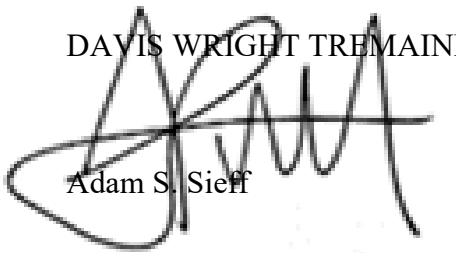
Idaho likewise has no power to restrict what Idahoans may read or hear about reproductive healthcare. The Ninth Circuit reaffirmed this principle against your office in *Matsumoto v. Labrador*, 122 F.4th 787, 812 (9th Cir. 2024), where it explained that the First Amendment "squarely protect[s]" providing "[i]nformation and instructions regarding the availability and

means of procuring an abortion procedure or drug," including "who the provider is, when and where the procedure would take place, or what a drug would cost."

Please therefore **confirm before April 15, 2026** that your office **will not take any action** against Mayday, the billboard operator Mayday has contracted with, or any other third parties under any state law—including but not limited to the Idaho Consumer Protection Act—either to prevent Mayday from displaying its billboard, or to penalize Mayday, the billboard operator, or any other third party for enabling or causing its display.

A federal court in the Southern District of New York temporarily enjoined the South Dakota Attorney General from penalizing Mayday for publishing identical materials earlier this year, *Mayday Health v. Jackley*, 2026 WL 143372 (S.D.N.Y. Jan. 17, 2026) (entering TRO), and later reaffirmed that the First Amendment protects Mayday's speech, *Mayday Health v. Jackley*, No. 1:26-cv-00078-KPF, ECF 48 at 15:12-17:4 (S.D.N.Y. Feb. 17, 2026) (preliminary injunction warranted if Court retained jurisdiction). We would expect the same result here.

DAVIS WRIGHT TREMAINE LLP



Adam S. Sieff


Pregnant?
Don't want to be?
Learn more at:
MAYDAY.HEALTH

Exhibit 15

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MAYDAY HEALTH,	:	Docket No.: 26-cv-00078
Plaintiff,	:	
v.	:	
MARTY J. JACKLEY,	:	New York, New York
	:	February 11, 2026
Defendant.	:	

PROCEEDINGS BEFORE
THE HONORABLE KATHERINE POLK FAILLA
UNITED STATES DISTRICT JUDGE

APPEARANCES:

For Plaintiff: DAVIS WRIGHT TREMAINE, LLP
BY: ADAM SIEFF, ESQ.
CHELSEA KELLY, ESQ.
AMBIKA KUMAR, ESQ.
350 S. Grand Avenue, 27th Floor
Los Angeles, California 90071

For Defendant: OFFICE OF THE ATTORNEY GENERAL
OF SOUTH DAKOTA
BY: MARTY J. JACKLEY, ESQ.
AMANDA MILLER, ESQ.
PAUL SWEDLUND, ESQ.
1302 East SD Highway 1889, Suite 1
Pierre, South Dakota 57501

Transcription Service: Marissa Lewandowski
Phone: (631) 813-9335
E-mail:marissamignano@gmail.com

Proceedings recorded by electronic sound recording;
Transcript produced by transcription service

THE DEPUTY CLERK: Your Honor, this is in the matter of Mayday Health vs. Jackley.

Counsel, please state your name for the record, beginning with plaintiff.

MR. SIEFF: Good afternoon, Your Honor. This is Adam Sieff of Davis Wright Tremaine for plaintiff. I am joined on the line with Counsel Chelsea Kelly and Ambika Kumar.

THE COURT: Good afternoon. This is Judge Failla. And I'm just confirming, Mr. Sieff, that you and your team are able to hear me.

MR. SIEFF: Confirmed, Your Honor. We can hear you.

THE COURT: Much appreciated, thank you.

And then representing Mr. Jackley this afternoon, which includes Mr. Jackley.

MR. JACKLEY: Good afternoon, Your Honor and Counsel. South Dakota Attorney General Marty Jackley, Civil Chief Amanda Miller, and Solicitor General Paul Swedlund.

THE COURT: Thank you all very much. Happy to have you all participating in this conference this afternoon.

