SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

THE PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York, Plaintiff, v. HEARTBEAT INTERNATIONAL INC., et al., Defendants.	**REPLY IN SUPPORT OF MOTION TO DISMISS UNDER CPLR § 3211(7) and 3211(g) PURSUANT TO CIVIL RIGHTS LAW §§ 70-a, 76-a** Index No. 45131/2024 IAS Part 46 Hon. Richard G. Latin

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INTRODUCTION

New York's Anti-SLAPP statute imposes a demanding threshold the Attorney General wholly fails to meet. Under CPLR 3211(g), this action *must* be dismissed unless the State demonstrates—through evidence rather than rhetoric—a "substantial basis" in law or fact for the AG's claims. That burden requires "relevant proof," not speculation, policy disagreements, or mere reliance on the complaint's allegations. But the AG offers nothing beyond that: volume in place of substance, conclusory assertions in place of evidence, and politically charged denunciation in place of legal or scientific support.

This case is not a consumer-protection action; it is a SLAPP suit aimed at suppressing Defendants' protected speech on a matter of public concern. Defendants' communications regarding abortion pill reversal ("APR")—a lawful treatment option supported by published case studies, widespread clinical experience, and legislative recognition across numerous states—are fully protected noncommercial advocacy. The AG does not and cannot show otherwise. Nor does she *show*, as opposed to merely *alleging*, that any of Defendants' statements are objectively false or materially misleading. At most, she highlights scientific disagreement, which courts have repeatedly held cannot be policed through state-sanctioned censorship.

Moreover, this SLAPP suit even "fails to survive ordinary CPLR 3211(a)(7) analysis," from which it follows that the AG has "failed to meet the higher burden under CPLR 3211(g)…" *Reeves v. Associated Newspapers, Ltd*., 232 A.D.3d 10, 12, 218 N.Y.S.3d 19, 22 (2024), *leave to appeal dismissed*, 44 N.Y.3d 990, 241 N.Y.S.3d 902 (2025). Dismissal under either CPLR 3211(a)(7) or CPLR 3211(g) is not only warranted but mandated under the First Amendment.

LEGAL ARGUMENT

I. NEW YORK'S ANTI-SLAPP LAW APPLIES TO GOVERNMENT ENFORCEMENT ACTIONS.

The primary rule of statutory construction in New York is that a statute's text governs, absent ambiguity or absurdity. Accordingly, courts "may not create a limitation that the Legislature did not enact." *James B. Nutter & Co. v. County of Saratoga*, 39 N.Y.3d 350 (2023); *accord Matter of Diegelman v. City of Buffalo*, 28 N.Y.S.3d 231 (2016); *Matter of Theroux v. Reilly*, 1 N.Y.3d 232, 240 (2003).

Ignoring that rule, the AG claims anti-SLAPP laws are "patently" inapplicable to her based on transcripts of two unpublished bench rulings. Opp. 2-3. Neither supports her. In the first, the judge said the question was close before somehow concluding that a press release stating "corporations and other powerful interests" file SLAPP suits showed that a government exception exists. *City of New York v. Exxon Mobil Corp.*, Index No. 451071/2021 (Sup. Ct. New York Cnty. Nov. 5, 2024), Doc. No. 210, at 96:1-97:11. In the second, a court *declined to hear the issue* and dismissed the AG's bogus consumer-fraud suit. *People of the State of New York v. JBS USA Food Co.*, Index No. 450682/2024 (Sup. Ct. New York Cnty.), Doc. No. 49 at 4:14-20; *id.* at 43:4-44:3.

The AG grasps at straws because her theory is nonsense in light of the statute's purpose. In the late 1980s, academics sounded the alarm over *government* filing thirty percent of all SLAPP suits. George W. Pring & Penelope Canan, *SLAPPs: Getting Sued for Speaking Out,* 46-82, 216 (Temple Univ. Press 1996). A panel they organized in 1989 included Robert Abrams, New York's *then-Attorney General*. *See* Robert Abrams, *Strategic Lawsuits Against Public Participation*, 7 Pace Envt'l L. Rev. 33 (1989). Abrams helped enact what was then the second-strongest anti-SLAPP law in the country. N.Y. Civ. Rts. Law §70-a (1994). But it proved insufficient as SLAPP

suits continued, with government entities often the filers. *See* George W. Pring & Penelope Canan, *SLAPPs* at 15, 55 n.24.

The 2020 amendments to New York's anti-SLAPP law reasserted New York's free-speech leadership—including against powerful government officials. *See* N.Y. Bill Jacket, 2020 A.B. 5991A, 243d Leg., Reg. Sess., ch. 250, at 16, 23, 25, 29-30, 37, 40 (2020); N.Y. State Legis., Press Release, *Senate and Assembly Majorities Advance Anti-SLAPP Legislation to Protect Free Speech* (July 22, 2020); Senator Brad Hoylman-Sigal (@bradhoylman), X.com (Oct. 29, 2020)(bill sponsor articulating its purpose); *id.* (July 22, 2020)(bill sponsor articulating its purpose). New York used California's statute as a baseline but, unlike other states, ***did not adopt California's government exception***. *See*, *e.g.* Nev. Rev. Stat. §41.637; Ind. Code §34-7-7-2; Va. Code Ann. §8.01-223.2(2); R.I. Gen. Laws §9-33-2(e).

The Uniform Public Expression Protection Act ("UPEPA") was altered in 2020 to provide an *optional* government exception, see *Memorandum After the Public Reading and Comments by 37 Commissioners* (Oct. 21, 2019); Draft UPEPA (Mar. 13-14, 2020), but New York ***did not include it*** in its 2020 amendments. Instead, New York followed thirty-five states with *no* or partial government exemption. *See* **Exhibit 1** to Reply Mem. Florida's anti-SLAPP law expressly subjects government entities to its protections. Fla. Stat. Ann Fla. Stat. Ann. §768.295(2)(a). See *Crosby v. Town of Indian River Shores*, 358 So. 3d 444, 447 (Fla. Dist. Ct. App. 2023).

The AG's reliance on cases from Maine and Massachusetts is unavailing. The Maine court *did not find a government exception*, but on the contrary noted that "unlike statutes in some other states, Maine's anti-SLAPP statute *does not expressly exempt government enforcement actions*…" *Town of Madawaska v. Cayer,* 2014 ME 121, ¶ 14, 103 A.3d 547, 551–52. The Court merely found that a zoning enforcement action "is not an appropriate occasion for application of the anti-

SLAPP statute…" *Id.* at ¶ 16, 103 A.3d at 552. Thus, the Court presumed that, absent an *express* government exemption, the law *would* apply to government entities in an appropriate case.

Massachusetts' law applies narrowly to protect only petitioning of government, requiring the plaintiff who brings a SLAPP suit to prove that a defendant's activity is "sham" petitioning. Mass. Gen. Laws Ann. ch. 231, §59H (2022). Importantly, in *Commonwealth v. Exxon Mobil Corp*., 489 Mass. 724, 729 (2022) the Court found that the Massachusetts AG is *expressly* not a "party" subject to an anti-SLAPP motion under that statute's protection because the AG's "party" status "is mentioned [only] in connection with her capacity to intervene, but not in any other capacity." And the legislative history "makes clear that *the motivation*…was vexatious, *private* lawsuits, *especially* ones filed by developers to prevent local opposition to zoning approval."[1] *Id.* at 732. In CPLR 3211, the term "party" appears throughout, and clearly applies to *any* party, not excluding the AG.

II. THE AG FAILS TO MEET THE "SUBSTANTIAL BASIS" BURDEN.

The "substantial basis in law" standard of CPLR 3211(g) means "such *relevant proof* as a reasonable mind may accept as adequate to support a conclusion or ultimate fact…rather than reliance on *the mere allegations in the complaint*." *Black v. Ganieva*, 236 A.D.3d 427, 428, 228 N.Y.S.3d 91 (2025)(cleaned up). The AG comes nowhere near meeting that burden, but rather merely thumps on the numerosity of "mere allegations in the complaint" without demonstrating with "relevant proof" that even one of Defendants' statements is actually false or misleading.

A. Defendants' APR promotion is noncommercial speech.

The AG makes no showing that Defendants' speech is regulable commercial activity. Under the federal constitutional standard that controls here, the speech of similarly situated

[1] Emphasis added throughout, unless otherwise indicated.

pregnancy help organizations ("PHOs") promoting APR has already been found to be fully protected *noncommercial* speech. *Nat'l Inst. for Fam. & Life Advocs. v. James,* 746 F. Supp. 3d 100, 120 (W.D.N.Y. 2024) ("*NIFLA II*"). For the same reasons this suit is a SLAPP suit, the Court in *NIFLA II* enjoined the AG's lawfare against those PHOs, rejecting application of GBL 349/350 to their APR advocacy. *Id.* at 124.

The AG fails to distinguish *NIFLA II*, providing a ludicrous parenthetical "summary" of its holding: "(granting preliminary injunction against Attorney General in the absence of an evidentiary hearing, and after failing to make evidentiary rulings or rely on expert affidavits where facts regarding APR were disputed)." Opp. 14. That "summary" only highlights why *NIFLA II* must apply here: the district court *did not need to weigh expert testimony and other eviden*ce to determine that the AG's targeting of APR speech by PHOs is noncommercial and thus fully First Amendment-protected.

The AG fails to address the Court's finding, in light of *Bolger v. Youngs Drug Prod. Corp.*, 463 U.S. 60, 65 (1983), that Defendants' promotion of APR is not speech that "does no more than promote a commercial transaction." *Id.* at 120 (quoting *Bolger*, 463 U.S. at 66). Nor has the AG shown any "economic motivation" for Defendants' advocacy because there is none. *Bolger*, 463 U.S. at 67. Even had Defendants referred to a "specific product" in advocating APR, that still would not make their speech commercial. *Id.* *Not one* of the *Bolger* tests is implicated here.

Citing inapposite cases and dicta, the AG argues commercial speech does not require an economic motive. Opp. 17-18. Nonsense. No court has ever so held. Rather, economic motive *must* be "the *primary purpose* for speaking," *Ariix, LLC v. NutriSearch Corp.*, 985 F.3d 1107, 1117 & n.7 (9th Cir. 2021), and pro-life speech like Defendants' is *quintessentially* non-

commercial. *See Greater Balt. Ctr. for Pregnancy Concerns, Inc. v. Mayor and City Council of Baltimore*, 879 F.3d 101, 108-09 (4th Cir. 2018).

Beyond an unpublished Dutchess County Supreme Court order from 1993 (Opp. 8; Opp. Ex. D), the AG provides *zero* New York or Second Circuit authority for the proposition that the speech of a nonprofit PHO is subject to GBL 349/350. That local court applied GBL 349/350 to a PHO and issued a preliminary injunction compelling it to state in its advertising that it was "A pro-life not-for-profit corporation" or "An anti-abortion not-for-profit corporation." That preposterous injunction would not survive one instant of scrutiny today. *Nat'l Inst. for Fam. & Life Advocs. v. Becerra*, 585 U.S. 755, 773 (2018) ("*NIFLA I*"); *Evergreen Ass'n, Inc. v. City of New York,* 740 F.3d 233, 245 (2d Cir. 2014). Lending the appearance of weight to this useless citation, the AG irrelevantly cites *Karlin v. IVF Am., Inc*., 93 N.Y.2d 282, 291 (1999), which merely refers to the legislative intent behind GBL 349/350. Opp. 8.

Because this SLAPP suit attempts to censor protected noncommercial speech, it must undergo strict scrutiny. *See* Mem. in Supp., Doc. 41 at 18 (citing cases). ***The AG waives this issue by failing to brief it.*** The SLAPP suit fails even intermediate scrutiny, ***an issue the AG likewise waives by failing to brief it***. *See* II. C., *infra*.

B. The very existence of a debate over APR precludes this SLAPP suit.

The AG concedes that doctor-supervised administration of supplemental progesterone to counteract the effects of mifepristone is a perfectly lawful reproductive choice. Unable to prevent women from making that choice in consultation with physicians, the AG's workaround is this SLAPP suit.

The safety and effectiveness of APR are supported by *four* peer-reviewed case studies showing a fetal survival rate of between 64-68% when APR is administered within 72 hours post-mifepristone. *See* **Exhibit C** to Motion, Doc. 44 (chart of studies); **Exhibit 2** to Reply Mem.

(copies of studies). It is medical common sense that progesterone in sufficient amounts binds with the same receptors as mifepristone, blocking and counteracting its effects. *See* **Exhibit C** (¶¶49-57).

