IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 1:23-cv-939-DDD-SKC

BELLA HEALTH AND WELLNESS, et al.,
Plaintiffs,
v.

PHIL WEISER, in his official capacity as Attorney General of Colorado, et al.,
Defendants.

STATE DEFENDANTS' RESPONSE TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

Philip J. Weiser, Attorney General of Colorado, and members of the Colorado Medical Board and Colorado State Board of Nursing, each in their official capacities, file this response to Plaintiffs' motion for a preliminary injunction (Doc. 92, filed September 22, 2023).

INTRODUCTION

Plaintiffs ask the Court to excuse medical practitioners from complying with the standard of care applicable to licensed professionals where their use of experimental treatments in the clinical setting is motivated by religious conviction. This Court should not, because doing so "would be to make the professed doctrines of religious belief superior to the law of the land, in effect to permit every citizen to become a law unto himself. Government could exist only in name under such circumstances." *Reynolds v. United States*, 98 U.S. 145, 166-67 (1878).

BACKGROUND

A. The medication abortion regimen.

Medication abortion is a method of ending an early pregnancy typically performed using two medications, mifepristone and misoprostol. (The Declaration of Dr. Rebecca Cohen, M.D., M.P.H, attached as **Exhibit 1**, at ¶ 6.) In the absence of progesterone, mifepristone acts as a progesterone receptor partial agonist. *Id.* This means mifepristone binds to the body's progesterone receptor and partially activates it, but it does not have the same effect as something like progesterone itself would. *Id.* However, mifepristone behaves differently if progesterone is present in the patient's body. *Id.* In the presence of progesterone, mifepristone acts as a competitive progesterone receptor antagonist. *Id.* Meaning, mifepristone binds tightly and preferentially to the patient's progesterone receptors without activating them, which prevents progesterone from having a biological effect on the patient's body. *Id.* The body rapidly absorbs mifepristone after ingestion and its elimination from the body is slow through the first 72 hours, after which point elimination becomes much more rapid. *Id.*

Mifepristone inhibits the activity of both endogenous (originating from within the body) and exogenous (originating outside the body) progesterone. (*Id.* at ¶ 7.) Mifepristone causes the pregnancy tissue and lining of the uterus to break down and separate from the uterine wall, in addition to other effects. *Id.* To perform a medication abortion, the patient first takes mifepristone orally by swallowing a pill.

(*Id.* at ¶ 8.) The patient then takes misoprostol buccally (placing inside the cheek) 24 to 48 hours later. *Id.* Misoprostol dilates the cervix and induces muscle contractions, clearing the uterus. *Id.* Time is of the essence with a medication abortion—the regimen is only approved for use by patients who are less than 70 days pregnant. *Id.*

Mifepristone is not a reliable abortifacient on its own. (*Id.* at ¶ 9.) Research suggests that as many as 46% of patients who take mifepristone without misoprostol will continue their pregnancies. *Id.* In contrast, the FDA-approved two-drug regimen is more than 97% effective in terminating a pregnancy. *Id.*

The two-drug regimen, when completed, is also extremely safe. (*Id.* at ¶ 10.) Serious adverse reactions were reported in less than 0.5% of women who completed it. *Id.* However, limited available evidence suggests that using mifepristone alone may be associated with an increased risk of severe hemorrhage. *Id.* Deciding to continue pregnancy after mifepristone also increases the patient's risk for later miscarriage and early delivery. (*Id.* at ¶ 14.) Consequently, it is critical that the patient is firm in their decision to end the pregnancy before initiating the regimen. (*Id.* at ¶ 10.) In fact, the FDA risk evaluation and mitigation strategy (REMS) requires both the patient and provider to sign a patient agreement form wherein the patient agrees to complete the regimen once starting it. *Id.*

Patients presenting to a clinic requesting abortion care are generally firm in the decision about the medical outcome they seek. (*Id.* at ¶¶ 11-12.) Nevertheless, practitioners who provide abortion care proceed through a full advisement with

patients about the care plan options, the associated risks, and the likelihood that each care plan will end the pregnancy. (*Id.* at ¶¶ 11-14.) Due to the high efficacy of a two-drug medication abortion regimen, providers do not prescribe the regimen to patients who are not firm in the decision to end the pregnancy. (*Id.* at ¶ 12.)

