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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF CALIFORNIA

CULTURE OF LIFE FAMILY SERVICES, INC., a California nonprofit corporation,  
  
Plaintiff,  
  
v.  
  
ATTORNEY GENERAL ROB BONTA, in his official capacity as the California Attorney General,  
  
Defendant.

Case No. 3:24-cv-01338-GPC-KSC

**(1) ORDER DENYING THE MOTION FOR PRELIMINARY INJUNCTION**

**(2) ORDER DENYING MOTION FOR LEAVE TO ALLOW NON-ELECTRONIC FILING**

**(3) ORDER GRANTING EX PARTE MOTION FOR LEAVE TO FILE SUPPLEMENTAL DECLARATION**

**[ECF Nos. 21, 26, 36]**

Plaintiff Culture of Life Family Services, Inc. (“COLFS”) brings a pre-enforcement action against California Attorney General Rob Bonta (“AG Bonta” or “Defendant”) seeking declaratory and injunctive relief. In its Amended Complaint, COLFS alleges that several statements it makes about abortion pill reversal treatment are constitutionally protected, and that AG Bonta’s alleged “attack against APR [abortion pill

1 reversal]” puts COLFS at risk of incurring enforcement actions by the State. ECF No. 20  
2 ¶ 12.

3 Before the Court is COLFS’s motion for preliminary injunction. ECF No. 21.  
4 Based on the reasons below, the Court DENIES Plaintiff’s motion for preliminary  
5 injunction.

6 **FACTUAL BACKGROUND<sup>1</sup>**

7 **I. Abortion Pill Reversal treatment**

8 COLFS is a Catholic community health clinic in San Diego County that provides  
9 free abortion pill reversal (“APR”) treatment.<sup>2</sup> ECF No. 20 (“Am. Compl.”) ¶ 4, 19, 21.  
10 APR is a medical procedure designed for pregnant women who have started the chemical  
11 abortion process by ingesting mifepristone, the first pill out of two<sup>3</sup>, and who later decide  
12 to keep the unborn child. *Id.* ¶ 2. APR consists of taking the hormone progesterone in  
13 order to counteract mifepristone’s blocking of the body’s natural supply of progesterone.  
14 *See id.* ¶¶ 2, 3, 33-34.

15 COLFS alleges that “[s]upplemental progesterone itself is indubitably safe.” *Id.* ¶  
16 30. The “first known attempt to reverse the effects of mifepristone using bioidentical  
17 progesterone” was in 2006, and the woman “went on to deliver a healthy baby.” *Id.* ¶ 31.  
18 A few years later, COLFS’s medical director, Dr. George Delgado “devised the APR  
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22 <sup>1</sup> The factual background of this case was detailed in the Court’s Order dated November  
23 12, 2024, ECF No. 17, and is, for the most part, incorporated herein.

24 <sup>2</sup> The Court recognizes the term, “abortion pill reversal treatment,” itself is contested,  
25 since AG Bonta alleges that “reverse” or “reversal” are in fact fraudulent statements for  
26 describing the supplemental progesterone treatment that is at issue here. Putting that  
27 aside, the Court will refer to this medical treatment as “abortion pill reversal treatment”  
28 or “APR treatment” throughout this Order, because that is the treatment’s common name.

<sup>3</sup> The first pill contains mifepristone, the second misoprostol. Am. Compl. ¶ 25.

1 protocol for reversing the effects of mifepristone and began to advise doctors on APR.”  
2 *Id.* ¶ 32.

3 **II. Heartbeat International and the Enforcement Action**

4 In light of what were viewed as successful APR interventions, COLFS’s medical  
5 director, Dr. George Delgado, set up a website and hotline in May 2012 to educate  
6 pregnant women seeking to counteract the effects of mifepristone and to connect them  
7 with licensed medical professionals. *Id.* ¶ 43. This became known as the “APR  
8 Network.” *Id.* In 2018, to “ensure expansion of the APR Network and increased public  
9 awareness of the APR protocol,” COLFS transferred the Network for the nominal sum of  
10 \$1 to Heartbeat International, a nationwide trade group that represents pro-life pregnancy  
11 resource organizations. *Id.* ¶ 44.

12 On September 21, 2023, Rob Bonta, the California Attorney General and the  
13 Defendant in this case, filed a complaint in California state court seeking a permanent  
14 injunction, civil penalties, and other equitable relief against Heartbeat International et al.  
15 for false and misleading advertising of APR treatment. ECF No. 4-2, Request for  
16 Judicial Notice (“RJN”), Ex. A. AG Bonta’s complaint against Heartbeat International et  
17 al. (“Enforcement Action” or “State Action”) alleges that there is no credible scientific  
18 evidence supporting the theory that progesterone counteracts mifepristone without  
19 harmful effects or that APR is safe. Ex. A ¶¶ 32, 33, 37, 40-45.

20 The Enforcement Action alleged two causes of action under California’s Unfair  
21 Competition Law (“UCL”), Business and Professions Code section 17200 *et seq.*, and  
22 False Advertising Law (“FAL”), Business and Professions Code section 17500 *et seq.*  
23 Ex. A ¶¶ 96-101. The Action alleged that Heartbeat International et al. promulgated eight  
24 statements in their APR advertisements and communications that are false and  
25 misleading because they are unsupported by credible scientific evidence: (1) the use of  
26 the terms “reverse” and “reversal”; (2) that APR “has been shown to increase the chances  
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1 of allowing the pregnancy to continue”; (3) that APR has a success rate of 64-68%; (4)  
2 that the rate of birth defects following APR is “less or equal to the rate in the general  
3 population”; (5) that “thousands of lives have been saved” through APR; (6) that APR  
4 may be effective beyond a 72-hour window following mifepristone administration; (7)  
5 that APR may be effective following administration of misoprostol and methotrexate; and  
6 (8) that APR can cause only non-life-threatening side effects, even though it can cause  
7 severe bleeding. Ex. A. ¶¶ 97, 100.

8 Heartbeat International and the other defendant RealOptions, Inc. filed demurrers  
9 asking the state court to dismiss the action, based on constitutional grounds, and  
10 Heartbeat International filed a motion to quash. Exs. C, D, E. In June 2024, the state  
11 court denied the motion to quash and overruled the demurrers. Exs. F, G. The  
12 defendants filed their joint answer, including as part of their affirmative defenses that the  
13 Action is unconstitutional under the First Amendment’s Free Exercise and Free Speech  
14 Clauses and under the Fourteenth Amendment’s Substantive Due Process Clause. Ex. B  
15 at 31-33.<sup>4</sup>

### 16 **III. COLFS and the current complaint**

17 COLFS sold to Heartbeat International, for a nominal sum, the APR Network that  
18 Dr. Delgado created, which included a website, a hotline, and a network of providers  
19 willing to provide APR treatment. Am. Compl. ¶¶ 43-44.

20 COLFS alleges the Enforcement Action is an “attempt to restrict APR,” *see id.* ¶¶  
21 122, 140, 151. COLFS alleges that the Enforcement Action has created its need for pre-  
22 enforcement relief from AG Bonta because COLFS alleges it makes the same or similar  
23 statements as those targeted in the Enforcement Action against Heartbeat International.  
24 *See id.* ¶¶ 97, 100, 102-05.

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27 <sup>4</sup> Page numbers in this Order will refer to the CM/ECF pagination.