The AG does not deny that the FDA's pharmacological assessment concludes that "the abortifacient activity of RU-486 [mifepristone] *is antagonized by progesterone* allowing for *normal pregnancy and delivery*." **Exhibit C, ¶**5. Nor does the AG deny that Yale School of Medicine scientist Dr. Harvey Kliman admitted that if one of his daughters accidentally took mifepristone during pregnancy, he would "tell her to take 200 milligrams of progesterone three times a day for several days." *See* **Exhibit A** to Motion, ¶ 57. That's a form of APR. Kliman's clinical intuition is confirmed by Dr. George Delgado, who has vast clinical experience with successful administration of APR, as his case studies show. The AG argues case studies are inadequate evidence, implying that only a randomized, double-blind trial is acceptable. Opp. 11. More nonsense. Such a trial would be utterly unethical, because random assignment to a placebo group would mean death for the unborn child a woman hopes to save. Thus, case studies are the best available evidence. ***And the AG does not deny that mifepristone itself was FDA-approved based on case studies****. See* Mem. in Support at 8 (citing mifepristone case studies).

The AG does not deny that APR is endorsed by the American Association of Pro-Life Obstetricians & Gynecologists, with more than 7,000 members, the Catholic Medical Association, and Canadian Physicians for Life, among others. *See* **Exhibit A** to Motion, ¶59**.** Nor does the AG deny that evidence supporting APR persuaded numerous state legislatures to enact laws requiring that APR be disclosed as a medical option in keeping with informed consent about abortion. *See*

Exhibit 3 to Reply Mem. (chart of pertinent state provisions).[2]

The AG argues, nevertheless, that she has borne her burden under CPLR 3211(g) merely by hurling 150 paragraphs of allegations of false and misleading statements. But none of those statements *is shown* to be actually false and misleading, as opposed to—at worst—eminently debatable. Opp.13.

The AG cites *Smartmatic USA Corp. v. Fox Corp.*, 213 A.D.3d 512 (1st Dep't 2023) for the proposition that her "meticulously drafted complaint" need only make numerous allegations to satisfy the "substantial basis" standard. ***But the AG makes no effort to link any statement from her opposing exhibits to any of her alleges of falsity***.

A careful review of the AG's opposition reveals only *one study*: by a Dr. Mitchell Creinin, a paid consultant for Danco, *the manufacturer of mifepristone*. Given the AG's reliance on Creinin, Defendants note he was censured by the FDA for *research malpractice* following his inadequate response to FDA findings against him. *See* FDA, Warning Letter to Mitchell D. Creinin, MD (June 12, 2002).[3] Creinin's supposedly randomized, double-blind—and thus, as noted above, unethical—study involved a statistically worthless cohort of twelve women, two of whom dropped out. But the results, for whatever they are worth, actually *support* APR.

The AG ***does not deny*** Defendants' contention that Creinin's abruptly terminated study backfired because it revealed that (1) administering progesterone after mifepristone (i.e., APR) gives a pregnant woman a better chance of a healthy pregnancy; and (2) administering progesterone after mifepristone (i.e., APR) gives a pregnant woman a better chance of avoiding

[2] That challenges to these laws in three states have resulted in injunctions (under a theory of compelled speech) is beside the point. The evidence that persuaded many state legislatures to endorse APR is precisely the evidence that precludes this SLAPP suit over a medical debate best resolved by women's personal reproductive choices.

[3] https://www.circare.org/fdawls3/creinin_20020612.pdf

severe bleeding. *See* Mem. in Supp., Doc. 41 at 9-10; **Exhibit A**, ¶¶73-75. ***Therefore, any enhanced risk to a woman taking mifepristone, then changing her mind about a chemical abortion would appear to arise from not receiving counteracting progesterone***. This is borne out by the FDA-required "black box" warning label: "*Mifepristone can cause severe bleeding.*" Progesterone causes *no* bleeding. Also ***not denied*** by the AG. Mem. in Support at 10.

Aside from the Creinin study, the AG's opposition exhibits are nothing more than policy statements against APR and criticisms of APR-supporting studies by speakers who have done *no clinical research* of their own. *See* Opp. Exhibits E-K. The AG merely lines up speakers on her side to *debate* speakers on Defendants' side of the APR issue.

Bereft of valid clinical evidence, the AG relies on inapplicable FTC regulatory cases for the claim that Defendants' pro-APR statements lack "a reasonable basis" because they are not based on "competent and reliable scientific evidence." Opp. 6-7. But those cases involve terms of art in expert agency practice concerning *marketed products*, not a random AG's misapplication of consumer fraud statutes to pure speech about *free services*.

In *F.T.C. v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1185 (N.D. Ga. 2008), a*ff'd*, 356 F. App'x 358 (11th Cir. 2009), the court found that the term "competent and reliable scientific evidence" encompasses "tests, analyses, research, *studies*, or *other evidence* … using procedures generally accepted in the profession to yield accurate and reliable results." Case studies clearly qualify as such evidence—again, the same sort of evidence used to approve mifepristone. Further, the court found that the defendant had *clinical studies* showing that the "*components*" of its product caused weight loss, just not *the product as marketed*. *Id*. at 1195. Here there is only one component—*FDA-approved* progesterone—and no product is involved. Moreover, even where a product is at issue "different scientific evidence is required for different claims impacting different

products…" *Id.* As already shown, case studies are the *only* ethically appropriate evidence respecting APR.

In *F.T.C. v. Nat. Sol., Inc*., 2007 WL 8315533, at *5 (C.D. Cal. Aug. 7, 2007) the Court found that claims about a naturopathic cancer treatment, *marketed for a profit*, lacked a reasonable basis because "Defendants did not provide the Court with even a single scientific study or trial of any kind." Here *multiple* studies support Defendants' position, *including the Creinin/Danco study*.

In sum, the most that is involved here is "legitimate ongoing scientific disagreement." *ONY, Inc. v. Cornerstone Therapeutics, Inc.,* 720 F.3d 490, 498 (2d Cir. 2013). Defendants' statements are thus "*non-actionable opinion*…under New York's General Business Law §349 or New York state common law." *Id.*

In vain does the AG attempt to distinguish *ONY* because the court presumed "non-fraudulent data, based on accurate descriptions of the data and methodology underlying those conclusions…" *Id.* The AG makes no claim of data fraud, and the published APR studies, **Exhibit 2** to Reply Mem., provide "accurate descriptions of the data and methodology…" *ONY*, 720 F.3d at 498. The AG fails to show that any Defendant misrepresented the studies' contents.

Nor is *ONY* distinguishable because promotional materials were directed to "health care providers" rather than "vulnerable consumers." Opp. 21. Health care providers *are* consumers, and the study was promoted in "a press release touting its conclusions and…promotional materials that cited the article's findings." *ONY*, 720 F.3d at 495. Further, the trial court noted that promotional material was distributed "to *current and potential customers*…" *Ony, Inc. v. Cornerstone Therapeutics, Inc.*, 2012 WL 1835671, at *3 (W.D.N.Y. May 18, 2012).

ONY, therefore, stands for the First Amendment principle that the "'State cannot engage in content-based discrimination to advance its own side of a debate.'" *NIFLA II*, 746 F. Supp. 3d at

122, quoting *Sorrell v. I.M.S. Health Inc.,* 564 U.S. 552, 577 (2011). Where scientific debate involves "a sufficiently novel area of research, propositions of empirical 'fact' advanced in the literature may be highly controversial… [and] courts are ill-equipped to undertake to referee such controversies." *ONY*, 720 F.3d

Finding no support under New York or Second Circuit law, the AG relies on district court decisions from North Dakota and California. Opp.17-18. None of them supports her claims of "consumer fraud".

American Medical Association v. Stenehjem, 412 F. Supp. 3d 1134 (D.N.D. 2019) involved one of many state laws requiring physicians to inform patients about APR—evidence that APR is safe and effective. The Court held physicians could not be *compelled* to mention APR because its science is *unsettled*. That is to say, APR is *freely debatable and freely practiced by any physician*. *Id.* at 1151. Thus, *Stenehjem* supports *Defendants'* view of APR.

All-Options, Inc. v. AG of Indiana, 546 F. Supp. 3d 754 (D. Ind. 2021) and *Planned Parenthood of Tennessee & N. Mississippi v. Slattery*, 523 F. Supp. 3d 985 (M.D. Tenn. 2021), both fail for the same reasons. *See* Opp.17-18.

Fargo Women's Health Organization, Inc. v. Larson, 381 N.W.2d 176 (N.D. 1986) was decided when commercial speech had much weaker protection than today. *See* II. C., *infra*. And the defendant there *knowingly lied in ads it ran in telephone books and newspapers* to redirect women seeking abortion from a clinic with a similar name to its own services, and many women were redirected. *Id.* at 181. The AG's suggestion that *Larson* is "almost identical" to this case, Opp. 18, is an egregious misrepresentation.

The AG also relies on two district court decisions in California that statements substantively similar to some the AG identifies are "potentially misleading" "given the lack of

robust scientific study" of APR's effectiveness. Opp.17-18. But those decisions conflict with *ONY* and *NIFLA II*, which bar application of GBL 349/350 to public medical debates over how "robust" the AG thinks science is. *ONY* and *NIFLA II* should control the outcome here.

Lastly, knowing full well that scientific evidence supports Defendants' statements, the AG falls back to the position that *even true statements* could mislead a reasonable person. Opp.18. But the AG vaguely asserts, with *no showing*, that Defendants' *true statements* create "an overall misimpression that APR is proven effective, safe, and uncontroversial." Opp.19. First of all, Defendants have never stated that APR is "uncontroversial." That false allegation aside, statements that are not untrue or *materially* misleading are immune from prosecution under GBL 349/350. *See Plavin v. Grp. Health Inc.*, 35 N.Y.3d 1, 10 (2020). And, as the AG carefully avoids mentioning, in *NIFLA II* "the [AG] conceded that *no one has been harmed by Plaintiffs' statements*." *NIFLA II*, 746 F. Supp. at 122. The *same statements* are at issue here.

C. Even if Defendants' statements were commercial, "heightened scrutiny" would apply.

The AG's complaint would still fail even if, contrary to fact, Defendants' statements were purely commercial. Any restriction of alleged commercial speech promoting APR would still have to directly and materially advance a substantial government interest and be "not more extensive than is necessary to serve that interest." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980). Because commercial speech "furthers the societal interest in the fullest possible dissemination of information," *Bolger*, 463 U.S. at 61, the First Amendment accords it "substantial protection." *Id.* at 68. This requires "heightened scrutiny", given the risk that government seeks "to keep people in the dark" for what it believes "is their own good." *Sorrell,* 564 U.S. at 577. Again, the AG ***fails to brief,*** and thus waives, the issue of heightened scrutiny.

Moreover, the Supreme Court has clarified that even restrictions on *demonstrably* "false" speech (an inherently content-based category) pose a danger of censoring speech with which the government simply disagrees, thus also chilling protected speech. *United States v. Alvarez*, 567 U.S. 709, 720 (2012) (plurality); *id.* at 733-34 (Breyer, J., concurring). Government can restrict "false" speech only if it causes "legally cognizable" or "specific" harms. *Id.* at 720, 723 (plurality); *id.* at 734 (Breyer, J., concurring). Further, "*mens rea* requirements . . . reduce[] an honest speaker's fear that he may accidentally incur liability for speaking." *Id*. at 733 (Breyer, J., concurring).

The AG targets Defendants' speech because of its *content*, deemed "false" or "misleading" based on the AG's preferred sources versus Defendants' sources. And the AG does so with no *mens rea* requirement. This "enforcement action" thus poses a risk of content- and viewpoint-based censorship (and of chilling well-intentioned protected speech) that triggers heightened scrutiny. *See Alvarez*, 567 U.S. at 724-29 (plurality); *id.* at 730-32 (Breyer, J., concurring).

Accordingly, the Second Circuit has long enforced narrow-tailoring requirements for restrictions on commercial speech, rejecting New York's demands for blanket advertising bans versus less-restrictive alternatives. *See, e.g.*, *Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth.*, 134 F.3d 87, 98–103 (2d Cir. 1998); *Alexander v. Cahill*, 598 F.3d 79, 90–94 (2d Cir. 2010). Here, obvious less restrictive alternatives exist, such as government counter-speech. *See NIFLA I*, 585 U.S. at 773; *NIFLA II*, 746 F. Supp. 3d at 121-22. Further, although disclaimer requirements might also be unconstitutional here, they are a more narrowly tailored than outright censorship. *See Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999). That the AG whistled past these options is telling.

CONCLUSION

This SLAPP suit "turns on nothing more than a difference of opinion." *Sorrell*, 564 U.S. at 579; *Thompson v. W. States Med. Ctr.,* 535 U.S. 357, 376 (2002). Simply calling Defendants' speech "misleading advertising" does not justify this suit because a "[s]tate cannot foreclose the exercise of constitutional rights by mere labels." *NAACP v. Button*, 371 U.S. 415, 429 (1963).