And the number of patients who wish to continue their pregnancy in the middle of the two-drug regimen is exceedingly rare—research suggests somewhere between 0.005% and 0.3% of patients change their mind after taking mifepristone. (*Id.* at ¶¶ 11-12.) The current standard of care for patients who do change their mind before ingesting misoprostol is to determine whether the pregnancy has continued, and if so, begin expectant management, also known as watchful waiting. (*Id.* at ¶ 14.)

B. There is no scientifically valid method of "reversing" a medication abortion.

The experimental treatment commonly referred to as "abortion pill reversal" originated with Dr. George Delgado, a California family medicine physician. (*Id.* at ¶ 15.) Dr. Delgado, relying on research related to the prevention of early pregnancy miscarriage, theorized that physicians could use supplemental progesterone to "outcompete" mifepristone and reverse its effects. *Id.*

However, when a patient ingests mifepristone, their body is already producing higher than normal levels of progesterone because they are pregnant. (*Id.* at ¶ 17.) Mifepristone is effective specifically because it outcompetes progesterone when both are present. (*Id.* at ¶ 17.) Based on the scientific evidence currently available, Dr. Delgado's experimental treatment for a patient who has changed their mind is no

more effective than the current standard of care—expectant management. (*Id.*; the Declaration of Dr. Patricia Cullen, Ph.D., CPNP-PC, attached as **Exhibit 2**, at ¶ 14.) Additionally, there is no reliable scientific evidence exploring the potential risks posed by Dr. Delgado's experimental treatment. (**Ex. 1** at ¶¶ 17, 33-35; **Ex. 2**, at ¶ 14.) The one study designed to explore the potential risks and benefits of Dr. Delgado's experimental treatment was halted early due to an unusually high rate of dangerous hemorrhage. (*Id.* at ¶¶ 37-39.)

Proponents of Dr. Delgado's experimental treatment point to two case series as evidence of its efficacy, both authored by Dr. Delgado, in 2012 and 2018. (*Id.* at ¶¶ 15, 18.) Both studies were published in low-impact journals not regularly relied upon by OB/GYNs and other medical professionals in the fields of reproductive healthcare. (*Id.* at ¶¶ 19, 23.) And in general, case series are a low-quality descriptive study that do not collect sufficient data to establish a causal effect of an experimental treatment. (*Id.* at ¶ 18; **Ex. 2**, at ¶ 14.)

In Dr. Delgado's 2012 case series, he reported on six allegedly "successful" uses of his experimental treatment. (**Ex. 1** at ¶ 19.) But the low-quality design, lack of control group, small sample size, inconsistent progesterone regimen, underreported demographic and safety information, flawed methodology, and Dr. Delgado's questionable ethical practices (as described below) all together render the study unreliable. (*See id.* at ¶¶ 18-22; **Ex. 2**, at ¶ 14.)

The biggest flaw in Dr. Delgado's 2012 study is its sample size of six, which is simply too small to draw any statistically significant generalizations. (**Ex. 1** at ¶ 19.) Additionally, the "successful" patients all had confirmed ongoing pregnancies before physicians administered progesterone—meaning that their bodies had already withstood the initial effects of mifepristone when it is at its most potent. (*Id.* at ¶ 21.) Because 46% of patients who take mifepristone without misoprostol will continue their pregnancies, the inclusion of only those patients who had confirmed pregnancies *after* using mifepristone injects selection bias towards patients predisposed to continue their pregnancies, regardless of the progesterone intervention. *Id.* Based on such data, no reasonable physician would conclude that exogenous progesterone can reliably reverse the effects of mifepristone. (*Id.* at ¶ 22; **Ex. 2** at ¶ 14.)