1 In bringing this claim against AG Bonta, COLFS alleges that “Bonta’s attack on  
2 APR is chock full of constitutional implications” that infringe on COLFS’s and their  
3 patients’ rights. *Id.* ¶ 56. These “constitutional implications” involve violations of the  
4 free exercise of religion, the right to free speech, and the right to make reproductive  
5 decisions. *Id.*

6 Specifically, COLFS alleges that the Enforcement Action constitutes a content-  
7 based restriction on speech about APR and thus violates the Free Speech Clause. *Id.* ¶  
8 112. COLFS also alleges that the Enforcement Action violates the Free Speech Clause’s  
9 protection of patients’ “right to receive information.” COLFS alleges that doctors have  
10 “third-party standing to assert the interests of their patients so long as the physician has  
11 also suffered injury himself.” *Id.* ¶ 145 (citing *McCormack v. Herzog*, 788 F.3d 1017,  
12 1027 (9th Cir. 2015)).

13 Furthermore, COLFS alleges that the Enforcement Action violates the Free  
14 Exercise Clause because it is not a generally applicable policy, since the Action does not  
15 apply to off-label uses of progesterone. *Id.* ¶ 137.<sup>5</sup>

16 Finally, COLFS alleges that the Enforcement Action violates the Substantive Due  
17 Process Clause of the 14th Amendment, because Bonta’s assertion that APR must be  
18 restricted violates COLFS’s patients’ right to “procreation, reproductive privacy, and to  
19 reject unwanted medical treatment.” *Id.* ¶ 159.

## 20 PROCEDURAL HISTORY

21 On July 30, 2024, COLFS filed its original complaint. ECF No. 1. On August 21,  
22 2024, AG Bonta filed a motion to dismiss, or alternatively stay, COLFS’s complaint.

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25 <sup>5</sup> COLFS feels “religiously obligated to offer Abortion Pill Reversal” by nature of its  
26 religious mission, so the provision of APR treatment, according to COLFS, is an exercise  
27 of religious freedom and expression that is protected under the First Amendment. *See id.*  
28 ¶ 122.

1 ECF No. 4. On November 5, 2024, COLFS filed a motion for preliminary injunction.  
2 ECF No. 13.

3 On November 12, 2024, this Court granted AG Bonta’s motion to dismiss, based  
4 on the finding that COLFS had not sufficiently alleged pre-enforcement standing, and  
5 granted COLFS leave to amend. ECF No. 17. The following day, the Court denied  
6 COLFS’s preliminary injunction request as moot. ECF No. 18. On November 15, 2024,  
7 COLFS filed its amended complaint and re-filed its preliminary injunction motion. ECF  
8 Nos. 19, 21. On December 10, 2024, AG Bonta filed a motion to dismiss COLFS’s  
9 amended complaint simultaneously with his opposition to COLFS’s preliminary  
10 injunction request. ECF Nos. 25, 27. On January 3, 2025, COLFS responded to the  
11 motion to dismiss, ECF No. 29, and filed a reply in support of its motion for preliminary  
12 injunction, ECF No. 30. On January 17, 2025, AG Bonta filed a reply in support of his  
13 motion to dismiss. ECF No. 31.

14 On June 13, 2025, this Court granted AG Bonta’s motion to dismiss the first  
15 amended complaint on counts two through four, but denied it as to count one. ECF No.  
16 43.

17 The Court now considers COLFS’s Motion for Preliminary Injunction (“Motion”  
18 or “Mot.”).

### 19 **REQUEST FOR JUDICIAL NOTICE**

20 Under Federal Rule of Evidence 201, a district court may take notice of facts not  
21 subject to reasonable dispute that are capable of accurate and ready determination by  
22 resort to sources whose accuracy cannot reasonably be questioned. Fed. R. Evid. 201(b).

23 Defendant seeks judicial notice of several exhibits, including court filings made in  
24 the State Action and court filings (expert declarations) made in other federal district court  
25 cases raising related legal issues. ECF No. 27, AG Bonta’s Request for Judicial Notice  
26 (“RJN”). Plaintiff objects as to the expert declartions but, in the event that the Court  
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1 takes judicial notice of these declarations, Plaintiff seeks judicial notice of Exhibits I  
2 through N, expert declarations in favor of APR that have been submitted in cases across  
3 the country. ECF No. 30, COLFS’s RJN.

4 The Court takes judicial notice of Exhibits A, B, and C from Defendant’s RJN  
5 because these are court filings in the State Action, which are both “matters of public  
6 record,” *Lee v. City of L.A.*, 250 F.3d 668, 689 (9th Cir. 2001) (citation omitted), and also  
7 highly relevant because Plaintiff has based its need for pre-enforcement relief on the  
8 existence of the pending State Action, Am. Compl. at 32. And neither party disputes its  
9 authenticity. *See Daniels-Hall v. Nat’l Educ. Ass’n*, 629 F.3d 992, 998-99 (9th Cir.  
10 2010). The Court does not, however, take judicial notice of the truth of any disputed  
11 facts contained in these exhibits. *See Lee*, 250 F.3d at 689.

12 As to the expert declarations found in Defendant’s Exhibits D through M and  
13 Plaintiff’s Exhibits I through N, the Court will take judicial notice of the existence of the  
14 documents and that they were publicly filed, but not the truth of matters stated therein.  
15 “Just because the document itself is susceptible to judicial notice does not mean that  
16 every assertion of fact within that document is judicially noticeable for its truth.” *Khoja*  
17 *v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 999 (9th Cir. 2018), *cert. denied sub nom.*  
18 *Hagan v. Khoja*, 587 U.S. 1014 (2019). That is true of court documents. *See GemCap*  
19 *Lending, LLC v. Quarles & Brady, LLP*, 269 F. Supp. 3d 1007, 1019 (C.D. Cal. 2017),  
20 *aff’d sub nom. GemCap Lending I, LLC v. Quarles & Brady, LLP*, 787 F. App’x 369 (9th  
21 Cir. 2019) (finding that a court may “take judicial notice of the existence of another  
22 court’s opinion or of the filing of pleadings in related proceedings; the Court may not,  
23 however, accept as true the facts found or alleged in such documents.”).

24 **LEGAL STANDARD**

25 “A preliminary injunction is an extraordinary remedy never awarded as of right.”  
26 *Winter v. Natural Resources Def. Council*, 555 U.S. 7, 24 (2008) (citation omitted).

1 Courts “must balance the competing claims of injury and must consider the effect on each  
2 party of the granting or withholding of the requested relief.” *Id.* (citation omitted). As  
3 such, the “grant of a preliminary injunction is a matter committed to the discretion of the  
4 trial judge[.]” *Evans v. Shoshone–Bannock Land Use Policy Comm’n*, 736 F.3d 1298,  
5 1307 (9th Cir. 2013) (citation omitted). “In exercising their sound discretion,” district  
6 courts “should pay particular regard for the public consequences in employing the  
7 extraordinary remedy of injunction.” *Weinberger v. Romero–Barcelo*, 456 U.S. 305, 312  
8 (1982).

9 District courts exercise this discretion according to a four-factor test rooted in well-  
10 established principles of equity. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391  
11 (2006). The moving party must show: (1) a likelihood of success on the merits; (2) a  
12 likelihood of irreparable harm to the moving party in the absence of preliminary relief;  
13 (3) that the balance of equities tips in the moving party's favor; and (4) that an injunction  
14 is in the public interest. *Winter*, 555 U.S. at 20.

15 Under the Ninth Circuit's “sliding scale” approach, “the elements of the  
16 preliminary injunction test are balanced, so that a stronger showing of one element may  
17 offset a weaker showing of another.” *Pimentel v. Dreyfus*, 670 F.3d 1096, 1105 (9th Cir.  
18 2012) (citing *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131 (9th Cir. 2011)).  
19 That being so, all four elements must be satisfied. *hiQ Labs, Inc. v. LinkedIn Corp.*, 31  
20 F.4th 1180 (9th Cir. 2022). The moving party carries the burden to meet the four *Winter*  
21 prongs. *All. for the Wild Rockies*, 632 F.3d at 1135.