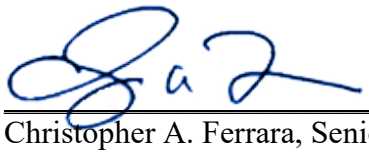
The AG is merely pitting speakers who agree with her against speakers who not only disagree with her but have successfully administered, without charge, *a lawful medical treatment* she opposes. The AG's *merely debatable* claim that APR is "unproven", *see* AG Complaint ¶¶ 5, 11, 81 & 153, does not show it is "*dis*proven" such that its promotion is objectively false or misleading. As the Supreme Court has made clear, the State has no authority to police public medical debates because medical professionals "might have a host of good-faith disagreements, both with each other ***and with the government***, on many topics…." *NIFLA I,* 585 U.S. at 772; *see also id.* at 773.

The AG's attempt to impose her side of the debate over APR by misapplying consumer fraud statutes is the essence of a SLAPP suit barred by CPLR § 3211 (g). Indeed, this suit "fails to survive ordinary CPLR § 3211(a)(7) analysis…" *Reeves*, 232 A.D.3d at 12. Either way, it must be dismissed.

Dated: November 20, 2025
New York, NY

Respectfully submitted,

THOMAS MORE SOCIETY



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WORD COUNT CERTIFICATION

The above signed counsel hereby certify, pursuant to Part 202.8-b of the Uniform Civil Rules for the Supreme Court and the County Court, that, according to the word count tool on Microsoft Word, the total number of words in this brief is 4179.

Dated: November 20, 2025

DEFENDANT'S EXHIBIT 1

GOVERNMENT EXEMPTIONS IN STATE ANTI-SLAPP STATUTES*					
None		*Partial* (only certain officials or types of actions)		*Blanket* (all state entities and enforcement actions)	
Arizona**	Ariz. Rev. Stat. Ann. § 12-751	**California**	Cal. Civ. Proc. Code § 425.16	**Delaware**	Del. Code Ann. tit. 10 § 6002(c)(2)
Arkansas	Ark. Code Ann. § 16-63-501	**Colorado**	Colo. Rev. Stat. § 13-20-1101(8)(a)	**District of Columbia**	D.C. Code Ann. § 16-5505(a)(2)
Florida**	Fla. Stat. Ann. § 768.295(4)	**Connecticut**	Conn. Gen. Stat. Ann. § 52-196a(h)(1)	**Oklahoma**	Okla. Stat. tit. 12 § 1439(1)
Illinois	735 Ill. Comp. Stat. Ann. 110/15	**Georgia**	Ga. Code Ann. § 9-11-11.1(g)	**Vermont**	Vt. Stat. Ann. tit. 12, § 1041(h)(1)
Indiana	Ind. Code Ann. § 34-7-7-2	**Kansas**	Kan. Stat. Ann. § 60-5320(h)(1)		
Maryland	Md. Code Ann., Cts. & Jud. Proc. § 5-807	**Kentucky**	Ken. Rev. Stat. 454.462(2)		
Massachusetts	Mass. Gen. Laws Ann. ch. 231, § 59H	**Louisiana**	La. Code Civ. Proc. Ann. art. 971(E)		
Missouri	Mo. Rev. Stat. § 537.528	**Hawaii**	HI ST § 634G-2(b)(2)		
Nebraska	Neb. Rev. Stat. Ann. § 25-21,241	**Idaho**	S.B. No. 1001, 68th Legis, 1st R.S. (2025), ch.39, § 6-3902(3)(b)		
Nevada	Nev. Rev. Stat. Ann. § 41.635	**Iowa**	Iowa Code § 652.2(3)(b)		
New Mexico	N.M. Stat. Ann. § 38-2-9.1	**Maine**	Maine Rev. Stat. tit.14, §733(3)(B)		
New York	N.Y. Civ. Rights §§ 70-a, 76-a	**Minnesota**	Minn. Stat. 554.08(c)(2)		
Oregon	O.R.S § 31.150 (2025)	**Montana**	H.B. 292, 68th Legis. § (2)(b) (2025)		
Pennsylvania	42 Pa. Stat. 8320.1	**New Jersey**	N.J.S.A. 2A:53A-50(c)(2)		
Rhode Island	R.I. Gen. Laws § 9-33-1	**Ohio**	Ohio Rev. Code §2747.01(C)(2)		
Virginia	Va. Code Ann. § 8.01-223.2	**Tennessee**	Tenn. Code Ann. § 20-17-101		
		Texas	Tex. Civ. Prac. & Rem. §§ 27.003(a), 27.010(a)(1)		
		Utah	Utah Code Ann. § 78B-25-102(3)(b)		
		Washington	Wash. St. 4.105.010(3)(a)(ii)		
16 STATES		*19 STATES*		*3 STATES + DISTRICT OF COLUMBIA*	

* Totals do not sum to 50 states because some states have not enacted anti-SLAPP laws.

* Arizona and Florida expressly allow anti-SLAPP suits against state entities

Progesterone Use to Reverse the Effects of Mifepristone

George Delgado and Mary L Davenport

OBJECTIVE: To present a series of cases demonstrating successful reversal of mifepristone effects in women who chose to reverse the medical abortion process.

CASE REPORTS: Four of 6 women who took mifepristone were able to carry their pregnancies to term after receiving intramuscular progesterone 200 mg.

DISCUSSION: Mifepristone has been available in the US since 2000. By 2008, approximately 25% of abortions prior to 9 weeks were accomplished with mifepristone. Some women who take mifepristone wish to reverse the medical abortion process. Progesterone competes with mifepristone for the progesterone receptor and may reverse the effects of mifepristone. A PubMed literature search from 1996 to May 2012 did not reveal any trials or case studies evaluating the efficacy of progesterone use to reverse the effects of mifepristone.

CONCLUSIONS: Health care professionals should be aware of the possible use of progesterone to reverse mifepristone in women who have begun the medical abortion process by taking mifepristone and then change their minds.

KEY WORDS: medical abortion, mifepristone, progesterone.

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Use of Intravenous Lipid Emulsion to Reverse Central Nervous System Toxicity of an Iatrogenic Local Anesthetic Overdose in a Patient on Peritoneal Dialysis

D Bruce Lange, Daniel Schwartz, Gerald DaRoza, and Robert Gair

OBJECTIVE: To describe a case of severe central nervous system toxicity after an overdose of lidocaine by local infiltration in a peritoneal dialysis patient and subsequent treatment of the toxicity with lipid emulsion.

CASE SUMMARY: A 31-year-old male received an iatrogenic overdose of 1600 mg of lidocaine 2% by infiltration during an attempt to remove and replace a peritoneal dialysis catheter. Within 10 minutes after the last lidocaine injection, the patient exhibited features of local anesthetic toxicity, which included tachycardia, hypertension, shortness of breath, dizziness, and a choking sensation that progressed to hallucinations, dysarthria, and uncoordinated, weak limb movement. Within 10 minutes after administration of a single 1.5-mg/kg intravenous bolus of 20% lipid emulsion, the patient improved dramatically. After observation overnight in a monitored care setting, the patient was discharged home with no apparent neurologic sequelae.

DISCUSSION: Systemic toxicity due to regional anesthesia with local anesthetic agents such as lidocaine has been well described in the medical literature. The use of lipid emulsion as an antidote to the toxicity of local anesthetics and other lipophilic drugs has been suggested as a valuable intervention in both early, rapidly progressive toxicity, as well as toxicity that is refractory to standard treatment. Patients with advanced chronic kidney disease may be more susceptible to systemic effects of lidocaine due to decreased drug elimination.

CONCLUSIONS: Central nervous system toxicity due to an overdose of lidocaine was quickly reversed by intravenous lipid emulsion in our patient.

KEY WORDS: chronic kidney disease, lidocaine, lipid emulsion, local anesthetic, overdose, peritoneal dialysis, toxicity.

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Full case reports, including abstracts, are available free online (www.theannals.com).

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CASE REPORT

Progesterone for preventing pregnancy termination after initiation of medical abortion with mifepristone

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ABSTRACT

Introduction: Abortion is often a difficult and traumatic decision for a woman to make. Perhaps greater distress occurs when a woman commences a medical abortion but then changes her mind and wishes to keep the now-threatened pregnancy. One published case series detailed a potential method to counter/reverse the abortifacient effect of mifepristone by administering parenteral progesterone in such situations.

Objectives: The present report details cases of women in similar circumstances who have been treated with progesterone. The aims were to document occurrences of where women have changed their mind after commencing medical abortion, as well as to explore some of the controversies and clinical issues surrounding their circumstances.

Methods: Women who had commenced medical abortion by ingesting mifepristone but who had not taken misoprostol independently contacted a national pregnancy support service the same day. Those meeting criteria for treatment received progesterone pessaries per vaginum for two weeks.

Results: Cases: 28-year-old woman, 6 weeks plus 1 day gestation; 35-year-old woman, 8 weeks plus 5 days gestation; and 27-year-old woman, 7 weeks plus 3 days gestation. Outcomes respectively were: healthy male baby delivered at 39 weeks gestation; healthy male baby delivered at term; and completed medical abortion.

Conclusions: Women have changed their mind after commencing medical abortion. Progesterone use in early pregnancy is low risk and its application to counter the effects of mifepristone in such circumstances may be clinically beneficial in preserving her threatened pregnancy. Further research is required, however, to provide definitive evidence.

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Abortion; progesterone; informed consent; reproductive rights; coercion; abortion seekers; mifepristone; off-label use

Introduction

Medical abortion using mifepristone and misoprostol has been registered for use in Australia up to 63 days gestation [1]. Abortion is one of the most common gynaecologic procedures performed in Australia [2] with an estimated 80,000 being performed each year [3]. One recent multicentre study reported on 15,000 women who underwent early medical abortion between March 2013 and September 2015 [4]. Results were consistent with international experience in demonstrating a high abortion success rate (complete abortion not requiring surgical intervention) of greater than 95%. This figure did not, however, account for the approximately 13% of women who were lost to follow-up, which was significantly greater in rural and remote areas. This is important from a safety perspective, but also highlights potential deficits in continuity of care by the treating practitioner. Reasons for lack of follow-up were postulated and included time and financial costs associated with rural or remote location [4]. Current recommendations are for access to 24-h clinical and emergency surgical support until the abortion is complete [5].

Issues recounted by women after undertaking abortion include being pressured by others (37–64%), being unsure about the decision at the time (38–54%), needing more time to make the decision (33–52%) and not being counselled on alternatives (45–79%) [6]. Figures for women being coerced to undergo termination of pregnancy are likely to be under-reported due to fear of being turned away from abortion services if the issue is raised [7]. Consequently, a proportion of women commencing the medical abortion regimen may change their mind before completing the drug course.

Progesterone is secreted by the corpus luteum and provides essential early pregnancy support in the luteal phase and first trimester until placental progesterone production begins. Low levels of circulating progesterone have been associated with early miscarriage [8] and there is increasing evidence that progesterone supplementation is beneficial in the setting of recurrent miscarriage [9]. Elsewhere, progesterone is recommended for routine use in situations such as in-vitro fertilisation [10]. Exogenous natural progesterone has no global safety issues when used in the first trimester of pregnancy [11]. Several decades of clinical use and non-clinical evidence have confirmed its safety profile, with no effect on embryo-foetal viability or malformations being identified [12].

The standard combination regimen for early medical abortion is mifepristone 200 mg administered orally, followed by 800 mg buccal misoprostol 36–48 h later [13].

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Mifepristone is a synthetic steroid with high affinity for the progesterone receptor. Progesterone is essential in the maintenance and development of a pregnancy. The competitive inhibition of progesterone's endometrial and myometrial effects by exogenous mifepristone causes deterioration of the endometrium, placental disruption and demise of the embryo. Other effects in pregnancy include increasing uterine contractility and sensitivity to prostaglandins and softening and dilation of the cervix [14]. Of particular significance in the circumstance of ongoing pregnancy after mifepristone administration, evidence demonstrates that mifepristone has no teratogenic effect on the embryo [15], a position which is also held by the American Congress of Obstetricians and Gynecologists [16].

The time-delay between administration of mifepristone and subsequent completion of the medical abortion protocol by taking misoprostol is 24–48h. This period may give women time to think more about their decision and, for some, to change their minds. In such circumstances, a number of women have reported that recommendations from abortion-providers have been to continue with the medical abortion protocol and that women had 'no choice' but to do so [17]. Women in Australia faced with this have sought treatment with progesterone in order to try and save their pregnancy [18] and are the subject of the present report.