What I am going to do now is to read into the record my oral decision. And I decided to give

an oral decision because I wanted to get information to you as quickly as possible. So I'll give you an opportunity to mute yourselves because there isn't oral argument, and I'll begin momentarily. Thank you.

Let me begin also by thanking you for your written submissions and for your oral presentations on January 16th and 29th of this year. I've considered all of those. I've considered as well, the post-hearing submission from Mr. Jackley. And I will now issue my oral decision on plaintiff's motion for a preliminary injunction.

As just a bit of procedural review, this Court heard a telephonic oral argument on plaintiff's motion for a temporary restraining order on January 16th of 2026. It issued an oral decision later that day granting the motion. And my oral decision was by my standards, long for an oral decision, it was nine pages. And I am incorporating here its discussion about the background section, the applicable law for a temporary restraining order, and its analysis of personal jurisdiction under New York's long-arm statute, which is founded Civil Practice Law and Rule Section 302(a).

And so I won't be repeating those

discussions here, but I will simply add to the injunctive relief discussion what the parties already know to be the standard, which is that a party seeking a preliminary injunction must show a likelihood of success on the merits, the possibility of irreparable harm if preliminary injunction is not granted, a balance of hardships tipping in the moving party's favor and the public's interest being served, or at least not disserved by relief. One case for that proposition is *Salinger v. Colting*, 607 F.3d 68, a Second Circuit decision from 2010. Where a state or federal government is a party, then factors three and four often merge. One case for that is *Nken vs. Holder,* 556 U.S. 418 from 2009.

So those things that I've just mentioned are what I'm not reconsidering. But what I have reconsidered is my Younger abstention analysis, and that is in light of the parties' submissions and my own research. In particular, and for the reasons that I'm about to describe, I do believe that the law requires me to abstain from exercising federal jurisdiction in this case, and as a result, I am denying plaintiff's motion for a preliminary injunction.

So I am focusing my discussion this

afternoon on Younger abstention law. I know that the parties are aware of Younger abstentions, so I'll discuss it in rather brief terms. It was summarized by the Second Circuit in the case of *Diamond "D" Construction Corporation vs. McGowan*, 282 F.3rd 191, in 2002. But rather than read all of these cites into the record, I'm just going to excerpt a couple of quotes that I think are important.

The Circuit found that *Younger v. Harris*, 401 U.S. 37, from 1971, generally requires federal courts to abstain from taking jurisdiction over federal constitutional claims that involve or call into question ongoing state proceedings. Although the Younger abstention doctrine was born in the context of state criminal proceedings, it now applies with equal force to state administrative proceedings. This doctrine of federal abstention rests foursquare on the notion that in the ordinary course, a state proceeding provides an adequate forum for the vindication of federal constitutional rights. Therefore, giving the respect to our coequal sovereigns, the principles of our federalism demand we generally prohibit federal courts from intervening in such matters. That is the end of my

quotation from that case.

Younger abstention is mandatory when, number one, there is an ongoing state proceeding; number two, an important state interest is involved; and number three, the plaintiff has an adequate opportunity for judicial review of his constitutional claims during or after the proceeding. Cases for that proposition include *Spargo v. New York State Commission on Judicial Conduct*, 351 F3d 65, a Second Circuit decision from 2003. When Younger applies, abstention is mandatory and its application deprives the federal court of jurisdiction in the matter. And that is found in cases including *Colorado Water Conservation District versus United States*, 424 U.S. 800 from 1976.

There are two exceptions recognized for Younger abstention. They're commonly referred to as the bad faith and extraordinary circumstances exceptions. In connection with the TRO hearing, plaintiffs suggested that the bad faith exception applied and as cited support the Second Circuit's decision in *Cullen vs. Flagler,* 18 F.3rd 96 from 1994 and Judge Gershon's decision in *Brooklyn Institute of Arts and Sciences v. City of New York*, 64 F. Supp. 2d 184, an Eastern District decision

from 1999.

After the TRO hearing and in connection with the preliminary injunction hearing, I did a deeper dive into Second Circuit case law in this area, which made it clear that the bad faith exception and the inquiry into it was more nuanced than it originally appeared. The *Cullen* case that I mentioned was one of the first in the Circuit to articulate the exception.