## 22 DISCUSSION

23 The Court turns to COLFS’s motion for preliminary injunction. Because the Court  
24 concluded in a prior order that Plaintiff failed to state a plausible claim for relief as to  
25 counts two through four, *see* ECF No. 43, the Court concludes that Plaintiff is unlikely to  
26 succeed on the merits as to those claims and accordingly DENIES the motion for  
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1 preliminary injunction as to those causes of action. *See Disney Enterp., Inc. v. VidAngel,*  
2 *Inc.*, 869 F.3d 848, 856 (9th Cir. 2017) (if a movant fails to meet the “likelihood of  
3 success on the merits” prong, the court need not consider the other factors).

4 The Court now considers Plaintiff’s surviving First Amendment claim: whether  
5 applying the UCL and FAL to COLFS’s statements about APR treatment would violate  
6 the Free Speech Clause. In its order granting the Defendant’s motion to dismiss, the  
7 Court previously found that taking the well-pleaded allegations as true, this claim  
8 contained sufficient facts to plausibly support a cognizable legal theory. With respect to  
9 the requested preliminary injunction, “in the First Amendment context, the moving party  
10 bears the initial burden of making a colorable claim that its First Amendment rights have  
11 been infringed, or are threatened with infringement, at which point the burden shifts to  
12 the government to justify the restriction” on speech. *Thalheimer v. City of San Diego*, 645  
13 F.3d 1109, 1116 (9th Cir. 2011), *overruled on other grounds by Bd. of Trs. of Glazing*  
14 *Health & Welfare Tr. v. Chambers*, 941 F.3d 1195, 1199 (9th Cir. 2019) (en banc). The  
15 Court finds that COLFS has failed to make a colorable claim and even if it has, the  
16 government has justified its restriction on speech.

17 **A. Likelihood of success on the merits**

18 1. The commercial nature of the speech

19 The Court has already found that the challenged laws are not content-based and do  
20 not warrant application of a strict scrutiny standard. *See* ECF No. 43 (Order Denying in  
21 Part and Granting in Part Motion to Dismiss) at 24. But as content-neutral regulations,  
22 they are generally subject to heightened scrutiny: the government may impose reasonable  
23 restrictions on the time, place, or manner of protected speech, provided the restrictions  
24 “are justified without reference to the content of the regulated speech, that they are  
25 narrowly tailored to serve a significant governmental interest, and that they leave open  
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1 ample alternative channels for communication of the information.” *Clark v. Community*  
2 *for Creative Non-Violence*, 468 U.S. 288, 293 (1984).

3 The threshold question is, however, whether the speech at issue is protected. To  
4 answer this, the Court takes up whether the subject speech is commercial or non-  
5 commercial. Because “the degree of protection afforded by the First Amendment depends  
6 on whether the activity sought to be regulated constitutes commercial or non-commercial  
7 speech,” the Court “must first determine the proper classification” of the speech at  
8 issue. *Bolger v. Youngs Drug Prod. Corp.*, 463 U.S. 60, 65 (1983). In general, laws  
9 regulating commercial speech are subject to a lesser standard of scrutiny. *See id.* at 64-  
10 65. Inherently false and misleading statements in commercial speech are given little  
11 constitutional protection. *See Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of*  
12 *N.Y.*, 447 U.S. 557, 563 (1980).

13 The Supreme Court has held that speech may be “characterized as commercial  
14 when (1) the speech is admittedly advertising, (2) the speech references a specific  
15 product, and (3) the speaker has an economic motive for engaging in the speech.” *Am.*  
16 *Acad. of Pain Mgmt. v. Joseph*, 353 F.3d 1099, 1106 (9th Cir.2004) (citing *Bolger*, 463  
17 U.S. at 66–67). While “[t]he combination of all of these characteristics ... provides strong  
18 support for the ... conclusion that [the communication is] properly characterized as  
19 commercial speech,” *Bolger*, 463 U.S. at 67, it is not necessary that each of the  
20 characteristics “be present in order for speech to be commercial,” *id.* n. 14.

21 COLFS argues that its APR speech is noncommercial because as a religious  
22 nonprofit, it seeks to “ensure that Christ-centered medical care and pregnancy clinic  
23 services are available to all women regardless of ability to pay.” *Am. Compl.* ¶ 21.  
24 However, as the Court noted in its order granting the motion to dismiss, this is not  
25 dispositive. Instead, the *Bolger* factors are applied in a “fact-driven” analysis, *First*  
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1 *Resort*, 860 F.3d at 1272, and courts take a “common-sense” approach, *Ariix, LLC v.*  
2 *NutriSearch Corp.*, 985 F.3d 1107, 1115 (9th Cir. 2021).

3 Relying on the Amended Complaint, as well as transcripts of videos that are played  
4 at annual fundraising galas, AG Bonta offers evidence that COLFS uses the APR  
5 statements in advertisements that are directed towards, and solicit, women to become  
6 potential clients. *See, e.g.*, Am. Compl. ¶¶ 4, 15, 19, 21, 97, 102, 104; Goyette Decl. ¶¶  
7 5-8; *id.* Ex. B at 4 (“COLFS Medical Clinic can perform the APR process, but you must  
8 contact us immediately.”), Ex. C (“Do you regret your decision and wish to reverse the  
9 effects of the abortion pill? We are here to help you!”), and Ex. H (“At COLFS Medical  
10 Clinic we can help you learn everything you need to know about the APR procedure...”).  
11 These advertisements are clearly about the particular service/product of APR treatment  
12 and are aimed at soliciting women who are pregnant and have taken the first drug in the  
13 abortion pill regimen. COLFS’s statements are “placed in a commercial context and are  
14 directed at the providing of services rather than toward an exchange of ideas.” *Fargo*  
15 *Women's Health Org., Inc. v. Larson*, 381 N.W.2d 176, 181 (N.D. 1986).

16 AG Bonta asserts that COLFS has an economic motivation because it uses the  
17 APR statements in its yearly fundraising gala and uses patient stories about APR to solicit  
18 donations. Opposition to PI at 14-15. In other words, the APR advertising statements  
19 solicit patients whose stories then boost the organization’s fundraising efforts. *See First*  
20 *Resort*, 860 F.3d at 1273 (“solicitation of a non-paying client base directly relates to  
21 [plaintiff’s] ability to fundraise”). In *Nat’l Inst. of Fam. & Life Advoc. v. Bonta*, a case  
22 nearly parallel to the instant one, the district court found *First Resort*’s logic and rationale  
23 to be determinative in concluding that NIFLA had an economic motivation. 2025 WL  
24 1140450, at \*5 (C.D. Cal. Mar. 6, 2025). The court stated that since one of the benefits  
25 that NIFLA provides to its members is advising on APR, and it is through their members  
26 that NIFLA raises funds, this was a “powerful economic motivation.” *Id.*

1 Not only does *First Resort*'s logic apply to COLFS as well, there is a stronger case  
2 here for economic motivation. "NIFLA does not on its own provide any direct APR  
3 services to the public," *id.*, at \*2, while COLFS actually provides the APR treatments  
4 itself to its own patients, Am. Compl. at 8. Although COLFS alleges that, as a religious  
5 nonprofit, it provides "numerous free services," including "free APR treatment," this  
6 belies the fact that it still accepts insurance and payment for APR treatments from women  
7 who *do* have the ability to pay. On COLFS's website, the "Abortion Pill Rescue FAQs"  
8 page states: "Cost of the treatment varies depending on the progesterone used. Insurance  
9 plans may cover treatment. COLFS Medical Clinics will cover expenses for our APR  
10 patients who do not have insurance or financial means to pay for treatment." Goyette  
11 Decl., Ex. H. Thus, it seems apparent that COLFS has an economic motivation behind its  
12 APR speech. But COLFS does not respond to these allegations in its motion or briefing.