Materials and methods

Once a woman made contact with a clinically staffed national pregnancy support service, usually via internet search, she was advised that she had three options: (1) do nothing at all and see if her pregnancy continues or miscarries; (2) continue with the medical abortion process and take the misoprostol; and (3) seek consultation with a doctor willing to prescribe progesterone. Women requesting progesterone were fully informed and given written information. Those wishing to proceed with progesterone treatment provided informed consent for this, including for collection of demographic and treatment/outcome data. If she was $<$48 h since taking mifepristone and she had not taken misoprostol, then she was commenced on progesterone vaginally: 400 mg twice a day for 3 days, then 400 mg at night for the next 6 days, then 200 mg at night for the next 6 days. A pelvic ultrasound scan was arranged to assess pregnancy viability and a follow-up appointment was made for 72 h after commencing progesterone treatment. After two weeks of progesterone, the pregnancy was managed with routine antenatal care on the assumption that the projected duration of action of mifepristone had been overcome [19].

De-identified clinical and demographic data for the present study was provided by the pregnancy support service for secondary analysis by a clinician not involved in care of the women. This project received approval by the Human Research Ethics Committee of the University of New England (HE17-198).

Results – case series

Patient N

A 28-year-old woman, gravida (G) 1, para (P) 0, had her last menstrual period (LMP) 43 days prior to attending an abortion clinic. Mifepristone was ingested at the clinic and that evening she began an Internet search for how to reverse its effects. She made contact with a doctor locally and commenced progesterone pessaries within 28 h of taking mifepristone. She experienced minor vaginal bleeding over the next 2 days. Pelvic ultrasound within 3 days demonstrated a gestational sac but no foetal pole; however, β-hCG level of 8708 IU/L on the day after mifepristone administration was acceptable for a gestation consistent with her menstrual dates. She completed 14 days of vaginal progesterone and follow-up ultrasound at that point showed a viable 8 week and 4 day-sized gestation. The remainder of the pregnancy was uncomplicated and a healthy male baby with no birth defects was delivered at 39 weeks gestation.

Patient T

A 35-year-old woman, G3 P2, had her LMP 61 days prior to attending an abortion clinic. Mifepristone was ingested at the clinic and within 90 minutes she sought to have its effects reversed. She made contact with a local doctor and commenced vaginal progesterone within 3.5 h of taking mifepristone. She experienced vaginal bleeding and a pelvic ultrasound scan in the Emergency Department of a hospital demonstrated a fetal heart beat and viable pregnancy. Follow-up ultrasound a week later again demonstrated a viable pregnancy. She completed 14 days of vaginal progesterone but was then lost to follow-up until she notified the doctor of the uneventful birth of a healthy baby boy with no birth defects 7 months later, likely at term according to her menstrual dates.

Patient O

A 27-year-old woman, G2 P1, had an unknown LMP but stated she had had an ultrasound scan by an abortion provider showing a pregnancy at $7\frac{1}{2}$-week gestation. She had attended an abortion clinic and ingested mifepristone on site. Within 30 min, she began searching for how to reverse its effects. She made contact with a local doctor and commenced vaginal progesterone within 31 h of taking mifepristone. That night she experienced heavy vaginal bleeding with clots and, believing she had miscarried, she did not continue progesterone. Follow-up ultrasound one week after ingesting mifepristone demonstrated an empty uterus and completed abortion.

Discussion

Findings and interpretation

The cases presented here demonstrate that some women who commence the medical abortion process then change their mind and instead wish to keep their pregnancy viable. These women independently and actively sought clinical treatment in the form of progesterone in an attempt to counter or 'reverse' the effects of mifepristone.

It has been proposed that abortion is fundamental to women's health [2]. In this regard, a reversal strategy for women who change their mind presents a dependent but similarly fundamental 'reproductive choice' option. It is one, however, that has more urgent need for action given the

pharmacological/physiological actions of mifepristone, with the highest risk being in the first 1–2 days [19].

Progesterone administration to antagonise the effect of mifepristone in medical abortion is off-label since this is not an indication listed in the drug product information (PI). Drugs are commonly used off-label based on common pharmacology and existing use for comparable approved indications, or where supported by high-quality clinical evidence [20], for example present/recent use of both mifepristone and misoprostol for medical abortion [4]. Where there is lack of good evidence for efficacy but where safety has been considered, exceptional circumstances may apply whereby off-label drug use can be considered appropriate. In justifying progesterone use to reverse a medical abortion: there is a serious underlying condition; there is some evidence to support potential beneficial effect; potential benefits outweigh potential risks; and no other treatment is available or appropriate [21]. Although critics have described such progesterone treatment as 'an affront … to the ethical practice of medicine' [19], these criteria as well as the significant distress of women seeking this treatment appropriately justify its use. Certainly, the unwanted procured termination of an early pregnancy has fittingly been described as entailing 'catastrophic sequelae' [22].

Results of other studies

An early animal study compared three groups of pregnant rats: one group was administered mifepristone only, one group was coadministered mifepristone plus progesterone, and a control group was administered the drug vehicle only. Serial sacrificial measurements were taken at days 1–4 post-administration of the vehicle/agent(s). Analysis demonstrated that after 48 h from administration of the agent, the mifepristone-only group experienced a 66.7% abortion rate while the mifepristone plus progesterone group had a 0% abortion rate compared with controls [23].

One human study reported six cases in the USA where women who had taken the mifepristone component had then changed their mind and sought to counter the abortifacient effect of mifepristone on their pregnancy [24]. Their published protocol recommended progesterone 200 mg intramuscularly be administered: as soon as possible after ingestion of mifepristone, then daily for two more days, then second-daily until 13 days after ingestion of mifepristone, then twice-weekly until the end of the first trimester. In contrast, the regimen for the women discussed in the present study relied on progesterone 200 mg pessaries delivered vaginally, twice-daily for two weeks. Direct comparison of the effectiveness of either of these regimens is not possible due to the small numbers of women included. Similarly, conclusions about the actual effectiveness of progesterone treatment in countering the abortifacient effect of mifepristone, at all or for either methodology, could not be drawn – nor was that the intent of this research.

A group in the USA currently coordinates progesterone-based mifepristone 'reversal' internationally, with a claimed success rate (continuation of pregnancy and delivery of a baby) of approximately 55% [17]. Critics in a recent review have stated that pregnancy continuation rate after ingestion of mifepristone alone is as high as 46% [19]. This figure, however, represents the results from one clinical trial in another published study [25] in which the original authors reported an overall continuation rate of 36.5% across all the clinical trials included. Of note is that the review included studies with faulty criteria for determining embryo survival, such as those that did not differentiate between incomplete evacuation of the uterus and embryo survival among the abortion failures. Furthermore, the review also omitted a number of other key eligible studies from their analysis [26]. The more current and correct pregnancy continuation rate for mifepristone 200 mg administered alone at $\leq$49 days gestation is $<$25% [26].

Strengths and weaknesses

A significant advantage of the regimen presented here is the availability and stability of progesterone as a vaginal pessary compared with parenteral formulations. The latter presents certain barriers including requiring sterile extemporaneous compounding in Australia, reduced stability and shelf-life, higher costs and less acceptable route of administration. In contrast, progesterone pessaries can be stored for longer and be available for use at immediate notice, thus decreasing the potentially adverse lag time between ingesting mifepristone and commencing progesterone treatment. Availability of a parenteral formulation may be less of an issue in other parts of the world where such a product is industrially produced and accessible.

A weakness of this study is the small number of women whose cases were reported. As a case series, data for analysis was only available for several representative women who undertook treatment to reverse the medical abortion they had already commenced. These may represent only a fraction of women who have similarly considered changing their mind after ingesting mifepristone but who have not had the awareness or opportunity to seek progesterone treatment to try and maintain pregnancy viability.

Future questions

There is currently no definitive evidence for the success of using progesterone to prevent the abortifacient effect of mifepristone. The number of cases in the literature does not lend itself to statistical analysis but instead illustrates a low-risk intervention with the potential for substantial benefit for the individual women involved. A placebo-controlled randomised or case–control study may not be ethically acceptable; however, historical control data for abortion completion rates with mifepristone alone has been detailed [26]. Prospective research to appropriate scientific standards is recommended in order to draw substantive clinical conclusions, including investigating effectiveness, formulation and timing issues.

A recent review cited, based on a personal communication with the drug manufacturer, that of the women taking mifepristone in the USA, less than 0.004% later chose to continue their pregnancy [19]. This would indicate that 6 of the approximately 145,434 women undertaking early medical abortion in the USA in 2012 [27] had changed their mind. Elsewhere, it is claimed that since the first case in 2006, there have been over 500 women who changed their mind and sought out progesterone treatment to save their threatened pregnancy [28].

The real prevalence of women who commence medical abortion but who then seek to preserve their pregnancy is

itself a research question. A deeper field of enquiry, however, is that of the reasons and circumstances surrounding women's decisions to abort their medical abortion procedure, given the often significant psychosocial stress involved in such situations and the decision-making process.

Conclusions

There is evidence in Australia that women have changed their minds shortly after commencing early medical abortion. The use of progesterone to counter the effects of mifepristone in such cases may be clinically beneficial in preserving her threatened pregnancy. Where the possible benefit is so great, the low risk of harm from using progesterone as well as the lack of teratogenicity of mifepristone supports this indication. As well as being potentially therapeutic for her pregnancy, such emergency treatment may also address a woman's short- and long-term emotional/psychological distress, and provide her with her rightful reproductive choice options.

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Disclosure statement

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

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A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone

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ABSTRACT:

Background: Some women who take mifepristone, a progesterone receptor antagonist, in order to terminate their pregnancies, change their minds and desire to stop the medical abortion process. There are only two articles in the medical literature documenting the reversal of the effects of mifepristone.

Objective: We present and analyze a series of women who attempted to reverse the effects of mifepristone by taking supplemental progesterone to determine if the reversal of the effects mifepristone with progesterone is possible and safe. Additionally, we compare different progesterone regimens to determine relative efficacies.

Methods: This is a retrospective analysis of clinical data of 754 patients who decided to attempt to reverse the medical abortion process after taking mifepristone but before taking the second drug in the protocol, misoprostol. We followed the patients, who were given progesterone in an effort to reverse

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the effects of mifepristone, and conducted statistical analyses to determine the efficacies of different protocols compared to a control mifepristone embryo survival rate, derived from the literature.
***Results*: Intramuscular progesterone and high dose oral progesterone were the most effective with reversal rates of 64% ($P < 0.001$) and 68% ($P < 0.001$), respectively. There was no apparent increased risk of birth defects.**
***Conclusions*: The reversal of the effects of mifepristone using progesterone is safe and effective.**

Introduction

Medical induced abortion utilizing mifepristone has been available in the United States since 2000. In 2014, 31% of non-hospital induced abortions were medical induced abortions.[1] Some women decide to attempt to reverse the medical abortion process after taking mifepristone but before taking misoprostol, and inquire about the possibility of reversing the effects of mifepristone.[2]

The new FDA protocol, approved for medical abortion in 2016, involves the administration of mifepristone 200 mg orally as a single dose, which leads to embryonic or fetal demise, followed 24-48 hours later by misoprostol 800 mcg buccally as a single dose, which stimulates myometrial contractions. The protocol is approved up to 70 days after the first day of the last menstrual period.[3] Misoprostol is part of the protocol because mifepristone alone has an incomplete abortion rate of 20-40%, as determined by the end point of complete expulsion.[4]

Pharmacology

Mifepristone is a competitive antagonist of progesterone at the progesterone receptor (PR). It binds to the PR twice as avidly as progesterone.[5] Mifepristone is an orally active compound with a nearly 70% absorption rate, but its bioavailability is reduced to approximately 40% because of the first-pass effect.[6]

Demethylation and hydroxylation are catalyzed by CYP3A4; three metabolites retain biologic activity. The half-life of mifepristone is approximately 18-25 hours. Mifepristone and its metabolites can be measured up to 72 hours after an ingested dose.[5] The half-life of progesterone is longer, approximately 25-55 hours.[6,7]

Effects of Mifepristone

By blocking progesterone receptors, mifepristone leads to the separation of the decidua basalis from the trophoblast. This separation diminishes the oxygen and nutrients that can be delivered to the embryo or fetus by the maternal circulation and is the primary embryocidal and feticidal effect of mifepristone.[4,8,9]

In addition to this primary effect, mifepristone causes softening and dilatation of the cervix.[4] It also leads to myometrial contractions, increased myometrial sensitivity to prostaglandins[4,10] and the disinhibition of prostaglandin synthesis by the myometrium.[11]

Progesterone has been shown to have an autoregulatory effect on progesterone synthesis by the corpus luteum. Blocking progesterone receptors with mifepristone decreases progesterone secretion by the corpus luteum.[12]

Logic of Using Progesterone to Reverse Mifepristone Effects

Mifepristone is a competitive inhibitor of the progesterone receptor. It is well known that receptor agonism and antagonism are parts of a dynamic process that can be influenced by changing concentrations of the agonist or antagonist. Therefore, it makes biologic sense that increasing the progesterone levels in a pregnant woman by giving supplemental progesterone would favor the agonist progesterone effects and blunt the abortifacient effects of mifepristone.