And here again, rather than putting citations into the record, I'm going to excerpt a few quotes from the decision. "Intervention would still be warranted upon a showing of bad faith, harassment or any other exceptional circumstance that would call for equitable relief. Generally, for such a showing to be made, the party bringing the state action must have no reasonable expectation of obtaining a favorable outcome. But a refusal to abstain is also justified where a prosecution or proceeding has been brought to retaliate for or to deter constitutionally protected conduct, or where a prosecution or proceeding is otherwise brought in bad faith or for the purpose to harass."

In that case, the Second Circuit found that based on a past history of personal conflict between

the plaintiff and the local school board, the strictly ad hominem manner in which the school board had disciplined him, they found that the school board disciplinary proceedings were retaliatory in nature and calculated to chill First Amendment expressive activity.

But later Second Circuit cases made clear that the bad faith exception also has a subjective component to it. One of those cases is *Schlagler v. Phillips*, 166 F.3rd 439, from 1999. The plaintiff in that case had posted pro-skinhead stickers in a Cafe in Monroe, New York and was charged with aggravated harassment under the New York penal law. While the criminal case was pending, he brought a Section 1983 action challenging the statute on First Amendment grounds. The district court rejected the state's Younger argument, concluding that although there was no evidence of any prosecutorial animus towards Schlagler, the statute itself was facially unconstitutional and therefore any prosecution under it could only be brought in bad faith. The Second Circuit reversed, reasoning that because the prosecution was not retaliatory or otherwise illegitimate in its motivation and in fact was nothing more than a straightforward enforcement of

the laws of New York, I found the case did not fall within the bad faith exception. In particular, the Court in *Schlagler* found that the district court's focus on the First Amendment and the issues related to the First Amendment, and I'm now going to quote, "Undercuts the rationale set forth in Younger, which was also a First Amendment challenge to a state criminal prosecution. Younger narrowly limited exceptions to cases involving retaliatory or bad faith efforts to regulate speech. If the district court's interpretation of the *Cullen* exception were followed to its logical conclusion, the exception would swallow the Younger rule."

Later on, the Court found that if the facts show that the prosecution is in retaliation for past speech or shows a pattern of prosecution to inhibit speech beyond the acts being prosecuted, the exception should apply and abstention may be improper. It wasn't found there, and therefore, the Court ruled as it did.

Later on in 2002, the Second Circuit tried to harmonize its case law on the bad faith exception. And that was in the *Diamond "D" Construction Corporation* case I mentioned a few moments ago. And that case detailed the history of

the exception in Second Circuit and Supreme Court case law. But it concluded, and again here I'm excerpting without giving the cites, "Our most recent cases concerning the bad faith exception have further emphasized that the subjective motivation of the state authority in bringing the proceeding is critical to, if not determinative of, this inquiry. A state proceeding that is legitimate in its purposes but unconstitutional in its execution, even when the violations of constitutional rights are egregious, will not warrant the application of the bad faith exception. Later on, the Court finds that we give states the first opportunity, but not the only or last, to correct those errors of a federal constitutional dimension that infect its proceeding."

And then still later, the Court says, "Federal interference with state proceedings, because it necessarily presumes that the state court review will be inadequate, affronts the dignity of the state sovereign. However, as we recognized in *Cullen*, a state has no interest in continuing actions brought with malevolent intent. Thus, it is only when the state proceeding is brought with no legitimate purpose that the state interest in

correcting its own mistakes dissipates and along with it, the compelling need for federal deference." That's the end of that quote.

This court has reviewed all of these Second Circuit decisions on the bad faith exception issued after *Diamond "D"* -- actually, all of ones really issued after *Cullen*. And I will tell you that there are some instances in which there are short-hands to that are used that I think arguably conflate the requirements of the exception.