13 The Court concludes that the subject speech is commercial.

14 2. Whether the speech is false and misleading

15 Next, the Court applies the *Central Hudson* test to determine whether a potential  
16 enforcement action against COLFS's commercial APR speech would be unlawful. *See*  
17 *Am. Academy of Pain Management v. Joseph*, 353 F.3d 1099, 1106 (9th Cir. 2004) (citing  
18 *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980)).

19 As a threshold question, "*Central Hudson* specifies that if the regulated  
20 [commercial] speech concerns illegal activity or is misleading, the First Amendment  
21 extends no protection and the analysis ends." *Erotic Serv. Provider Legal Educ. & Rsch.*  
22 *Project v. Gascon*, 880 F.3d 450, 460 (9th Cir. 2018). Specifically, for "inherently  
23 misleading" commercial speech, there is no First Amendment protection at all. *Am.*  
24 *Academy of Pain Management*, 353 F.3d at 1107. For "potentially misleading"  
25 commercial speech, "the speech regulation must satisfy the remaining three factors  
26 specified in *Central Hudson*." *Id.*

1 This is not the first case where statements regarding the efficacy and safety of APR  
2 have been subjected to First Amendment scrutiny. Three district courts have struck down  
3 state laws that required abortion providers, under threat of criminal sanction, to inform  
4 patients about supplemental progesterone therapy in language providers objected to for  
5 being untruthful or misleading. *See Am. Med. Ass'n v. Stenehjem*, 412 F. Supp. 3d 1134,  
6 1147–52 (D.N.D. 2019); *Planned Parenthood of Tenn. & N. Miss. v. Slatery*, 523 F.  
7 Supp. 3d 985, 1005 (M.D. Tenn. 2021); *All-Options, Inc. v. Atty. Gen. of Ind.*, 546 F.  
8 Supp. 3d 754, 770 (D. Ind. 2021). Two district courts have addressed the particular  
9 procedural posture here: a pro-life organization asking for a preliminary injunction that  
10 would disallow an attorney general from pursuing a hypothetical enforcement action  
11 against them based on APR-related speech. The courts went oppositely. *See Nat'l Inst.*  
12 *for Fam. & Life Advocs. v. James*, No. 24-CV-514 (JLS), 2024 WL 3904870, at \*12  
13 (W.D.N.Y. Aug. 22, 2024) (injunction granted after applying strict scrutiny); *Nat'l Inst.*  
14 *for Fam. & Life Advocs. v. Bonta*, 2025 WL 1140450, at \*5 (injunction denied after  
15 applying *Central Hudson*).

16 The Court now turns to whether this commercial speech is false or misleading.  
17 Because COLFS has alleged that they make the same or similar statements as those that  
18 AG Bonta is targeting in the State Action, *see Am. Compl.* ¶¶ 97, 100, 102-05, the Court  
19 will examine each of these statements to find whether they are inherently or potentially  
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1 false and misleading – or not. The Court, in doing so, relies on the exhibits and expert  
2 declarations submitted by both parties.<sup>6,7</sup>

3 **a. Use of the terms “reverse” and “reversal”**

4 AG Bonta’s civil enforcement action against Heartbeat International targets  
5 statements that supplemental progesterone treatment “reverses” medical abortions. These  
6 statements are based on Dr. Delgado’s theory that supplemental progesterone can  
7 “outcompete” mifepristone to counteract or “reverse” the effects of mifepristone.  
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10 <sup>6</sup> AG Bonta filed an objection to the declarations of Plaintiff’s experts, Dr. Valley and Dr.  
11 Kraus, on the grounds that neither are qualified to provide the opinions they offer in their  
12 declarations, and that their opinions are not reliable. ECF No. 28. **The Court**  
13 **OVERRULES these objections.** Both experts are qualified to opine on Abortion Pill  
14 Reversal, as they are medical professionals who have practiced and specialized in the  
15 OB/GYN field. ECF No. 30-9 (Plaintiff’s Response to Defendant’s Evidentiary  
16 Objections). Federal Rule of Evidence 702, which requires a testifying expert to be  
17 qualified, “contemplates a broad conception of expert qualifications.” *Hangerter v.*  
18 *Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1015 (9th Cir. 2004) (citation omitted).  
19 Dr. Valley and Dr. Kraus’s opinions are also reliable. They are based on work  
20 experience and medical literature, including peer-reviewed human studies. *See Daubert*  
21 *v. Merrell Dow Pharm. Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995). In any case, “the  
22 Federal Rules of Evidence do not strictly apply in the preliminary injunction context.”  
23 *Flathead-Lolo-Bitterroot Citizen Task Force v. Montana*, 98 F.4th 1180, 1189 (9th Cir.  
24 2024).

25 <sup>7</sup> On April 2, 2025, Plaintiff filed an ex parte application for leave to submit a  
26 supplemental declaration of Dr. Kraus in support of its motion for preliminary  
27 injunction. ECF No. 36. **The Court GRANTS this ex parte application.** Dr. Kraus’s  
28 supplemental declaration opines on a new study published on March 19, 2025, which  
examines the effects of progesterone on the inner lining of the uterus after ingestion of  
mifepristone. Because this study is relevant to the issues of this case, and because it was  
not yet published when briefing was concluded, the Court finds good cause to grant this  
ex parte application, and will consider the supplemental declaration in its analysis herein.  
The Court also accepts, for consideration, Defendant expert Dr. Creinin’s declaration that  
was filed in response to Dr. Kraus’s supplemental declaration. ECF No. 40.

1 Connolly Decl. Ex. 3 at 16. Typically, mifepristone acts as a “competitive binder of the  
2 progesterone receptor – it binds to progesterone receptors at twice the avidity of  
3 progesterone itself, thus blocking endogenous progesterone from acting to support a  
4 pregnancy.” Kraus Decl. ¶ 33; Creinin Decl. ¶ 21 (mifepristone “works by binding more  
5 rightly and more preferentially to the progesterone receptors in the uterus and cervix”).  
6 “By preventing progesterone from binding with those progesterone receptors, the uterus  
7 begins to shed its lining and becomes more sensitive to prostaglandins, like misoprostol,  
8 that cause the uterus to contract.” Creinin Decl. ¶ 21.

9 According to Plaintiff’s expert Dr. Kraus, the influx of additional progesterone  
10 could “bind the receptors, and can ultimately outcompete mifepristone for the receptors.  
11 The effect is a competitive inhibition of the mifepristone that curbs and even negates its  
12 effects.” Kraus Decl. ¶ 33. This is the pharmacology behind the theory of using  
13 progesterone to “reverse” medication abortions after mifepristone is administered. *Id.*

14 However, as Defendant’s expert Dr. Creinin notes, “[d]uring pregnancy, the  
15 amount of progesterone the body produces increases substantially and these levels remain  
16 high throughout the entire pregnancy.” Creinin Decl. ¶ 37. Thus, even given the high  
17 amounts of progesterone, mifepristone is able to do its work in attaching to progesterone  
18 receptors. In other words, it’s not for lack of progesterone that mifepristone is able to  
19 work. Simply adding more progesterone would be like “rain on a swimmer in a pool –  
20 the swimmer cannot get more wet.” *All-Options, Inc.*, 546 F. Supp. 3d at 768  
21 (paraphrasing testimony from expert who did not believe additional progesterone would  
22 prevent an abortion).