An Animal Model

A Japanese rat study provides basic-science evidence of the ability of progesterone to negate the effects of mifepristone. In this experiment, one group of pregnant rats was given mifepristone while a second was given mifepristone and progesterone. In the group that only received mifepristone, only 33% of the pups survived. In the group that received mifepristone and progesterone, 100% of the pups survived. Furthermore, the first group had characteristic changes in the myometrium and ovaries; the group that received the combination had no such changes.[13]

Early Mifepristone Studies Reporting Continuing Pregnancy

When mifepristone was first studied as an abortifacient, misoprostol was not part of the protocol. During the 1980's, researchers determined that even though mifepristone was effective as an abortifacient, they believed it was necessary to add a prostaglandin analog to achieve a satisfactory complete uterine evacuation rate.[4] We must emphasize that the definition of incomplete abortion is incomplete emptying of the uterus.[14] Embryo or fetus survival is not implied.

The earliest studies also revealed that some embryos survived mifepristone. Baulieu, the principal developer of the drug, stated that at 4-7 weeks the percentages of efficacy of the regimen were approximately 70% for complete abortions, 20% for incomplete abortions and 10% for ongoing pregnancies (i.e., presumed embryo survival). For gestations 8-10 weeks, the comparable rates were 50% for complete abortions, 35% for incomplete abortions and 15% for embryo survival.[15]

In 2015, Grossman et al. published a review of the first case series of progesterone reversal of mifepristone, as well as 13 studies from the 1980's, addressing continuing pregnancies after mifepristone. The authors concluded that there was insufficient evidence to show that progesterone therapy improved survival over expectant management, based on the reported high ongoing pregnancy rates in some of these older studies.[16] However, closer scrutiny of the studies cited for high ongoing pregnancy rates reveals inadequate criteria for the diagnosis of continuing pregnancies. Many early researchers focused on an efficacy end point of complete uterine evacuation, and did not distinguish missed or incomplete abortions from continuing pregnancies (embryo or fetus

survival).[17] Only eight studies cited by Grossman had criteria sufficient to determine embryo survival and showed continuing pregnancy rates of 8-25%.[17]

A recent review found that 18 of the 30 articles investigating mifepristone monotherapy had adequate criteria to determine embryo survival.[17] After eliminating duplicate publications, 12 studies were identified which utilized follow-up ultrasound to distinguish between incomplete or missed abortion and embryo survival at the end of the study period. The mean percentage of embryos surviving mifepristone among all studies was 12.6%.[17] A single dose of 600 mg in five studies of early gestations 42-49 days in 493 subjects showed survivals of 9.4-17.1%.[17,18,19,20,21] Three studies of 58 women with gestations <49 days, using the current predominant 200-300 mg doses, noted embryo survival rates of 10-23.3%.[19,22,23,24] Four studies of 83 women included gestations up to 70 days, daily doses of 100-200 mg, and total doses 400-800 mg.; in three of these four studies, embryo survival was <25%.[25,26,27,28,29,30,31]

Methods

This is a retrospective analysis of clinical data of a group of pregnant women who took progesterone in an effort to reverse the effects of mifepristone. The study was reviewed and approved by an institutional review board. The lead author contributed clinical data from a variety of clinical settings across the United States and several other countries for comparison.

Subjects were pregnant women who had taken mifepristone, but had not yet taken misoprostol, and were interested in reversing its effects. Subjects called an informational hotline linked to an informational website and staffed by nurses and a physician assistant. After receiving information about the reversal process, those who decided to proceed with reversal were referred to physicians and mid-level practitioners in their respective geographic areas for treatment. The women gave written informed consent for treatment to their respective treating medical professionals that included permission to track their data. Data were collected from the women themselves and from their treating healtcare professionals.

Data were collected for different variables including gestational age at the time of mifepristone ingestion, mode of delivery of progesterone given, amounts of progesterone received, birth defects and preterm delivery. Progesterone was given in a variety of regimens by the 325 different medical professionals who treated these women. The modes of delivery of progesterone were intramuscular injection of progesterone in oil, oral administration of micronized progesterone, vaginal use of oral micronized progesterone capsules, compounded micronized progesterone vaginal suppositories, progesterone vaginal gel and progesterone vaginal suppositories.

We selected a 25% embryo or fetus survival rate, if mifepristone alone is administered, as a control because it is at the upper range of mifepristone survival rates and close to the 23% survival rate of the one early study that used a single 200 mg dose, the dose currently favored for medical abortions.[17] This study is designed to ascertain which progesterone treatments clinicians have offered to women seeking mifepristone

reversal that demonstrate efficacy beyond the 25% embryo survival rate, and compares the relative efficacies of different treatment protocols to the historic control.

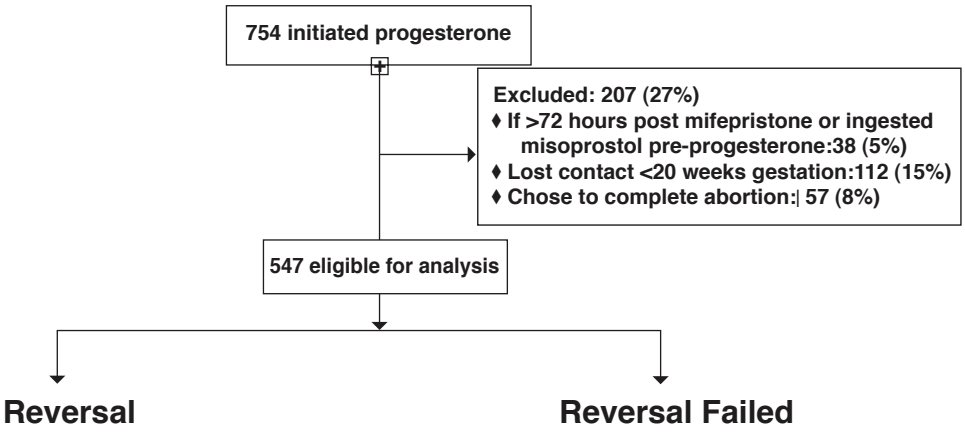
Results

From June 24, 2012 to June 21, 2016, 1,668 calls were received by the hotline from women who had taken mifepristone and were interested in reversal. Seven hundred fifty-four (45%) actually initiated progesterone therapy.

Subjects were included in the study if they were 72 hours or less post-mifepristone and had not taken misoprostol; 38 (5%) did not meet these criteria. Of the women who started progesterone therapy and met inclusion criteria, 116 (15.4%) were lost to follow-up at some point. Of those,112 (14.9%) were lost to follow-up prior to 20 weeks gestation and were excluded from the analysis. Four (0.5%) women remained pregnant with viable fetuses but were lost to follow-up after twenty weeks gestation and were included in the analysis as reversals.

Fifty-seven (7.6%) of the women, after starting progesterone therapy, changed their minds again and either took misoprostol to complete the medical abortion or procured surgical induced abortion. Of those 57, 39 (5.2%) chose to complete abortion medically with misoprostol, seven (0.9%) procured surgical abortions and 11 (1.5%) completed

Figure 1



abortion by unspecified means. These were not included in the analysis as they chose to no longer attempt reversal. See Figure 1.

Women who delivered babies after progesterone therapy or who were lost to follow-up after 20-weeks gestation were considered to have reversed their medical abortions, since any pregnancy loss after 20 weeks would be unlikely to be attributable to the early mifepristone exposure. The data analysis was accomplished using the Statistical Hypothesis Test on a population proportion.

After exclusions, there were 547 patients with analyzable outcomes who underwent progesterone therapy. There were 257 births (47%). Another four were pregnant with viable fetuses but were lost to follow-up after 20 weeks gestation (0.7%). The overall rate of reversal of mifepristone was 48%.

Two subgroups had the highest reversal rates. Those who received progesterone intramuscularly (IM) initially or exclusively had a 64% reversal rate. One subject in this group had an undocumented number of injections. The high-dose oral subgroup received oral progesterone, 400 mg twice a day for three days, followed by 400 mg once a day until the end of the first trimester and had a reversal rate of 68%, similar to the IM group. These survival rates compare favorably with published embryo and fetal survival rate of 25%, if no treatment is attempted,[17] the rate used as a control. See Table 1.

The gestational age at the time of ingestion was directly related to reversal success. See Table 2. This is not surprising since mifepristone embryocidal and feticidal rates fall with advancing gestational age.[33]

There was no correlation between maternal age and rate of reversal. In the subset of records noting time intervals, the time between mifepristone ingestion and the first progesterone dose was not statistically significant in relation to the success rate for reversals attempted within 72 hours of mifepristone injection.

Birth Defects

There were seven reported birth defects in the women who had reversals and follow-up after their deliveries for a rate of 7/257 (2.7%). See Table 3. This is equal to the birth defect rate in the general population of approximately 3%[34] and suggests that there is no increased risk of birth defects in babies born after mifepristone reversal.

Preterm Delivery

There were seven deliveries at <37weeks for a preterm delivery rate of 2.7%. The United States average is 10%.[35]

Multiple Gestations

There were nine sets of twins (4.3% of the pregnancies). There were no higher order multiples.

Discussion

Progesterone Safety

Progesterone is a naturally occurring hormone produced by the corpus luteum and by the placenta, and is essential for maintenance of the maternal fetal interface of pregnancy. It has been used safely in pregnancy for over 50 years.[36] The American Society of Reproductive Medicine states that no long-term risks have been identified when progesterone is used in pregnancy.[37] The FDA has given progesterone a category B rating in pregnancy, in contrast to synthetic progestins.[38]

Table 1: Reversals Compared to Reported Control of 25% Survival if No Treatment Undertaken

Progesterone Group	Number	Reversals	Reversal Failures	Percent Reversals	P Value	95% Confidence Intervals
All Groups	547	261	286	48%	<0.001	0.44-0.52
High Dose Oral	31	21	10	68%	<0.001	0.51-0.84
Intramuscular, All groups	125	80	45	64%	<0.001	0.56-0.72
IM, 1 Injection	50	24	26	48%	<0.001	0.34-0.62
IM, 2-5 Injec.	36	21	15	58%	<0.001	0.42-0.74
IM, 6-8 Injec.	9	9	0	100%	<0.001	0.67-1
IM, 9-10 Injec.	10	9	1	90%	<0.001	0.77-1.0
IM, 11 or More Injec.	19	17	2	89%	<0.001	0.76-1.0
Oral, All Groups	119	64	55	54%	<0.001	0.45-0.63
Oral Caps Vaginally, All Doses	156	61	95	39%	<0.001	0.31-0.47
Vaginal Suppository	34	11	23	32%	0.161	0.17-0.48

A recent retrospective study of a Danish infertility cohort suggested a possible increased risk of acute lymphocytic leukemia and sympathetic neural tumors in children born to mothers who had taken progesterone during pregnancy and before pregnancy. The increased risk was greatest in women who had taken progesterone for three or more cycles.[39] However, the infertility population examined in the Danish study, exposed to

Table 2: Gestational Age Compared to Reversal Rate

Gestational Age	Total	Reversal	Reversal Failure	Reversal %	*P* value	95% Confidence Intervals
5 weeks	76	19	57	25%	0.5	0.15-0.35
6 weeks	113	52	61	46%	<0.001	0.37-0.55
7 weeks	102	50	52	49%	<0.001	0.39-0.59
8 weeks	88	54	34	61%	<0.001	0.51-0.72
9 weeks	30	23	7	77%	<0.001	0.62-0.92

Table 3: Birth Defects

Birth Defect	Instances
Port Wine Stain	1
Bilateral Absent Toe	1
Unilateral Two Absent Fingers	1
Choroid Plexus Cyst	1
Cystic Kidney	1
Unilateral Failed Hearing Test	1
Heart Murmur	1

many cycles of progesterone and other medications, differs significantly from our population of fertile women who had a single exposure to progesterone.

Mifepristone Teratogenicity

While previous human studies are not large in number, the available evidence suggests that mifepristone is not teratogenic.[4,40,41] The American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin March 2014 states that there is no evidence that mifepristone is associated with teratogenicity.[42] Our data set, the largest of babies exposed to mifepristone in utero, also indicates that the birth defect risk in women who have reversed mifepristone abortions is no higher than the risk in the general population.

Study Limitations

This study is limited in that it is not a randomized placebo-controlled trial. However, a placebo-controlled trial in the population of women who regret their abortion and

want to save the pregnancy would be unethical. Furthermore, although the number of women lost to follow-up was small, it could have affected the results. In addition, some data collection was incomplete.