In 2018, Dr. Delgado published a second study in another attempt to support his experimental treatment. (**Ex. 1** at ¶ 23.) He described this study as an "observational case study," which is not a term generally used in the field of medical research. (*Id.* at ¶ 24.) In reality, Dr. Delgado's second study was a prospective case series masquerading under another name. *Id.* This study was once again plagued with ethical concerns, but this time they were significant enough to warrant withdrawal shortly after publication. (*Id.* at ¶¶ 25-28.) Specifically, Dr. Delgado misrepresented that his study was approved by the University of California San Diego (UCSD) institutional review board (IRB), when in actuality, the IRB had only approved a *retrospective* analysis of de-identified patient data. (*Id.* at ¶ 26.) He never

told the IRB that he intended to follow patients *prospectively* after they received an experimental intervention and, consequently the UCSD asked Dr. Delgado to withdraw the study.[1] (*Id.* at ¶¶ 24-26.) Additionally, Dr. Delgado did not obtain proper informed consent from patients for participation in medical research, nor did his study adhere to the ethical and regulatory standards of clinical trials. (*Id.* at ¶¶ 25-28.)

Setting aside the ethical concerns, Dr. Delgado's 2018 study is also methodologically flawed. (*Id.* at ¶¶ 29-30; **Ex. 2** at 14.) Once again, Dr. Delgado only included participants with confirmed ongoing pregnancies following mifepristone ingestion, biasing the results towards patients predisposed to continue their pregnancies. *(***Ex. 1** at ¶¶ 29-30.) Dr. Delgado also used a flawed historical control group, as it included ten separate progesterone regimens and it underreported key participant information. *Id.* And because Dr. Delgado's 2018 study is a case series, it is of too low quality to establish the safety or efficacy of his experimental treatment. (*Id.* at ¶¶ 18, 24, 29-30; **Ex. 2**. at ¶ 14.)

[1] *See also Planned Parenthood of Tennessee & N. Mississippi v. Slatery*, 523 F.Supp.3d 985, 994 (M.D. Tenn. 2021) ("As for the publication itself, Dr. Delgado conceded that *Issues in Law & Medicine* is not particularly well-known in the medical field, and that it publishes legal briefs along with medical studies. One of the entities that publishes the periodicals funds pro-life research…All the other journals to which Dr. Delgado submitted the case series declined to publish it. Dr. Delgado also explained that, before the case series was published, he sought approval from the [IRB] at the University of San Diego and received an exemption. But after the case series was published, the IRB at that university asked Dr. Delgado to withdraw the case series.").

C. Senate Bill 23-190.

On April 14, 2023, Governor Polis signed Senate Bill 23-190 (the Act) into law. Relevant here, the Act directs three state boards to develop rules "concerning whether engaging in medication abortion reversal is a generally accepted standard of practice." *Id.*, § 3. It further provides that anyone licensed by these boards—the Medical Board, the State Board of Pharmacy (Pharmacy Board), and the Nursing Board—"engages in unprofessional conduct or is subject to discipline" if the licensee "provides, prescribes, administers, or attempts medication abortion reversal," unless the boards enact rules "finding that it is a generally accepted standard of practice to engage in medication abortion reversal." *Id.* The Act instructs the boards to promulgate rules no later than October 1, 2023. *Id.*

The Act also contains a legislative declaration stating, among other things, that the General Assembly "finds and declares" that "advertising for or offering to provide or make available medication abortion reversal" falls within Colorado's prohibition on deceptive trade practices. *Id.*, § 1. But the Act does not enact any statutory law affirmatively making such advertisements illegal. The Act does, however, make it a deceptive trade practice for a person to advertise that the person offers abortions or emergency contraceptives when they do not. *Id.*, § 2.

D. Rulemaking by the Colorado Medical Board and Board of Nursing Board.

The Medical Board and Nursing Board (collectively, "Boards") are charged with regulating medical practitioners to protect Coloradans from the unauthorized,

unqualified, and improper practices of medicine and nursing, respectively. Colo. Rev. Stat. §§ 12-240-102, 12-255-102. To that end, the Boards hold rulemaking powers and authority to conduct investigations related to their respective practices. Colo. Rev. Stat. §§ 12-240-106(1)(a)-(b), 12-255-107(1).