23 Dr. Kraus disagrees, asserting that “if the substrate concentration (progesterone) is  
24 increased (that is, above normal levels in the body, which are already elevated), the  
25 understood result is that it outcompetes the inhibitor at the receptor.” Kraus Decl. ¶ 20.  
26 “In these cases, it is still the administration of even more competition (in this case, more  
27  
28

1 progesterone) that overcomes the inhibitory action of the mifepristone bound to  
2 progesterone receptors.” *Id.* Dr. Kraus seems to believe that introducing more  
3 progesterone would have some significant effect in outcompeting mifepristone, even  
4 though there are already-inflated levels of progesterone.

5 In support, Plaintiff’s other expert Dr. Valley asserts that there is scientific  
6 evidence backing this premise that progesterone, on a molecular level, can outcompete or  
7 reverse the effects of mifepristone. Valley Decl. ¶¶ 27, 29. He points to a study that was  
8 part of the submission to the FDA during the New Drug Application process for  
9 mifepristone. In this study, rats were given mifepristone with and without progesterone.  
10 When given only mifepristone, the fetal loss rate was 66-100%. Valley Decl. ¶ 29. For  
11 the group of rats given the highest dose of progesterone, the fetal loss rate was 10.78%.  
12 *Id.* The authors of the study wrote, “Thus the abortifacient activity of RU486  
13 (mifepristone) is antagonized by progesterone allowing for normal pregnancy and  
14 delivery.” *Id.* (citing Mifeprex Drug Approval Package, *Pharmacology Review(s)*, FDA  
15 16-17 (Sept. 28, 2000)).

16 Dr. Valley also points to another study done on rats. Three groups of pregnant rats  
17 were studied: one was given only mifepristone, another was given both mifepristone and  
18 progesterone, and a control group was given neither drug. *Id.* ¶ 32. The continued  
19 pregnancy rate in the group receiving *both* mifepristone and progesterone was 81.3%,  
20 similar to the continued pregnancy rate in the control group that received no mifepristone  
21 and no progesterone. *Id.* The group given only mifepristone had no resulting viable  
22 pregnancies. *Id.*

23 Of course, animal studies can be an important “pre-clinical tool to developing a  
24 knowledge base about potential human safety and efficacy,” Creinin Decl. ¶ 33, but  
25 naturally, they are limited in justifying the clinical use of a drug on humans. This is all  
26 the more apparent here because “there are significant differences between rat and human  
27  
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1 pregnancies and progesterone’s actions in each” and “[p]rogesterone receptors also vary  
2 widely between species in their responsiveness to different molecules...” *Id.* ¶ 59.<sup>8</sup> All  
3 experts agree that the “gold standard for experimental research is a randomized controlled  
4 trial” (“RCT”) conducted on humans. *Id.* ¶ 32; Valley Decl. ¶ 19a; Kraus Decl. ¶ 34.

5 More persuasive, therefore, is a recently published study by lead author Pilar Vigil,  
6 MD, PhD (“Vigil Study”), which was designed to examine the effects of progesterone  
7 supplementation, after mifepristone administration, on the endometrium (the inner lining  
8 of the uterus where implantation occurs). This was a placebo-controlled trial.  
9 Endometrial biopsies were obtained 7 days after ovulation and analyzed. Dr. Kraus states  
10 that the study’s findings suggest that supplemental progesterone may help promote  
11 restoration of the endometrium for implantation, counteracting the changes caused by  
12 mifepristone. ECF No. 36, Supplemental Declaration of Elena Kraus, M.D., Ph.D.  
13 (“Kraus Supp. Decl.”) ¶ 9. The study’s findings also suggest that “specific gene  
14 expression that is affected by mifepristone in the human endometrium is reversed by  
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17 <sup>8</sup> Dr. Creinin also argues that because the animals were given progesterone at the same  
18 time as mifepristone, the studies did not accurately reflect how APR usually works  
19 (progesterone given at some point after mifepristone). Creinin Decl. ¶ 58. The analysis  
20 therefore depends in part on *when* mifepristone actually works in the body. This is a  
21 point of contention between the experts. Dr. Creinin states: “Mifepristone is absorbed  
22 quickly within one to two hours after ingestion, is metabolized slowly over the first 72  
23 hours, then more quickly after 72 hours. Thus, by the time that progesterone is taken in  
24 an attempt to halt the effects of the mifepristone, the mifepristone actions have largely  
25 already occurred.” Creinin Decl. ¶ 22. Dr. Kraus, in turn, states that “mifepristone is  
26 absorbed quickly, but its action occurs over a more prolonged period.” Kraus Decl. ¶ 26.  
27 “During this period of activity in its target areas, mostly within about 72 hours,  
28 supplemental progesterone would have time to counteract its effects, and hold potential  
for being applicable for effectively outcompeting mifepristone and its actions at  
progesterone receptors.” *Id.* The Court does not presume to make a finding on the exact  
timing of mifepristone’s effects, but finds that it is possible that the fullest extent of  
mifepristone’s effects have not occurred within 72 hours.

1 exogenous progesterone when administered 24 hours later.” *Id.* ¶ 10. Dr. Kraus admits  
2 that “[f]urther studies are needed to establish a direct regulatory effect of exogenous  
3 progesterone administered after mifepristone” but that the study nevertheless provided  
4 further support for the “potential effectiveness of supplemental progesterone in reversing  
5 the effects of mifepristone when used for medication abortions.” *Id.* ¶ 11.

6 Dr. Creinin found the new study unpersuasive because it used nine *nonpregnant*  
7 individuals as subjects. ECF No. 40, Declaration of Dr. Mitchell Creinin Opposing Ex  
8 Parte Application for Leave to Submit Supplemental Expert Declaration (“Creinin Supp.  
9 Decl.”) ¶ 10. The endometrial lining, uterus, and hormonal milieu of a pregnant person  
10 are all “vastly different” from those of a nonpregnant person. *Id.* This extends to the  
11 genetic transcription occurring within the endometrium as well: during pregnancy, the  
12 specific genes that were examined in the Vigil Study undergo significant changes, such  
13 that the genetic activity presents “a wholly different baseline upon which mifepristone  
14 and progesterone administered during pregnancy will act.” *Id.* Dr. Creinin also criticized  
15 the study for its focus on examining tissue samples rather than “actual bodies,” making it  
16 more of a laboratory than clinical study, and for having a small sample size (9  
17 individuals) which would mean that any findings would not be conclusive of causation  
18 and instead would be at most “hypothesis generating.” *Id.* ¶¶ 11, 13.

19 The Court concludes that the findings of the Vigil Study are inherently limited  
20 because only a few nonpregnant individuals were studied. However, the Court finds that  
21 the findings are still important and valuable to consider, especially given the weighty  
22 ethical considerations that impede conducting RCTs in this area of study. Kraus Decl. ¶  
23 34; Valley Decl. ¶ 57 (“It would not be ethical to ask women, who wanted to attempt to  
24 reverse their medication abortion with progesterone, to enroll in a randomized controlled  
25 trial where they would randomly receive either progesterone or placebo.”). The Vigil  
26  
27  
28

1 Study’s findings may not be exactly on-point for the scientific question at issue, but this  
2 goes to weight and not admissibility.