As one example of that, in the case of *Wilson v. Emond*, 373 F.App'x98 in 2010, a Second Circuit decision from 2010, the Court referred to the bad faith exception as covering cases of proven harassment or prosecutions undertaken by state officials in bad faith without hope of obtaining a valid conviction. And the Court there didn't really get into the subjective element, although I suppose the reference to bad faith may have made it implicit. And so there are some other cases that really don't speak at length about the subjective element, and they include *Weiss v. New York*, 2024 Westlaw 283-7623, *Daniel vs. Doe 1 through Doe 10*, 2024 Westlaw 213-1446, *Lowell v. Vermont Department of Children and Families* 835 F. App'x 637, and then

Glatzer v. Barone 394 F. App'x 763.

But there are other Second Circuit decisions that have confirmed the continuing importance of the subjective component of the bad faith inquiry. They include the Second Circuit's 2020 decision as distinguished from its 2019 decision in *Trump vs. Vance* 977 F.3rd 198, *Miller vs. Sutton* 697 F. App'x 27 from 2017, *Schorr v. DoPico* 686 F. App'x 34 also from 2017, *Jackson Hewitt Tax Services Incorporated vs. Kirkland*, 455 F. App'x 16 Second Circuit decision from 2012.

And I'll note as well that in the case of *Kern vs. Clark*, 331 F.3d 9, a Second Circuit decision from 2003, they actually remanded to the district court for a hearing on the subjective element of the bad faith exception. And the quote of import there is, "In the present case, the factfinder could infer bad faith or improper motive if it credited the evidence that Kern claims demonstrates that the defendants aggressively prosecuted him in a string of weak cases brought on behalf of Kern's political enemies."

So turning now to my analysis, with that case law out of the way, as suggested by my TRO decision and my questioning two weeks ago, I find

that the pending civil enforcement action under SDCL Section 37-24-23 meets all three of the Younger criteria, and that for me the remaining question was whether the bad faith exception applies. I find that it does not.

Focusing first on the subjective analysis, the Court cannot find on the record before it subjective bad faith on the part of Mr. Jackley. The South Dakota Attorney General's Office received numerous complaints, formal and informal, regarding Mayday's gas station placards. Mr. Jackley was requested by the Governor of South Dakota to look into the matter. And to be clear, I don't find that to be an indication of pretext or bad faith, and I don't think it is analogous to what happened in Judge Gershon's decision. Mr. Jackley then sent a cease and desist letter to Mayday. I understand him to have considered proceeding under South Dakota Criminal Statutes concerning solicitation and facilitation, but to have instead chosen the less drastic option of a civil enforcement action under South Dakota's deceptive trade practices statute. Mr. Jackley also cited the example of, all caps, JEN as an abortion rights organization whose conduct he believes balances First Amendment rights of free

expression with South Dakota laws restricting abortion access. On the objective front, I cannot say that Mr. Jackley has no reasonable expectation of obtaining a favorable outcome in the civil enforcement action.

Now, as I will elaborate in just a moment, I do believe that the proper way to view Mayday's website and the materials on it is noncommercial speech subject to protection under the First Amendment. But I understand that Mr. Jackley holds a different view and believes that abortion pill providers who cannot sell their products in South Dakota are using Mayday as an end run around the restrictive statutes of that state such that the speech is commercial and potentially within the ambit of the statute that I cited earlier, and I think he should be permitted to pursue those arguments in South Dakota court.

In light of the findings I've just made, I am constrained to find that Younger abstention applies and that I lack jurisdiction to consider plaintiff's motion for a preliminary injunction. Now, as suggested by my introductory comments to the bad faith exception, federal courts have to trust their state court analogs, and I trust that the

South Dakota court will get it right.

Let me just note on that point that I've done my best here -- I suppose that goes without saying. I've done my best to interpret Second Circuit law on the Younger abstention doctrine and its bad faith exception. If I've gone too far, if I've misunderstood the law or where it is today, I invite the Second Circuit to clarify my jurisdictional obligations to clarify the bad faith exception and, as appropriate, to reverse me. And I say that not because I'm here tempting fate, but because unless there be any doubt about this, I absolutely agree that this case is the mirror image of the factual situation presented in the Second Circuit's late 2025 decision in *National Institute of Family and Life Advocates v. James*, 160 F.4 360. I think that the Second Circuit's analysis applies equally here and that absent Younger abstention, this Court would be granting plaintiff's motion for injunctive relief. My read -- what the materials I have before me suggest that Mayday's website contains, under what I will call the NIFLA case, noncommercial speech. It is speech that is based on moral beliefs with no economic motivation. The plaintiff does not charge the patrons of the website