One potential confounding variable is the use of ultrasound to select for living embryos prior to the first progesterone dose. It is possible that those embryos who were alive at the time of sonogram may have survived without progesterone therapy. However, our study also included some women who started progesterone therapy prior to sonographic documentation that the embryo was alive. Undoubtably, this group included women who already had an embryonic demise prior to initiation of progesterone therapy. Inclusion of these women would falsely lower the success rate of progesterone therapy. The numbers of women who received or did not receive ultrasound exams prior to initiating therapy were not available to our researchers. If ultrasound is readily available, sound practice would dictate that embryonic or fetal viability should be confirmed, or at least suggested, before treatment is started in order to avoid giving women progesterone unnecessarily and to exclude ectopic pregnancy before starting progesterone therapy.

Conclusions

The use of progesterone to reverse the effects of the competitive progesterone receptor blocker, mifepristone, appears to be both safe and effective. Progesterone therapy makes biologic sense, has been previously published as effective in an animal model and is supported by this case series which demonstrates a statistically significant difference in survival between treatment groups and the historic control. Mifepristone is embryocidal and feticidal but not teratogenic; progesterone is not associated with birth defects.

Based on these new data, two reasonable protocols can be suggested for women who seek to reverse the effects of mifepristone:

1. Progesterone micronized 200 mg capsule two by mouth as soon as possible and continued at a dose of 200 mg capsule two by mouth twice a day for three days, followed by 200 mg capsule two by mouth at bedtime until the end of the first trimester; and

2. Progesterone 200 mg intramuscular as soon as possible and continued at a dose of 200 mg intramuscular once a day on days two and three, then every other day for a total of seven injections. Some clinicians may choose to continue intramuscular treatment longer since this recommendation is based on relatively small numbers.

Recommendations for Future Research

We propose that further research employing randomized controlled trials comparing progesterone doses and routes of administration are needed to confirm which mode of delivery, dose and duration of progesterone therapy is most efficacious and carries the least burden for the patient.

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Mifepristone Antagonization with Progesterone to Avert Medication Abortion: A Scoping Review

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Abstract

The safety and efficacy of mifepristone antagonization with progesterone to avert medication abortion, also known as abortion pill rescue, is a subject of vigorous debate. Two prominent medical associations have taken positions that either entirely reject or fully support its use. This scoping review aimed to gain insight into the safety and efficacy of its use. Analysis of 16 studies showed that the continuing pregnancy rate after ingesting mifepristone alone is ≦25 percent for gestational ages ≦49 days. Analysis of four studies showed that two-thirds of the women who changed their minds and received progesterone after initiating their medication abortion with mifepristone could safely continue their pregnancies. There is no increased maternal or fetal risk from using bioidentical progesterone in early pregnancy. If a woman has already taken mifepristone for her medication abortion and then changes her mind, timely supplementation with progesterone may allow her pregnancy to continue. The conclusion that mifepristone antagonization with progesterone is a safe and effective treatment has implications for medication abortion informed consent.

Summary: Two-thirds of the women who changed their minds and received progesterone after initiating their medication abortion with mifepristone could safely continue their pregnancies. If a woman has already taken mifepristone for her medication abortion and then changes her mind, timely supplementation with progesterone may allow her pregnancy to continue. Physicians should disclose this treatment option to their patients at the time of informed consent.

Keywords

Abortion pill reversal, Abortion pill rescue, Chemical abortion, Medication abortion, Mifepristone antagonization, Mifepristone reversal, Mifeprex, RU-486

Introduction

Medication abortion is a two-drug regimen that uses the drugs mifepristone (aka Mifeprex and RU-486) and misoprostol (FDA 2016) (FDA 2017). The regimen begins with mifepristone ingestion, followed 24–48 h later with 800 mcg of misoprostol taken buccally (in the cheek pouch) (ACOG 2020). The FDA manages the regimen under the Risk Evaluation and Mitigation Strategy (REMS). In 2023, the FDA permanently removed the REMS in-person dispensing

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requirement and added a process to certify pharmacies but retained other REMS requirements, such as the need for prescriber certification (FDA 2023, 1).

Mifepristone contraindications include confirmed/suspected ectopic pregnancy, chronic adrenal failure, concurrent long-term corticosteroid therapy, concurrent anticoagulant therapy, and the presence of an intrauterine device in place (FDA 2016). The American College of Obstetricians and Gynecologists (ACOG) recommends that healthcare providers administer Rh D immune globulin to Rh D-negative women who have a medication abortion (ACOG 2017, e63). Recent studies propose a "no-test" protocol that eliminates pre-abortion ultrasound, pelvic examination, and Rh D-negative testing (Raymond et al. 2020, 362).

In 2016, the FDA modified the regimen by expanding use from 49 to 70 days gestation and by reducing mifepristone dosage from 600 to 200 mg. The FDA also removed the requirement that prescribers submit adverse event reports (AER) but retained the requirement to report deaths (Aultman et al. 2021, 7). In 2021, the FDA removed the requirement to dispense mifepristone in clinics, medical offices, and hospitals (Cavazzoni 2021). This decision created the opportunity for women to receive mifepristone without being examined by a medical professional.

Medication abortion accounts for 50 percent to 60 percent of all US abortions (Guttmacher Institute 2022). Dozens of websites such as PlanCPills, HeyJane, and AidAccess sell medication abortion kits for $200—$400 per kit (Mosbergen and Vibhuti 2022). Many of the websites provide incomplete information that undermines informed consent and increases the risk of severe illness and possible death. For instance, AbortionRx does not mention mifepristone contraindications such as ectopic pregnancy, concurrent long-term corticosteroid therapy, or concurrent anticoagulant therapy. Nor does it mention the need for Rh D immune globulin for Rh D-negative women (Abortionrx 2023, 1).

Progesterone plays a critical role in the normal functioning of the human female reproductive system. It promotes placental development, prepares the uterus for embryo implantation (Coomarasamy et al. 2015, 2142), and inhibits uterine contractions (Scarpin et al. 2009, 1). Mifepristone is a progesterone receptor antagonist that binds more aggressively to the progesterone receptors in the uterus than progesterone. The primary effect of mifepristone is to cause a separation of the decidua basalis from the trophoblast, which results in embryo demise (AAPLOG 2022, 1). Misoprostol triggers uterine contractions, expelling the embryo.

Some women change their mind about their medication abortion after ingesting mifepristone but before taking misoprostol. For example, a study by Aultman et al. analyzed 19 years of mifepristone AER. They found 102 of the 452 patients (22.6 percent) with a continuing pregnancy after mifepristone alone changed their mind and chose to continue their pregnancy (Aultman et al. 2021, 4). Thus, even after initiating their medication abortion, some women change their mind.

The concept of mifepristone antagonization is to use high doses of progesterone to halt the effects of mifepristone and increase the continuing pregnancy rate. A patient must receive progesterone within 72 h after taking mifepristone but before taking misoprostol (AAPLOG 2022, 3). The increase in progesterone concentration displaces mifepristone binding at the progesterone receptors to reestablish regular progesterone binding and encourage healthy embryo development (AAPLOG 2022, 2). Proponents claim that there have been thousands of documented cases of mifepristone antagonization (aka "abortion pill rescue") that resulted in live births (Heartbeat International 2023).

At least twelve states require physicians to inform women seeking a medication abortion of mifepristone antagonization using progesterone (Forsythe and Harrison 2022, 406). Two prominent medical associations have taken positions that either entirely reject or fully support mifepristone antagonization with progesterone to avert medication abortion. The American Association of Pro-life

Obstetricians and Gynecologists (AAPLOG) states that the action of mifepristone "can be slowed or arrested with progesterone based on biological plausibility and limited cohort data" and is based upon "limited and inconsistent scientific evidence (Level B)" (AAPLOG 2022, 4). They fully support informing women of the option of mifepristone antagonization as part of informed consent prior to a medication abortion (AAPLOG 2019). The ACOG states that claims of medication abortion reversal are "not supported by science" and "do not meet clinical standards" (ACOG 2022). They entirely reject any attempts to mandate disclosing mifepristone antagonization as part of informed consent prior to medication abortion. This paper examines the scientific evidence to answer the question, "Is mifepristone antagonization with progesterone a safe and effective treatment to avert medication abortion?"

Methods

Since 2015 three journal articles have been published that reviewed mifepristone research studies to determine the continuing pregnancy rate after mifepristone alone (Grossman et al. 2015; Davenport et al. 2017; Creinin and Chen 2019). In total, the three articles reviewed 16 studies. However, each article reviewed a different subset of the studies and reported different results. This scoping review began by analyzing the 16 studies cited by the three articles to determine the continuing pregnancy rate after mifepristone alone.

Since 2012 four journal articles have been published that documented the continuing pregnancy rate after ingesting mifepristone followed by progesterone (Delgado and Davenport 2012); Garratt and Turner 2017; Delgado et al. 2018; Creinin et al. 2020). This scoping review next analyzed the four articles to determine the continuing pregnancy rate after ingesting mifepristone followed by progesterone.

Lastly, this scoping review analyzed safety considerations, including the safety of using progesterone during pregnancy and the safety of using mifepristone alone without misoprostol.

Results

The following section organizes results into three groups: continuing pregnancy rate after mifepristone alone, continuing pregnancy rate after mifepristone and progesterone, and safety considerations.

Continuing Pregnancy Rate after Mifepristone Alone

It is essential to establish the continuing pregnancy rate after ingesting mifepristone alone because it provides a baseline against which to compare the efficacy of progesterone as a mifepristone antagonist. ACOG states that "as many as half of women who take only mifepristone continue their pregnancies" (ACOG 2022). ACOG's only citation for this statement relies upon a systematic review that analyzed continuing pregnancy after mifepristone alone (Grossman et al. 2015). However, since 2015 there have been two additional publications (Davenport et al. 2017; Creinin and Chen 2019) that analyzed continuing pregnancy after mifepristone alone.

There are three possible results after ingesting mifepristone alone; (1) embryo demise with the complete evacuation of the uterus (complete abortion); (2) embryo demise with incomplete uterine evacuation or no evacuation at all (incomplete abortion); (3) embryo survival (continuing pregnancy) (Davenport et al. 2017, 9). The 16 studies aimed to determine the efficacy of mifepristone as an alternative to surgical abortion (complete abortion). As a result, four of the 16 studies did not clearly distinguish between an incomplete abortion and continuing pregnancy when reporting mifepristone treatment failure. The remaining 12 studies used ultrasound to determine the presence of a living embryo to differentiate between an incomplete abortion and a continuing pregnancy.

In the Grossman article previously mentioned, the authors reviewed 11 studies (1092 women). They concluded that the "proportion of pregnancies continuing 1–2 weeks after mifepristone alone varied from 8 percent (95 percent CI 3–22 percent) to 46 percent (95 percent CI 37–56 percent)" and that "continuing pregnancy was more common with lower mifepristone doses and advanced gestational age" (Grossman et al. 2015, 206). However, the review included four studies (Birgerson and Odlind 1988; Grimes et al. 1988; Swahn et al. 1989; Zheng 1989) that did not use ultrasound to verify the presence of a living embryo when they reported mifepristone treatment failure.

Birgerson relied upon changes in hCG levels to determine "continuing pregnancy" (Birgerson and Odlind 1988). Grimes defined therapeutic success (complete abortion) as vaginal bleeding and declining beta-human chorionic gonadotropin (ß-hCG) titer. Otherwise, the patient was classified as "failed to abort" and underwent suction curettage (Grimes et al. 1988). Swahn classified women with "intact amniotic sac" as a "treatment failure" but did not verify the existence of a living embryo (Swahn et al. 1989). Zheng define "persisting pregnancy" as "no expulsion of the conceptus" and "gradual" increase of serum or urine hCG. The authors did not define "gradual" (Zheng 1989).

Thus, the reported continuing pregnancy rates for these four studies ($N = 516$) may have overstated the actual continuing pregnancy rate. The remaining seven studies used ultrasound to verify embryo survival and reported continuing pregnancy rates ranging from 0 percent to 25 percent ($N = 576$).

In 2017, Davenport published a systematic review of 12 studies (675 women). All studies cited by Davenport used ultrasound verification to document living embryos were present at follow-up. The continuing pregnancy rate using "total doses of 200–300 mg ranged from 10–23.3 percent" and "regimens with total doses ≥400 mg had embryo survivals ranging from 0–18.1 percent when followed ≥14 days post mifepristone, and 0–50 percent when followed for 6–8 days after mifepristone." The continuing pregnancy rate for "studies including gestations up to 70 days was ≤25 percent in three of four studies" (Davenport et al. 2017, 3–4). Eleven of the 12 studies reported continuing pregnancy rates ranging from 0 percent to 25 percent ($N = 657$). One study had a continuing pregnancy rate of 50 percent (Elia 1985, $N = 18$).