3 Finding that the science here is unclear on how exactly supplemental progesterone  
4 reacts with mifepristone, the Court turns to the common understanding of the word  
5 “reverse” to determine whether it accurately captures what we *do* know about the effects  
6 of supplemental progesterone. According to dictionary definitions, “reverse” means “to  
7 change the direction, order, position, result, etc. of something to its opposite.”<sup>9</sup> Or, “to  
8 turn completely about in position or direction” or “to undo or negate the effect of  
9 (something, such as a condition or surgical operation).”<sup>10</sup>

10 Thus, a “reversal” of an abortion implies that there is a complete change in  
11 direction or position, a negation of a condition, or an undoing of an effect. That does not  
12 seem to capture entirely and accurately what is happening here. *See* Creinin Decl. ¶ 44  
13 (“Medication abortion cannot be ‘reversed,’ which would imply putting an aborted  
14 pregnancy back in the uterus.”). Supplemental progesterone possibly could be inhibiting  
15 mifepristone’s effects or competing with mifepristone for receptors. But this does not  
16 really mean – less so guarantee – a reversal of mifepristone’s effects or of the abortion as  
17 a whole. *See Slatery*, 523 F. Supp. 3d at 1003 (“The word ‘reversal’ makes the mandated  
18 message untruthful and/or misleading because it promises more than progesterone  
19 therapy has even attempted to deliver.”).

20 Not only has COLFS not provided evidence that greater amounts of progesterone  
21 can unseat mifepristone from progesterone receptors, it may instead be the case that  
22

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23  
24 <sup>9</sup> *Cambridge Dictionary*, “Reverse” (last updated May 5, 2025),  
25 <http://dictionary.cambridge.org/us/dictionary/english/reverse>.

26 <sup>10</sup> *Merriam-Webster*, “Reverse” (last updated May 5, 2025),  
27 <http://www.MerriamWebster.com/dictionary/reverse>.

1 “failing to continue taking the second drug in the medication abortion regimen,  
2 misoprostol, may result in continued pregnancy in some percentage of women who take  
3 mifepristone[.]” Creinin Decl. ¶ 46b. In the absence of such evidence, it would be at the  
4 very least potentially misleading to state that supplemental progesterone can “reverse” an  
5 abortion.

6 **b. “Effectiveness” statement**

7 COLFS alleges that it engages in statements asserting that APR is effective and can  
8 increase the chances of continued pregnancy. *See* Am. Compl. ¶ 102.

9 COLFS relies heavily on Dr. Delgado’s 2018 Report, which purportedly shows  
10 that progesterone increases the chances of a pregnancy continuing after taking  
11 mifepristone.<sup>11</sup> As AG Bonta notes, however, there are several methodological and  
12 structural flaws with this Report. Some patients were screened by ultrasound for viable  
13 pregnancies before joining the study, which biased the data towards pregnancies already  
14 likely to continue. Connolly Decl. Ex. 3 at 22. The Report also did not record how far  
15 along in her pregnancy each patient was or how much progesterone each patient took –  
16 even though mifepristone is less effective at terminating pregnancies as they progress in  
17 gestational age. Connolly Decl. Ex. 3 at 19. Finally, there were no controls in the study,  
18

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19  
20 <sup>11</sup> Besides the 2018 Report, Plaintiff and experts draw conclusions from three other APR  
21 analyses: a 2012 case series by Delgado and Davenport with six patients, a 2017 case  
22 series involving three patients, and a 2023 pilot study with six patients. Connolly Decl.  
23 Ex. 2; Creinin Decl. Exs. P, GG (respectively). According to a statement by the  
24 American College of Obstetricians and Gynecologists, “[The 2012 case series] is not  
25 scientific evidence that progesterone resulted in the continuation of those pregnancies.”  
26 Connolly Decl. Ex. 8 at 14. “Case series with no control groups are among the weakest  
27 forms of medical evidence.” *Id.* at 15. Because of the small sample size of all these  
28 analyses – and other methodological flaws – the results of these analyses do not provide  
meaningful statistical support for the effectiveness of APR treatment. *See* Creinin Decl. ¶  
55.

1 especially as the patients were treated by 325 different medical providers. *See All-*  
2 *Options, Inc.*, 546 F. Supp. 3d at 766. For these reasons, the 2018 Report does not  
3 support the accuracy of the statements that APR is “effective” in continuing pregnancies.

4 A significant assumption made by the 2018 Report, in purporting that  
5 supplemental progesterone was effective, was that less than 25% of pregnancies will  
6 continue after taking mifepristone alone. Connolly Decl. Ex. 3 at 19. To determine if  
7 APR treatment is effective at continuing pregnancy, it is important to establish what is  
8 called the “continuing pregnancy rate” for mifepristone alone, *without* misoprostol or  
9 progesterone. This rate would be the baseline, against which the continuing pregnancy  
10 rate for mifepristone *plus* supplemental progesterone would be compared. In theory, if  
11 supplemental progesterone actually had an effect on fetal survival, the rates would be  
12 significantly and statistically different. In other words, if the continuing pregnancy rate  
13 of **mifepristone + progesterone** was not meaningfully different from the continuing  
14 pregnancy rate for **mifepristone alone**, then APR treatment would be considered  
15 ineffective.

16 The problem is that there is no agreed-upon rate of continuing pregnancy for  
17 mifepristone alone; no baseline rate has been universally accepted.<sup>12</sup> A systematic review  
18

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19  
20 <sup>12</sup> According to Dr. Creinin, “It is difficult to accurately estimate the rate of continuing  
21 pregnancy following mifepristone alone for a few reasons: (1) there are very few studies  
22 showing the proportion of pregnancies in which mifepristone alone caused complete  
23 abortion due to the fact that during early studies (before FDA approval), researchers  
24 understood that mifepristone alone was not very effective at ending a pregnancy but,  
25 when used in combination with a prostaglandin analogue, it became very effective; (2)  
26 almost all studies of mifepristone-alone efficacy focused on pregnancies that were less  
27 than 49 days gestation and higher doses of mifepristone than the dosage used under the  
28 FDA approval/guidance; (3) none of the studies of mifepristone alone have included a  
wide enough range of gestational ages, including up to 70 days gestation, to encompass  
the upper gestational duration approved by the FDA for medication abortion with  
mifepristone and misoprostol; and (4) there are no large population-based studies

1 of studies on embryo survival after mifepristone-only was published in 2015 (“Grossman  
2 Systematic Review”). Valley Decl. ¶ 50. The studies reviewed, however, were very  
3 heterogenous, involving different doses of mifepristone, such that the authors concluded  
4 that no conclusions could be made about continuing pregnancy rates with mifepristone  
5 alone. *Id.* The continuing pregnancy rates ranged from 8% to 46%, depending on the  
6 mifepristone regimen used. *See id.*; Creinin Decl. ¶ 39. The review’s lead author, Dr.  
7 Grossman, concluded that there was inadequate evidence to establish that supplemental  
8 progesterone increased the likelihood of pregnancy continuation following mifepristone.  
9 Kraus Decl. ¶ 38.

10 Another systematic review of pregnancy continuation after mifepristone alone was  
11 conducted in 2017 (“Davenport Systematic Review”). Valley Decl. ¶ 51. Most of the  
12 studies that were reviewed involved a dosage level that was more than 200mg of  
13 mifepristone, the current commonly prescribed dose. *Id.* The Davenport Systematic  
14 Review also included studies that did not clearly define a continuing pregnancy as a  
15 viable pregnancy (either by not defining the term or by including pregnancies that had  
16 fetal death but not full tissue expulsion). Creinin Decl. Ex. I at 2. One study that used  
17 the single mifepristone dose at 200mg showed a continuing pregnancy rate of 23.3%.  
18 Valley Decl. ¶ 51. This is the rate that the 2018 Report relied on as its baseline  
19 percentage. But this study only had a sample size of 30 women, not enough to glean a  
20 “statistically reliable pregnancy continuation rate.” Creinin Decl. ¶ 40.