or the service providers for referrals and the fact that the website solicits donations does not transform its contents into commercial speech, as made clear by cases including *Connecticut Bar Association vs. United States*, 620 F.3d 81, a Second Circuit decision from 2010. That in turn focused on the Supreme Court's 1988 case in *Riley v. National Federation for the Blind*. The *NIFLA* case as well made clear that if its holding were different than it was, it could potentially inappropriately limit 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 for free. I also do not believe that the website solicits or abets acts that are illegal under South Dakota law. And here I'll just cite to the parties *Ashcroft v. Free Speech Coalition*, 535 U.S. 234, and the section that I was focusing on is found at pages 253 to 254.

And so as a result, I mean, I suspect -- or let me say it this way, if I had jurisdiction, which I don't believe I do, I think the South Dakota statute would be subject to strict scrutiny analysis and we would see whether it was narrowly tailored to serve a compelling state interest under NIFLA, the

answer would probably be no. Indeed, if in fact a court were to find that the statute was noncommercial speech, not sure the statute cited to me under South Dakota law would be applied at all. But as it happens, I have to decide this issue on jurisdictional grounds and given that I am deciding the matter the way I am, I'm denying the motion. I think the next steps for the parties would be -- and I will issue an order to show cause to explain in writing why I should not dismiss this matter for lack of jurisdiction. I'm going to ask the parties to file simultaneous letter briefs on or before March 2nd, 2026. I'm going to direct the clerk of court to terminate the motions that are currently pending at docket entries 14 and 20. I will issue a bottom line order later today that includes the order to show cause language but also gives a written document in case either side wishes to take an appeal. And given the disposition of the motion and my issuance of an order to show cause, I am staying Mr. Jackley's obligation to answer, move, or otherwise respond until after the order to show cause is resolved.

Mr. Sieff, is there anything that is unclear about the decision that I've just issued?

MR. SIEFF: No, Your Honor. I think that that was an extremely helpful explanation of your reasoning, and we appreciate all aspects of the order, and we understand the next steps with respect to responding to the order to show cause.

THE COURT: I appreciate that. Thank you. And let me say this, Mr. Sieff, something I hadn't considered, and I'll say this for both sides, is I suppose if either side were to file an appeal from this decision, you'd have to let me know your view as to whether I had jurisdiction to do anything on the order to show cause. But if you'll excuse my grandmother's old expression, we'll burn that bridge when we get to it.

Mr. Jackley, is there anything that is unclear about my decision?

MR. JACKLEY: Your Honor, I want to be completely respectful of what the Court has said and noting the March 2, 2026 order to show cause filing date. We have a state court hearing scheduled for February 20th. Is it the Court's ruling that that can proceed, or do I need to seek a continuance?

THE COURT: Very fair, sir. Right now, I have denied the plaintiff's application for injunctive relief. I don't even think I have

jurisdiction with this to proceed with the case that is before me. I don't have the power to stop you or to stop the state court from proceeding.

MR. JACKLEY: Thank you, Your Honor.

THE COURT: Of course, sir. Now, if anybody were to tell me otherwise -- if the Second Circuit disagrees, they'd let me know. But no one's told me that yet, and I think the clock is ticking. So I very much appreciate your inquiry so that I could clarify my decision to the extent it was unclear.

MR. JACKLEY: Thank you, Your Honor.

THE COURT: All right. I thank you all very much. I know you've been working very hard on very short time frames. I really do appreciate your efforts. I will let you go because I know you have other things to do. You have my thanks. We're adjourned.

C E R T I F I C A T E

I, Marissa Lewandowski, certify that the foregoing transcript of proceedings in the case of Mayday Health v. Jackley, Docket #1:26-cv-00078-KPF, was prepared using digital transcription software and is a true and accurate record of the proceedings.