On August 17, 2023, the Medical Board convened a rulemaking hearing regarding Rule 1.32, Rules and Regulations Regarding Generally Accepted Standards of Medical Practice Regarding Pregnancy-Related Services. In addition to public comment during the rulemaking hearing, the Medical Board reviewed public comment offered during two public joint stakeholder meetings convened on June 5, 2023, and August 4, 2023, to collect comment on the Medical, Nursing, and Pharmacy Board rules. Following the conclusion of the public testimony, the Medical Board deliberated and voted to approve a final rule, stating in pertinent part:

> Although the Board will not treat medication abortion reversal as a *per se* act of unprofessional conduct, the Board does not consider administering, dispensing, distributing, or delivering progesterone with the intent to interfere with, reverse, or halt a medication abortion undertaken through the use of mifepristone and/or misoprostol to meet generally accepted standards of medical practice under section 12-240-121(1)(j), C.R.S. For other conduct that could meet the definition of medication abortion reversal, the Board will investigate such deviation on a case-by-case basis. Licensees are expected to practice evidence-based medicine, and any licensee who provides unscientific treatments that fall below the generally accepted standard of care may be subject to discipline.

On September 21, 2023, the Nursing Board convened a rulemaking session regarding Rule 1.35, Rules and Regulations Regarding Generally Accepted Standards of Nursing Practice Regarding Pregnancy-Related Services. Following the conclusion

of the public testimony, the Nursing Board deliberated and voted to approve a final rule stating in pertinent part, "The Board will not treat…medication abortion reversal as a *per se* act subjecting a licensee to discipline pursuant to Title 12, C.R.S. Rather, the Board will investigate all complaints related to medication abortion reversal in the same manner that it investigates other alleged deviations from generally accepted standards of nursing practice under section 12-255-120(1),C.R.S."

ARGUMENT

"A preliminary injunction is an extraordinary remedy, the exception rather than the rule." *Lawrence v. Colorado*, 455 F. Supp. 3d 1063, 1070 (D. Colo. 2020) (quotations omitted). A plaintiff seeking a preliminary injunction must establish (1) a substantial likelihood of success on the merits, (2) they will suffer irreparable injury if the preliminary injunction is denied, (3) the threatened injury outweighs the injury caused by the injunction, and (4) an injunction is not adverse to the public interest. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Plaintiffs bear the burden of proof to demonstrate that each factor tips in their favor. *Heideman v. S. Salt Lake City*, 348 F.3d 1182, 1188-89 (10th Cir. 2003).

I. Plaintiffs are not substantially likely to succeed on the merits.

A. The Act and its implementing regulations are entitled to a strong presumption of validity and are rationally related to legitimate state interests.

"A law regulating abortion, like other health and welfare laws, is entitled to a 'strong presumption of validity.'" *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228, 2284 (2022) (citation omitted). These laws "must be sustained if there is

a rational basis on which the legislature could have thought that it would serve legitimate state interests." *Id.* (citations omitted). "A statute is presumed constitutional, and the burden is on the one attacking the legislative arrangement to negate every conceivable basis which might support it, whether or not the basis has a foundation in the record." *Heller v. Doe by Doe*, 509 U.S. 312, 320 (1993) (cleaned up). Under rational basis review, courts are "compelled to accept the legislature's generalizations" even if there is an "imperfect fit of means and ends." *Id.* Legitimate state interests include, among others, the protection of maternal health and safety, as well as the preservation of the integrity of the medical and nursing professions. *See Dobbs*, 142 S. Ct. at 2284 (citations omitted); *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997).

Similarly, states have a "compelling interest in the practice of professions within their boundaries," and as part of their police powers, states have "broad power" to regulate the practice of professions. *Goldfarb v. Virginia State Bar*, 421 U.S. 773, 792 (1975); *accord Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 460 (1978) ("The state bears a special responsibility for maintaining standards among members of the licensed professions."). A state has such a strong interest in regulating its licensed professionals that "prophylactic measures whose objective is prevention of harm before it occurs" are within the state's police powers, even when the measure implicates constitutional rights. *Ohralik*, 436 U.S. at 464, 467.