21 In a recent systematic review from 2024, the Stifani Systematic Review, the  
22 continuing pregnancy rate for individuals with  $\leq 7$  weeks in gestational age who received  
23 progesterone was determined to be 42% (confidence interval of 37-48) compared with  
24 \_\_\_\_\_  
25  
26 examining this question because very few women elect to discontinue their medication  
27 abortion after having taken mifepristone.” Creinin Decl. ¶ 39.

1 22% (confidence interval of 11-39) for mifepristone alone. While the difference between  
2 the rates appears significant, “[m]ost of the data in this analysis were collected as part of  
3 a large case series with ethical and methodological issues.” Connolly Decl. Ex. 7 at 9.  
4 Namely, the 2018 Delgado Report, which purported a success rate of progesterone  
5 treatment of up to 68%. As analyzed above, however, the 2018 Report was flawed in  
6 many ways, including the fact that at least several women demonstrating no fetal  
7 heartbeat were excluded from the study. “Only selecting individuals who had gestational  
8 cardiac activity at the time they sought abortion reversal would falsely inflate  
9 progesterone’s success rate...” *Id.* Since much of the data analyzed in the Stifani  
10 Systematic Review derived from the 2018 Delgado Report, the results of the systematic  
11 review are not free of the Report’s original flaws. The authors concluded as much:  
12 “Based mostly on poor-quality data, it appears the ongoing pregnancy rate in individuals  
13 treated with progesterone after mifepristone is not significantly higher compared to that  
14 of individual receiving mifepristone alone.” Connolly Decl. Ex. 7 at 2.

15 Well-respected professional organizations have also cast doubt on the effectiveness  
16 of APR: the American College of Obstetricians and Gynecologists, the Society of  
17 Obstetricians and Gynecologists of Canada, and the Royal College of Obstetricians and  
18 Gynecologists have all stated that there is no strong scientific evidence supporting or  
19 recommending APR. Creinin Decl. ¶ 47a.-c.

20 The Court finds that given the lack of robust scientific study on this issue,  
21 statements on the effectiveness of APR are potentially misleading.

22 **c. “Side effects” statement**

23 There is not enough medical evidence to conclude with confidence that APR is  
24 safe. No study offered or used by COLFS appears to track health or safety outcomes for  
25 the pregnant individual. Connolly Decl. Ex. 7 at 9. No study affirmatively concludes  
26 that APR only has non-life-threatening side effects. The 2018 Report, the largest case  
27  
28

1 series on APR, “lacked any data about health or safety outcomes for the pregnant  
2 patients.” Creinin Decl. ¶ 53. There was only data on preterm delivery or birth defects,  
3 but no other pregnancy complications were recorded, and there was no information on  
4 what happened to the women for whom the pregnancy did not continue. *Id.*

5 Plaintiff’s experts have emphasized the safe and common use of progesterone for  
6 other issues arising in pregnancy. Valley Decl. ¶¶ 34-35; Kraus Decl. ¶ 32; Kraus  
7 Rebuttal Decl. ¶ 42. Dr. Creinin notes that there are still some risks involved with  
8 progesterone use, including hypertension, jaundice, and thyroid cancer, but does not  
9 provide any information on any life-threatening risks. Creinin Decl. ¶¶ 68-69.

10 The issue is less so whether supplemental progesterone – in general and in other  
11 prenatal contexts – is dangerous to women, but rather whether administering mifepristone  
12 *without misoprostol* (and therefore halting the medication abortion halfway) would be  
13 dangerous. *See* Creinin Decl. Ex. I at 221 (Dr. Creinin and Chen’s 2019 commentary)  
14 (progesterone “likely not” harmful “based on widespread use within obstetrics,” but there  
15 is no answer to whether “NOT using misoprostol [is] harmful, especially if the patient is  
16 beyond 49 days of gestation”). The first and only randomized clinical study to attempt to  
17 test the safety and efficacy of APR was initiated at UC Davis in 2019 by Dr. Creinin, but  
18 had to stop because of the serious “safety concerns” after 3 of the 12 participants  
19 experienced “severe bleeding” after taking mifepristone without misoprostol. Two of  
20 those three received a placebo (one of them eventually required a blood transfusion); the  
21 third person had been given progesterone and required no intervention. Dr. Valley  
22 interpreted this to mean that “giving the progesterone after mifepristone was safe” and  
23 that the “significant safety concerns were in the placebo arm only.” Valley Decl. ¶ 43.  
24 Dr. Creinin interpreted this to mean that taking mifepristone without following it up with  
25 misoprostol could lead to severe bleeding. Creinin Decl. ¶ 66 (“Patients in early  
26 pregnancy who use only mifepristone may be at risk of significant hemorrhage.”).

1 Professional organizations have also expressed disconcertment with the lack of  
2 evidence on the safety of APR treatment. The American College of Obstetricians and  
3 Gynecologists, on its website, states that it “ranks its recommendations on the strength of  
4 the evidence and does not support prescribing progesterone to stop a medication  
5 abortion.” Connolly Decl. Ex. 8. More directly, the Society of Obstetricians and  
6 Gynecologists of Canada released a public statement on APR, saying that it “can also  
7 result in serious complications for the patient.” Connolly Decl. Ex. 9. Finally, the Royal  
8 College of Obstetricians & Gynaecologists, along with other professional groups in the  
9 UK, released a joint statement on APR treatment and said that apart from the abandoned  
10 Creinin Study, they “do not recognise the legitimacy of any other studies used to  
11 evidence the safety or efficacy of progesterone as an abortion ‘reversal’ treatment  
12 because they do not follow the usual standards of reporting and study design for  
13 observational trials.” Connolly Decl. Ex. 10.

14 Due to the dearth of medical evidence on the effects of mifepristone without  
15 misoprostol and the effects of progesterone after mifepristone, the Court finds it  
16 potentially misleading to say that APR can only cause non-life-threatening side effects.

17 **d. “Birth defects” statement**

18 AG Bonta’s Enforcement Action alleges that Heartbeat International’s statements  
19 that the rate of birth defects following APR “is less or equal to the rate in the general  
20 population” are false and misleading. Am. Compl., Ex. 3 at 26. COLFS also propagates  
21 similar statements on its website. Am. Compl. at 34. These statements are based on the  
22 2018 Report, *see id.* at 32, 34, and the 2012 Delgado/Davenport small case series as well  
23 as another case series from 2017 conducted in Australia, *id.* at 13.

24 Plaintiff’s expert declarations support this reading of the 2018 Report. *See* Kraus  
25 Decl. ¶ 37; Valley Decl. ¶ 36 (the 2018 Report “did not show any increased risks of birth  
26 defects compared to the expected rate in the population”). On the other hand, Dr. Creinin  
27

1 stated that although the birth defect rate might be comparable to the background rate of  
2 approximately 3%, the 2018 Report did not state *what* those defects were. Creinin Decl.  
3 ¶ 51e. If the defects were all similar, this could indicate that pregnancies affected by  
4 APR (no misoprostol plus supplemental progesterone treatment) have a higher likelihood  
5 of certain birth defects than average.

6 It's unclear and difficult to make any definitive conclusions from these studies. In  
7 addition to all the flaws of the 2018 Report that are detailed above, the 2012  
8 Delgado/Davenport and 2017 Australia case series are too limited in scope to support the  
9 statement that the rate of birth defects following APR is equal to or less than the  
10 background rate.

11 There is also some debate among the experts on whether supplemental  
12 progesterone – apart from APR treatments – can increase the rate of genital  
13 abnormalities. *Compare* Creinin Decl. ¶ 67 (noting a “possible association” between  
14 progesterone use and genital defects) *with* Kraus Decl. ¶ 32 and Kraus Rebuttal Decl. ¶  
15 41 (“propensity of the data indicates that supplemental progesterone does not increase the  
16 rate of genital abnormalities”).