Signature Marissa Lewandowski

Marissa Lewandowski

Date: February 12, 2026

Exhibit 16

From: Sieff, Adam <AdamSieff@dwt.com>
Sent: Friday, April 17, 2026 8:43 AM
To: aaron.green@ag.idaho.gov; kyle.grigsby@ag.idaho.gov; james.craig@ag.idaho.gov
Cc: Strobel, Melissa <MelissaStrobel@dwt.com>; Kelly, Chelsea <ChelseaKelly@dwt.com>; Handman, Laura <laurahandman@dwt.com>
Subject: Fw: Mayday Health Planned Campaign

Aaron, Kyle, and James -

Good morning. I represent Mayday Health. Please see my attached correspondence to your office from last week and let me know, today, if your office can provide the assurances we request. I'm reaching out because you've appeared on pleadings in cases that raise similar issues. We're hoping to avoid any disputes here.

You can call my cell at 818-489-4294 or reach me here by email. I'll follow up by phone with your office as well. Time is pressing so I would very much appreciate a response today so I can advise my client before Monday.

Thank you for your attention,
Adam

Adam S. Sieff
Partner, Davis Wright Tremaine LLP
P 213.633.8618 **E** adamsieff@dwt.com
A 350 South Grand Avenue, 27th Floor
Los Angeles, CA 90071

From: Strobel, Melissa <MelissaStrobel@dwt.com>
Sent: Wednesday, April 8, 2026 12:47 PM
To: AGLabrador@ag.idaho.gov <AGLabrador@ag.idaho.gov>
Cc: Sieff, Adam <AdamSieff@dwt.com>; Kelly, Chelsea <ChelseaKelly@dwt.com>; Handman, Laura <laurahandman@dwt.com>
Subject: Mayday Health Planned Campaign

Hon. Raul R. Labrador:

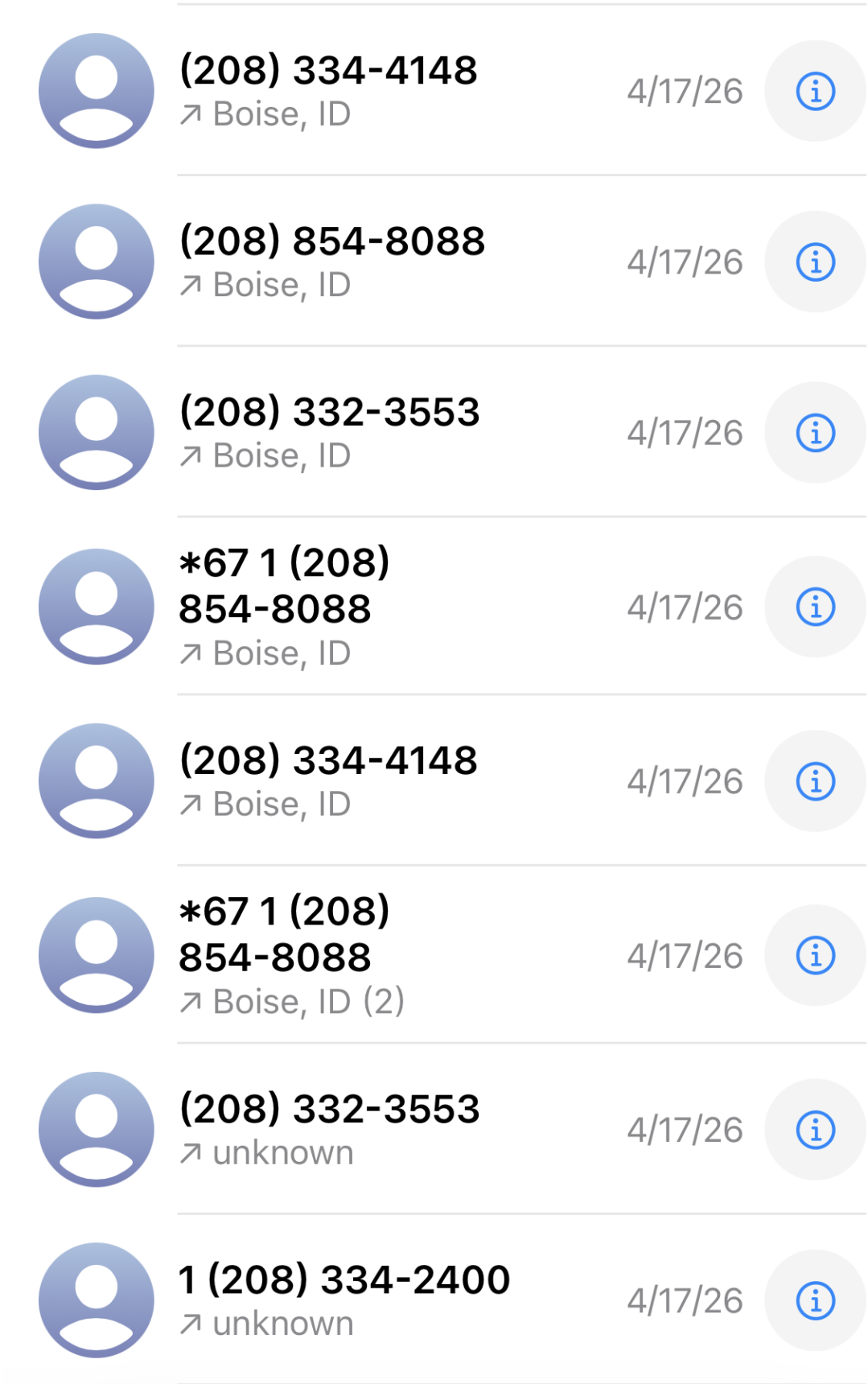
Attached please find correspondence from Adam Sieff, counsel to Mayday Health.
A hard copy will follow via overnight mail.