In 2019, Creinin published a review of seven studies (550 women). All studies cited by Creinin used ultrasound verification to document living embryos were present at follow-up. This review reported that "the continuing pregnancy rate was higher with 200 mg (7/30 [23 percent, 95 percent confidence interval 8–38 percent]) than 600 mg (29/420 [7 percent, 95 percent confidence interval 4–9 percent])" (Creinin and Chen 2019, 428). The authors concluded that the data was inadequate to determine the continuing pregnancy rate after mifepristone alone because there was not enough data from studies using the FDA recommended 200 mg dosage ($N = 30$) (Creinin and Chen 2019, 428). These seven studies reported continuing pregnancy rates ranging from 0 percent to 25 percent ($N = 550$).

In total, the three articles analyzed 16 studies (1191 women). Each article analyzed a different subset of the 16 studies. Table 1 summarizes the findings.

Combining data to perform a meta-analysis across the 16 studies is not possible because of the varied dose regimens. However, the continuing pregnancy rate for each of the 12 studies that verified embryo survival never exceeded 25 percent, except for Elia (1985), $N = 18$, regardless of mifepristone dose, gestational age, or follow-up period. Studies with a shorter follow-up period after the last mifepristone dose, such as Elia (1985) (2 days after last dose), tended to have higher embryo survival rates, and vice-versa.

Mifepristone doses varied from 200 to 1000 mg across the 16 studies. Some studies used multiple treatment groups resulting in 22 treatment groups across the 16 studies. Six

Table 1. Studies Reporting Continuing Pregnancy Rate Following Mifepristone.

Study (Literature Review)	Mifepristone Dose (mg) × (days)	Gestational Age Limit (days)	Follow Up (days)	Surviving Embryos (# / N)	Continuing Pregnancy (%)
Vervest and Haspels 1985 (c,d)	200 × 4	56–70	14	0/9	0.0%
Kovacs et al. 1984 (c,d,g)	200 × 4	≦ 42	14	0/8	0.0%
Vervest and Haspels 1985 (c,d)	100 or 200 × 4	35–55	14	0/35	0.0%
Maria et al. 1988b EJ (c,d,g)	600 × 1	≦ 42	7	14/149	9.4%
[1]Grimes et al. 1988 (g)	600 × 1	≦ 49	14	5/50	10.0%
Kovacs et al. 1984 (c,d,g)	100 × 4	≦ 42	14	1/10	10.0%
Sitruk-Ware et al. 1985 (d)	1000[2]	≦ 49	14	1/10	10.0%
Swahn et al. 1985 (d)	50 x (4 or 6)	≦ 49	14	1/10	10.0%
Ylikorkala et al. 1989 (c,d,g)	600 × 1	≦ 43	14	5/47	10.6%
Kovacs et al. 1984 (c,d,g)	50 × 4	≦ 42	14	2/18	11.1%
Maria et al. 1988a JG (c,d,g)	600 × 1	≦ 49	7	20/174	11.5%
Carol and Klinger 1989 (c,d,g)	600 × 1	33–43	NR	6/50	12.0%
Swahn et al. 1985 (d)	100 × 4	≦ 49	14	1/6	16.7%
Somell and Olund 1990 (d,g)	600 × 1	≦ 42	7	12/70	17.1%
Herrmann et al. 1985 (d)	200 × 4	42–56	7	2/11	18.2%
Maria et al. 1988a JG (c,d,g)	200 × 4	≦ 49	7	7/30	23.3%
Cameron et al. 1986 (c,d,g)	150 × 4	≦ 56	14	5/20	25.0%
[1]Birgerson and Odlind 1988 (g)	20, 50, or 100 × 7	≦ 49	7, 14	41/153	26.8%
[1]Zheng 1989 (g)	600 × 1	≦ 42	7	64/204	31.4%
[1]Swahn et al. 1989 (g)	100 × 4	≦ 49	14	5/14	35.7%
[1]Zheng 1989 (g)	600 × 1	≦ 49	7	44/95	46.3%
Elia 1985 (d)	200 × 4	35–63	6	9/18	50.0%

c = Creinin and Chen 2019, d = Davenport et al. 2017, g = Grossman et al. 2015, NR = Not Reported.
1. Study did not verify continuing pregnancy using ultrasound at follow-up.
2. Administered on a sliding scale: 400, 300, 200, and 100 mg/day for four successive days.

treatment groups used mifepristone doses of 200–400 mg ($N = 88$). Ten treatment groups used mifepristone doses of 600–700 mg ($N = 1012$). Six treatment groups used mifepristone doses of 800–1000 mg ($N = 91$).

The gestational age limit ranged from ≤42 days to ≤70 days across the 22 treatment groups. Seventeen treatment groups reported a gestational age limit of ≤49 days ($N = 1098$). Five treatment groups reported a gestational age limit of 50–70 days ($N = 93$).

Four studies (Elia 1985; Grimes et al. 1988; Herrmann et al. 1985; Zheng 1989) found that the continuing pregnancy rate was more common with advanced gestational age. Davenport et al. also reported data from a 1986 Elia report showing that the continuing pregnancy rate increased as the gestational age limit increased (Davenport et al. 2017, 12). Table 2 summarizes the five studies (754 women) that reported continuing pregnancy rates by gestational age.

In summary, Tables 1 and 2 show that the continuing pregnancy rate after ingesting mifepristone alone is generally ≤25 percent for gestational ages ≦49 days. There is insufficient evidence to establish the continuing pregnancy rate after mifepristone alone for gestational age ≥50 days. The evidence also shows that continuing pregnancy is more common with lower mifepristone doses and greater gestational ages.

Continuing Pregnancy Rate after Mifepristone and Progesterone

ACOG states there is "no credible scientific evidence" that progesterone will halt

Table 2. Studies Reporting Continuing Pregnancy Rate by Gestational Age.

Study	*N*	Gestational Ages (days), Continuing Pregnancy Rate (%)				
[1]Zheng 1989	95	=35, 7.4%	36–42, 19%	43–49, 20%		
[1]Grimes et al. 1988	50	<34, 0%	35–41, 4%	42–48, 6%		
Davenport et al. 2017	434	<35, 9%	35–42, 16%	43–49, 27%		
Davenport et al. 2017	146	<35, 0%	35–42, 16%	43–49, 23%		
Herrmann et al. 1985	11	42–45, 0%	46–48, 0%	49–52, 9%	53–55, 9%	
[2]Elia 1985	18	35–41, 0%	42–48, 43%	49–55, 60%	56–61, 0%	63–69, 100%

1. Study did not verify continuing pregnancy using ultrasound at follow-up.
2. Elia had the shortest follow-up period of all 16 studies (6 days). Studies with shorter follow-up periods tended to have higher embryo survival rates.

mifepristone binding from uterine progesterone receptors (ACOG 2022). However, researchers at French pharmaceutical company Roussel Uclaf, developer of mifepristone, published research in 1984 demonstrating the dissociation rate of mifepristone binding from rat uterus progesterone receptors when exposed to progesterone (Baulieu and Segal 1985, 91, Figure 3). Their research demonstrated that high progesterone concentrations can trigger mifepristone disassociation from uterine progesterone receptors.

Research published by Yamabe et al. studied how mifepristone and progesterone affect the luteal function during pregnancy in rats (Yamabe et al. 1989). The researchers gave one group of pregnant rats mifepristone and a second group mifepristone and progesterone. The study found that 33 percent of the mifepristone only group delivered live offspring but 100 percent of the mifepristone plus progesterone group delivered live offspring (AAPLOG 2022, 2).

Two case series documented mifepristone antagonization in humans. In 2012, Delgado documented a series of six case reports. Four of six women (67 percent) who received progesterone after ingesting mifepristone alone delivered a viable infant without birth defects (Delgado and Davenport 2012, e36). The other two cases resulted in a complete abortion. In 2017, Garratt documented a series of three case reports. Two of three women (67 percent) who received progesterone vaginally after ingesting mifepristone alone delivered a viable infant without birth defects (Garratt and Turner 2017, 473). The other case resulted in a complete abortion.

In 2018, Delgado published a case series of 547 patients who attempted mifepristone antagonization with progesterone to avert medication abortion (Delgado et al. 2018, 25). The patients received progesterone using six delivery regimens; intramuscular injection of progesterone in oil, oral administration of micronized progesterone, vaginal use of oral micronized progesterone capsules, compounded micronized progesterone vaginal suppositories, progesterone vaginal gel, and progesterone vaginal suppositories (Delgado et al. 2018, 24). Patients who received intramuscular progesterone had a 64 percent continuing pregnancy rate ($N = 125$), and those who received high-dose oral progesterone had a 68 percent continuing pregnancy rate ($N = 31$) (Delgado et al. 2018, 26). Delgado reported that the gestational age at the time of the mifepristone ingestion was directly related to the embryo survival rate: 35 days (25 percent), 42 days (46 percent), 49 days (49 percent), 56 days (61 percent), 63 days (77 percent). 71 percent of the patients ($N = 291$) in the Delgado case series report had a gestational age of 49 days or less.

Delgado reported seven birth defects (2.7 percent) for the 257 patients that had live births and post-delivery follow-up. The reported birth defects were port wine stain (1), bilateral absent toe (1), unilateral two absent fingers (1), choroid plexus cyst (1), cystic kidney (1), unilateral failed hearing test (1), heart murmur (1). This birth defect

rate is comparable to the 3 percent birth defect rate in the general population (Delgado et al. 2018, 26).

In 2020, Creinin published a randomized controlled trial designed to study the safety and efficacy of mifepristone antagonization using high-dose oral progesterone (Creinin et al. 2020). Two of the 12 patients voluntarily exited the study. Of the ten remaining patients, five received 200 mg of oral progesterone, and five received a placebo. Gestational cardiac activity continued for two weeks for four of five patients (80 percent) receiving progesterone and for two of five patients (40 percent) receiving a placebo (Creinin et al. 2020, 158). Three patients experienced hemorrhage and were transported by ambulance to the hospital. Two of three patients received a placebo, the other received progesterone. Both patients who received a placebo required aspiration, and one placebo patient also required transfusion. The patient who received progesterone did not require any medical treatment. The authors halted the study after the third hemorrhage, though all hemorrhages requiring medical treatment occurred in the placebo group.

Table 3 summarizes the four human studies, broken down by delivery regimen and progesterone dose. The continuing pregnancy rates for all doses and delivery regimens ranged from 32 percent to 100 percent ($N = 359$). The continuing pregnancy rate for the delivery regimens *intramuscular* (all groups) and *high-dose oral* was 65 percent ($N = 130$) and 69 percent ($N = 36$), respectively. The continuing pregnancy rate for the *vaginal* delivery regimen was 38 percent ($N = 193$).

The Delgado case series articles have been criticized because they lacked the rigor of double-blind, placebo-controlled randomized trials (Grossman and White 2018, 1493). The case series articles did not use a randomly assigned, mifepristone-only placebo control group. This limits the generalization of the case series data because it is not possible to compare the effectiveness of the progesterone treatment against a control group that did not receive the treatment.

However, placebo usage opposes the bioethical principle of autonomy ("self-rule") because it rejects the patient's decision to continue her pregnancy (Beauchamp and Childress 2019, 99). Placebo usage also

Table 3. Studies Reporting Continuing Pregnancy Rate Following Mifepristone and Progesterone.

Study	Delivery Regimen. Progesterone Dose (mg)	Surviving Embryos (# / N)	Continuing Pregnancy (%)
Delgado et al. 2018	Vaginal suppository. Dose not reported	11/34	32%
Delgado et al. 2018	Vaginal oral capsules. Variety of doses not reported.	61/156	39%
Delgado et al. 2018	IM. 200 mg x 1 injection	24/50	48%
Delgado et al. 2018	IM. 200 mg x 2–5 injections	21/36	58%
Delgado and Davenport 2012	IM and/or oral. 200 mg (1 or 2 per day), duration 9 weeks to 5 months.	4/6	67%
Garratt and Turner 2017	Vaginal. 400 mg (2 per day) for 3 days, 400 mg at night for 6 days, and 200 mg at night for 6 days.	2/3	67%
Delgado et al. 2018	High-dose Oral. 2 × 200 mg capsules (2 per day) for 3 days, 2 × 200 mg capsules daily until end 1st trimester	21/31	68%
Creinin et al. 2020	High-dose Oral. 2 × 200 mg capsules (2 per day) for 3 days, 2 × 200 mg capsules daily until study exit visit	4/5	80%
Delgado et al. 2018	IM. 200 mg × 11 + injections	17/19	89%
Delgado et al. 2018	IM. 200 mg × 9–10 injections	9/10	90%
Delgado et al. 2018	IM. 200 mg × 6–8 injections	9/9	100%

The mifepristone dose was 200 mg for Creinin et al. 2020. Dose not reported for all other studies.
IM: Intramuscular injection

opposes the bioethical principle of beneficence ("to do good") because it withholds a treatment that increases the probability of embryo survival (Beauchamp and Childress 2019, 157). Placebo usage in this case lacks equipoise and is therefore unethical.