17 Given the lack of scientific evidence on this specific question, the Court finds the  
18 statements on birth defects following APR to be potentially false and misleading.

19 **e. “Success rate” statement**

20 That APR has a 64-68% success rate is unsupported, because it derives from the  
21 2018 Report, which, as detailed above, is faulty. In the 2018 Report, there was an overall  
22 “reversal rate of 48%” but a purported 64% rate for a subgroup of those receiving  
23 intramuscular injections and 68% (31 patients) for those in the high-dose oral subgroup.  
24 Creinin Decl. ¶ 52. Thus, different administration methods likely have different “success  
25 rates.” According to COLFS’s APR FAQs, patients will be prescribed progesterone  
26 “given as a pill to be taken orally or vaginally or possibly by intramuscular injection.”  
27

1 Goyette Decl. Ex. H 4. It is unclear what percentage of COLFS patients prescribed  
2 progesterone will take it via high-dose pills, vaginal intake, or intramuscular injection,  
3 and therefore unclear what the actual aggregate success rate would be. Statements  
4 purporting a 64-68% success rate are therefore inherently false and misleading.

5 **f. “Thousands of lives saved” statement**

6 According to AG Bonta’s Enforcement Action, Heartbeat International makes  
7 representations that “thousands of lives have been saved” through the use of APR. Am.  
8 Compl., Ex. 3 at 19; Kraus Decl. ¶ 26 (“Data from Heartbeat International... indicates  
9 they receive approximately 150 calls a month from women seeking APR and have  
10 ultimately helped save over 5,000 lives.”). AG Bonta alleges that this statement is based  
11 primarily on two numbers: the number of pregnant people who undertook APR and were  
12 confirmed by Heartbeat International to remain pregnant at 13 weeks, *plus* the number of  
13 those who started APR (but Heartbeat cannot confirm remained pregnant) multiplied by a  
14 64% success rate, obtained from the 2018 Report. As analyzed above, the 64% success  
15 rate is not a reliable statistic because it is based on a specific administration method of  
16 progesterone, and there is no reason to generalize this statistic to all women who started  
17 APR. The Court therefore finds these kinds of statements potentially false and  
18 misleading.

19 **g. Statements on non-standard situations**

20 AG Bonta is also targeting statements that APR is effective after 72 hours have  
21 passed from the ingestion of mifepristone and that APR is effective after taking the  
22 second pill of medication abortion (misoprostol). Because APR is usually considered to  
23 be the administration of progesterone within 72 hours after the first pill (mifepristone),  
24 these statements refer to non-standard APR situations. *See* Mot. for Prelim. Injunction at  
25 5; *see also* Creinin Decl. ¶ 62 (describing design of study aimed to measure effects of  
26 standard APR). From the Court’s review, nothing from the expert declarations submitted  
27

1 by COLFS even purports to support either of these statements. In fact, although Dr.  
2 Creinin and Dr. Kraus disagree about the exact timing of mifepristone’s effects, *see supra*  
3 fn. 5, Dr. Kraus concedes that mifepristone’s “period of activity in its target areas [is]  
4 mostly within about 72 hours.” Kraus Decl. ¶ 26.

5 Additionally, nothing in the 2018 Report supports these statements on non-  
6 standard situations. The Report actually eliminated patients who received misoprostol or  
7 who had taken mifepristone outside of the 72-hour window. Connolly Decl. Ex. 3 at 18.  
8 Thus, the statements that APR treatment could work in non-standard situations are  
9 inherently misleading.

10 3. Central Hudson analysis

11 There are some statements that the Court has found to be inherently false and  
12 misleading, and others to be only *potentially* so. As such, the Court engages in the next  
13 inquiry of the *Central Hudson* analysis. AG Bonta’s targeting of any of these statements  
14 would pass *Central Hudson* intermediate scrutiny.

15 *Central Hudson* requires AG Bonta to demonstrate that this regulation directly  
16 advances a substantial government interest. This is easily met here. According to the  
17 Ninth Circuit, “[t]here is no question that California has a substantial interest in  
18 protecting consumers from misleading advertising by medical professionals.” *Am.*  
19 *Academy of Pain Management*, 353 F.3d at 1108. Additionally, the U.S. Supreme Court  
20 has “noted the special interest that states have in regulating professions.” *Id.* (citing *Fla.*  
21 *Bar v. Went For It, Inc.*, 515 U.S. 618, 625 (1994)). The State of California has a  
22 substantial interest in protecting women from false advertising regarding reproductive  
23 rights.

24 Next, *Central Hudson* demands that AG Bonta show that the speech regulation  
25 directly advances the asserted government interest and that it is not more extensive than  
26 necessary to serve that interest. Here, the regulation directly advances California’s  
27

1 interest in protecting women from false advertising because Sections 17200/17500 are  
2 consumer protection statutes that aim to protect against false and misleading conduct and  
3 speech. This is a more than sufficient close fit. Although this regulation involves  
4 reproductive rights, AG Bonta is not aiming to limit the actual practice of APR. And  
5 reproductive choices are not apart from consumer choices: women, in exercising their  
6 reproductive rights, are also consumers who must be given the correct information to  
7 make knowledgeable decisions for themselves.

8 In any case, Plaintiff does not argue that the regulations fail to advance the asserted  
9 interest or that the regulations are not narrowly tailored. *See generally* Mot. for Prelim.  
10 Injunction.

11 In sum, Plaintiff cannot carry its burden of showing likelihood of success.  
12 Commercial speech that is inherently false or misleading does not receive First  
13 Amendment protection. For potentially misleading speech, the AG has more than carried  
14 his burden under *Central Hudson*.

### 15 **B. Irreparable harm**

16 It is well established that a deprivation of constitutional rights “unquestionably  
17 constitutes irreparable injury.” *Melendres v. Arpaio*, 695 F.3d 990, 1002 (9th Cir. 2012).  
18 However, as discussed above, Plaintiff has not established a likelihood of success on the  
19 merits for its First Amendment claim. Plaintiff does not aver any other injury that could  
20 constitute irreparable harm. And as AG Bonta noted, Plaintiff waited over a year after  
21 the filing of the Enforcement Action before initiating the instant action. Goyette Decl.  
22 Ex. A. This undermines Plaintiff’s argument that it is at risk of some irreparable harm.  
23 *See Lydo Enter., Inc. v. City of Las Vegas*, 745 F.2d 1211, 1213 (9th Cir. 1984). Thus,  
24 Plaintiff fails to meet its burden for this prong.

### 25 **C. Balance of the equities and public interest**

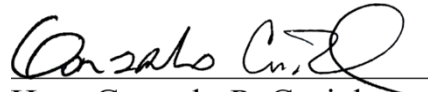
1 “When the government is a party,” the balance of equities and public interest  
2 “factors merge.” *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014).  
3 Because the Court finds that Plaintiff has not met the likelihood of success on the merits,  
4 Plaintiff also fails to meet these factors. Instead, this prong favors the Attorney General  
5 because if the preliminary injunction were granted, he would be unable to protect the  
6 public against false and misleading statements that advertise a medical procedure that has  
7 not been approved by the FDA. *See Maryland v. King*, 567 U.S. 1301, 1303 (2012)  
8 (“[A]ny time a State is enjoined by a court from effectuating statutes enacted by  
9 representatives of its people, it suffers a form of irreparable injury.”)

10 **CONCLUSION**

11 Based on the foregoing reasons, the Court DENIES Plaintiff’s motion for  
12 preliminary injunction.

13 **IT IS SO ORDERED.**

14 Dated: June 13, 2025

15   
16 Hon. Gonzalo P. Curiel  
17 United States District Judge  
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