Best regards,

Melissa Strobel, CCLS
Assistant to John Tate, Mary Haas, Janet Grumer, Sean Sullivan, Vandana Kapur, Adam Sieff & Maria Arakelian | Davis Wright Tremaine LLP
P 213.633.6844 **E** melissastrobel@dwt.com
A 350 South Grand Avenue, 27th Floor, Los Angeles, CA 90071

DWT.COM

Exhibit 17


(208) 334-4148
↗ Boise, ID
4/17/26
(208) 854-8088
↗ Boise, ID
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(208) 332-3553
↗ Boise, ID
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(208) 334-4148
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*67 1 (208) 854-8088
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4/17/26
(208) 332-3553
↗ unknown
4/17/26
1 (208) 334-2400
↗ unknown
4/17/26

Exhibit 18

Archived: Friday, May 29, 2026 9:35:30 AM
From: James Craig
Sent: Mon, 27 Apr 2026 23:26:32
To: Wendy Heipt
Subject: RE: Check in
Importance: Normal
Sensitivity: None

Hi Wendy,

The Attorney General does not provide legal advice to private parties.

Thanks,

Jim

James E. M. Craig | Division Chief
Civil Litigation and Constitutional Defense
Office of the Attorney General | State of Idaho
O: 208-854-8088 | W: ag.idaho.gov

From: Wendy Heipt <wheipt@legalvoice.org>
Sent: Monday, April 27, 2026 8:38 AM
To: James Craig <James.Craig@ag.idaho.gov>
Subject: Check in

Hi Jim,

Good morning. I am hoping you have time today for a quick check-in regarding the mobile billboard that Mayday wants to display. As you know, the billboard will state the following, "*Pregnant? Don't want to be? Learn more at mayday.health*." We want to be sure that neither the AG, nor anyone else, will penalize Mayday or any third party for this display. I would appreciate your response---if you prefer, I am happy to hop on a call. Thank you Jim.

Sincerely,
Wendy

Wendy Heipt
Legal Voice
Senior Reproductive Justice Counsel
Pronouns: she/her
wheipt@legalvoice.org

GET LEGAL VOICE UPDATES

CERTIFICATE OF SERVICE

I hereby certify that on the date set forth below I served a true and correct copy of the foregoing **DECALARATION OF ADAM S. SIEFF IN SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION** was served by electronic mail upon all registered CM/ECF users, and by United States Postal service upon all non-registered CM/ECF users in this case as indicated below:

Raúl R. Labrador
Office of the Attorney General
State of Idaho
700 W. Jefferson Street
P.O. Box 83720
Boise, ID 83720

Dated this 29th day of May, 2026.

/s/ Kelly O'Neill

Kelly O'Neill