AAPLOG recommends the delivery regimens *high-dose oral* and *intramuscular injection (7 or more)* for women who change their mind after taking mifepristone (AAPLOG 2022, 3). They also recommend an immediate sonogram to determine "intrauterine location, viability, and gestational age" and advise delaying treatment if there is suspicion of "an ectopic pregnancy, septic abortion or other complication that requires immediate gynecologic attention in a hospital or similar setting" (AAPLOG 2022, 4).

In summary, the evidence shows that the continuing pregnancy rate using the progesterone delivery regimens *intramuscular injection* and *high-dose oral* are 65 percent and 69 percent, respectively. The *vaginal delivery* regimen is less effective, having a continuing pregnancy rate of 38 percent.

Safety Considerations

Physicians have used bioidentical progesterone in reproductive medicine for over fifty years (Di Renzo et al. 2020). The term bioidentical progesterone refers to progesterone that is biologically identical to that produced by the human body (Di Renzo et al. 2020, 3). Progesterone is "a critical regulator" of normal human female reproduction (Scarpin et al. 2009, 1) and reduces the risk of premature birth (Di Renzo et al. 2021, 1).

The American Society for Reproductive Medicine reports no increased risk from using bioidentical progesterone in early pregnancy (ASRM 2008, 791) (The case series study by Delgado et al. found that there was no increase in birth defects after receiving progesterone treatment [2.7 percent] as compared to the birth defect rate in the general population [3 percent] [Delgado et al. 2018, 26]).

The AGOG has questioned the safety of using mifepristone alone without misoprostol. They state that "limited available evidence suggests that use of mifepristone alone without subsequent administration of misoprostol may be associated with an increased risk of hemorrhage" (ACOG 2020, e33). The only evidence cited by ACOG is the previously discussed randomized controlled trial in which there was bleeding after mifepristone without misoprostol (Creinin et al. 2020). Three of the ten patients visited the hospital because of bleeding, two in the placebo group and one in the progesterone group. Both patients in the placebo group experienced an incomplete abortion and required dilation and curettage. One patient in the placebo group also required a transfusion. The patient in the progesterone group experienced a complete abortion and required no treatment.

Each of the previously discussed 16 studies reported the level of uterine bleeding experienced by research participants after mifepristone alone. There was a total of 19 hemorrhage events among the 1191 research participants (1.6 percent). Table 4 lists the number of hemorrhage events for each study and the reported hemorrhage event description.

In summary, healthcare professionals have safely used progesterone in reproductive medicine for over fifty years. There is insufficient evidence to establish that mifepristone, followed by progesterone, has a higher risk of hemorrhage than mifepristone, followed by misoprostol.

Conclusion

Mifepristone antagonization with progesterone to avert medication abortion is a safe and effective treatment. The continuing pregnancy rate after ingesting mifepristone alone is ≤25 percent for gestational age ≦49 days. The continuing pregnancy rate after ingesting mifepristone, followed by progesterone, is 65 percent and 69 percent using the delivery regimens intramuscular injection and high-dose oral, respectively. There is no increased maternal or fetal risk from using bioidentical progesterone in early pregnancy.

Table 4. Studies Reporting Hemorrhage Events Following Mifepristone Alone.

Study	*N*	Hemorrhage Events	Hemorrhage Event Description
Birgerson and Odlind 1988	153	1	Profound bleeding that required blood transfusion.
Cameron et al. 1986	20	2	Heavy bleeding. One patient required blood transfusion.
Carol and Klinger 1989	50	1	Excessive bleeding with resulting anemia.
Elia 1985	18	0	
Grimes et al. 1988	50	0	
Herrmann et al. 1982, 1985	11	1	Heavy bleeding. D & C performed after expulsion.
Kovacs et al. 1984	36	2	Heavy bleeding requiring blood transfusion and curettage.
Maria et al. 1988b	149	2	Heavy bleeding requiring curettage but no transfusion.
Maria et al. 1988a	204	3	Significant hemorrhage and uterine revision. No transfusion.
Sitruk-Ware et al. 1985	10	0	
Somell and Olund 1990	70	0	
Swahn et al. 1985	16	1	Heavy bleeding. Blood transfusion, removal of conceptus.
Swahn et al. 1989	14	0	
Vervest and Haspels 1985	44	2	Severe blood loss requiring blood transfusions.
Ylikorkala et al. 1989	47	0	
Zheng 1989	299	4	Heavy bleeding requiring curettage but no transfusion.

The conclusion that mifepristone antagonization with progesterone is a safe and effective treatment has implications for medication abortion informed consent. The primary bioethical principle underlying informed consent is patient autonomy. Physicians must safeguard patient autonomy by disclosing medical risks and benefits (AMA 2023). This obligation includes the legal responsibility to disclose safe and effective treatment options that a reasonable person in the patient's position would find important (Nixdorf v. Hicken 1980). Before this treatment was studied, many women changed their minds about their medication abortion (Aultman et al. 2021, 4). It is, therefore, reasonable to assume that women seeking a medication abortion would find the knowledge of this treatment important.

Mifepristone antagonization with progesterone is a time-sensitive treatment. The patient must receive progesterone no later than 72 h after taking mifepristone but before taking misoprostol. Therefore, physicians should not only disclose this treatment to their patients but should do so at the time of informed consent. Failure to inform the patient prior to mifepristone ingestion could cause a delay that leads to fetal demise as the patient searches for a treatment to avert medication abortion.

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Biographical Note

Paul L. C. DeBeasi, BS Eng, M Eng, MS Bioethics, is a bioethics author and speaker. He received his master's degree in bioethics from the University of Mary and holds engineering degrees from Cornell University and Boston University. Prior to his focus on bioethics, he was a Chief of Research at Gartner and a product management executive at several technology firms. He began his career as a systems engineer at Bell Laboratories.

DEFENDANT'S EXHIBIT 3

STATES WITH MANDATORY ABORTION PILL REVERSAL COUNSELING BEFORE A CHEMICAL-ABORTION REGIMEN IS COMMENCED

State	Statute	Year Enacted	Mandatory APR-Related Informed Consent Language
Arizona	Ariz. Rev. Stat. § 36-2153(B)*	2015 (amended 2016)	"If a woman has taken mifepristone as part of a two-drug regimen to terminate her pregnancy, has not yet taken the second drug and consults an abortion clinic questioning her decision to terminate her pregnancy or seeking information regarding the health of her fetus or the efficacy of mifepristone alone to terminate a pregnancy, the abortion clinic staff shall inform the woman that the use of mifepristone alone to end a pregnancy is not always effective and that she should immediately consult a physician if she would like more information."
Arkansas	Ark. Code Ann. §§ 20-16-1703, -1704 *(enjoined)**	2015 (amended 2017)	"Mifepristone … alone is not always effective in ending a pregnancy. It may be possible to reverse its intended effect if the second pill or tablet has not been taken or administered. If you change your mind and wish to try to continue the pregnancy, you can locate immediate help by searching the term 'abortion pill reversal' on the internet."
Idaho	Idaho Code § 18-609(2)(f)*	2018	"Information directing the patient where to obtain further information and assistance in locating a health care provider whom she can consult about chemical abortion, including the interventions, if any, that may affect the effectiveness or reversal of a chemical abortion, and informs the patient that if she wants to consult with such health care providers, she should contact those health care providers before she takes the abortifacient."
Indiana	Ind. Code § 16-34-2-1.1(a)(1)(C) *(enjoined)*	2021	"Some evidence suggests that effects of Mifespristone may be avoided, ceased, or reversed if the second pill, Misoprostol, has not been taken. Immediately contact the following for more information at (insert applicable abortion inducing drug reversal website and corresponding hotline number)."

State	Statute	Year Enacted	Mandatory APR-Related Informed Consent Language
Kansas	Kan. Stat. Ann. § 65-6716 *(enjoined)*	2023	"Except in the case of a medical emergency, no physician shall provide, induce or attempt to provide or induce a medication abortion that use mifepristone without informing the woman, in writing … and also either by telephone or in person, at least 24 hours prior to the medication abortion: (A) That it may be possible to reverse the intended effects of a medication abortion that uses mifepristone, if the woman changes her mind, but that time is of the essence; and (B) information on reversing the effects of a medication abortion that uses mifepristone is available on the department of health and environment's website … and other relevant telephone and internet resources…"
Kentucky	Ky. Rev. Stat. § 311.774(2)	2019	"Information on the potential ability of a physician to reverse the effects of abortion-inducing drugs … including where additional information about this possibility may be obtained and contact information for assistance in locating a physician who may aid in the reversal, shall be provided with each prescription issued for an abortion-inducing drug for which the primary indication is the induction of abortion…"
Louisiana	La. Rev. Stat. § 40:1061.11.1(B)	2021	"Research has indicated that the first pill provided, identified as mifepristone, is not always effective in ending a pregnancy. If after taking the first pill you regret your decision, please consult a physician or healthcare provider immediately to determine if there are options available to assist you in continuing your pregnancy." (internal marks omitted)
Montana	Mont. Code Ann. § 50-20-707(5)(f) *(struck down)*	2021	"The consent form must include … (f) information about the possibility of reversing the effects of the chemical abortion if the pregnant woman changes her mind and that time is of the essence."

State	Statute	Year Enacted	Mandatory APR-Related Informed Consent Language
Nebraska	Neb. Rev. Stat. § 28-327(1)(e)	2019	"Research indicates that mifepristone alone is not always effective in ending a pregnancy. You may still have a viable pregnancy after taking mifepristone. If you change your mind and want to continue your pregnancy after taking mifepristone, information on finding immediate medical assistance is available on the website of the Department of Health and Human Services."
North Dakota	N.D. Cent. Code § 14-02.1-02.1(1)(e) *(enjoined)*	2019	"Materials including information it may be possible to reverse the effects of an abortion-inducing drug but time is of the essence. The materials must include information directing the patient where to obtain further information and assistance in locating a medical professional who can aid in the reversal of abortion-inducing drugs."
Oklahoma	Okla. Stat. tit. 63, § 1-756.6(A), (E)(6) *(enjoined)*	2019	"No abortion-inducing drug shall be provided without the informed consent of the pregnant woman as described in this section to whom the abortion-inducing drug is provided. … (The consent form shall include, but is not limited to, the following: … That it may be possible to reverse the effects of the chemical abortion should she change her mind, but that time is of the essence…"
South Dakota	S.D. Codified Laws § 34-23A-10.1(1)(h)*	2016	"A consent to an abortion is not voluntary and informed, unless, in addition to any other information that must be disclosed under the common law doctrine, the physician provides that pregnant woman with the following information: … A statement in writing providing the following information: … That even after a pregnant mother takes Mifepristone, or another drug approved by the United States Food and Drug Administration for the same use, it is still possible to discontinue a drug-induced abortion by not taking the prescribed Misoprostol."
Tennessee	Tenn. Code Ann. § 39-15-218(e)(1) *(enjoined)*	2020	"Except in the case of a medical emergency, a chemical abortion involving the two-drug process of dispensing mifepristone first and then misoprostol shall not be performed or induced or attempted to be performed or

State	Statute	Year Enacted	Mandatory APR-Related Informed Consent Language
			induced unless the woman is informed by the physician who is to perform the abortion at least forty-eight (48) hours before the abortion, that: … It may be possible to reverse the intended effects of a chemical abortion utilizing mifepristone if the woman changes her mind, but that time is of the essence…"
Utah	Utah Code Ann. § 76-7-305.5(2)(u)*	2017	"In order to ensure … informed consent, the department shall … develop an information module and maintain a public website…. The information module … shall:… include the following statement …, 'Research indicates that mifepristone alone is not always effective in ending a pregnancy. You may still have a viable pregnancy after taking mifepristone. If you have taken mifepristone but have not yet taken the second drug and have questions regarding the health of your fetus or are questioning your decision to terminate your pregnancy, you should consult a physician immediately.'"
West Virginia	W. Va. Code § 16-2i-2(a)(4)	2021	"If a chemical abortion involving the two-drug process of mifepristone is initiated and then a prostaglandin such as misoprostol is planned to be used at a later time, the female shall be informed that: (A) Some suggest that it may be possible to counteract the intended effects of a mifepristone chemical abortion by taking progesterone if the female changes her mind, before taking the second drug, but this process has not been approved by the Food and Drug Administration. (B) After the first drug involved in the two-drug process is dispensed in a mifepristone chemical abortion, the physician or agent of the physician shall provide written medical discharge instructions to the pregnant female which shall include the statement: "If you change your mind and decide to try to counteract the intended effects of a mifepristone chemical abortion, if the second pill has not been taken, please consult with your physician.

* *Enacted even before publication of the large 2018 Delgado case series, which is the APR study with the highest ACOG level of scientific evidence yet published in a peer-reviewed journal and which found APR to increase pregnancy continuation rates to a near statistical certainty.*