1. The Act is rationally related to the legitimate state interest of protecting maternal health and safety.

The Act and the Boards' implementing rules (Rules) are rationally related to the legitimate state interests of protecting maternal health and safety. The medication abortion regimen is extremely safe and effective when patients take both mifepristone and misoprostol. (**Ex. 1** at ¶¶ 9-10.) However, the best available evidence suggests use of mifepristone without misoprostol may be associated with an increased risk of potentially life-threatening hemorrhage. (**Ex. 1** at ¶¶ 10, 37-39) (*citing* Mitchell D. Creinin et al., *Mifepristone Antagonization with Progesterone to Prevent Medical Abortion: A Randomized Controlled Trial,* 135(1) Obstetrics & Gynecology 158 (2020); Am Coll. Of Obstetricians & Gynecologists and Soc'y of Family Planning, *Practice Bulletin No. 225: Medication Abortion up to 70 Days of Gestation*, 136 Obstetrics & Gynecology 1, 3 (2020)). A patient who continues their pregnancy following the use of mifepristone also risks a miscarriage later in the pregnancy and early delivery. (**Ex. 1** at ¶ 14.) Additionally, there is insufficient data with respect to Dr. Delgado's experimental treatment to show that his proposed regimen is both safe and effective. (**Ex. 1** at ¶¶ 33-34, 36; **Ex. 2** at ¶ 14.)

Finally, even a low-risk medication is not without risk, and it is inappropriate to expose a patient to those risks when the best available science suggests Dr. Delgado's theory is no more efficacious than expectant management. (**Ex. 1** at ¶¶ 33-34, 36-39; **Ex. 2** at ¶ 14.) It violates basic tenets of medicine to subject patients to treatments that effectively do nothing when the risk of the treatment is unclear.

2. The Act is rationally related to the legitimate state interest of protecting the integrity of the medical profession.

The Act and its implementing rules are also rationally related to the legitimate state interest of protecting the integrity of the medical and nursing professions. Dr. Delgado's progesterone therapy theory based on a flawed interpretation of an irrelevant study focused on the prevention of first trimester miscarriages. (*See* **Ex. 1** at ¶¶ 15-20; **Ex. 2** at ¶ 14.) Plaintiffs even conceded the two studies Dr. Delgado originally used for the basis of his theory showed no "significantly higher incidence of live births" among patients who received progesterone. (Doc. 94 at ¶¶ 76-77.)

Dr. Delgado's theory started with a flawed premise, and the two primary authorities supporting it—Dr. Delgado's own case series published in 2012 and 2018—were conducted in ways that violated generally accepted ethical norms of medical research. (**Ex. 1** at ¶¶ 18-30; **Ex. 2** at ¶¶ 14, 17-19.)[2] Dr. Rebecca Cohen, the Medical Board's expert, serves on an IRB and is a reviewer for some of the most influential medical journals in the field of reproductive health. (*Id.* at ¶ 3.) Medical research is her life's work. Similarly, Dr. Patricia Cullen, the Board of Nursing's expert has spent her career conducting and reviewing medical research, as well as serving as chair of an IRB. (**Ex. 2** at ¶¶ 1-5; 17-19.) Dr. Delgado's violations are so

[2] Experts have even suggested that Dr. Delgado's 2012 case series isn't a case series at all, but instead a research study disguised as a case series to avoid IRB oversight. *See* Daniel Grossman et al., *Continuing Pregnancy after Mifepristone and "Reversal" of First-Trimester Medical Abortion: A Systematic Review*, 92(3) Contraception 206, 210 (2015) ("While Delgado and Davenport published their findings as a "case report," their study is clearly 'research' as defined in federal policy."); *see also* 45 C.F.R. §§ 46.102, 46.109 (requiring IRB review and approval for any prospective research involving human subjects).

severe that researchers who committed these same offenses would likely be banned from conducting future research, or at the very minimum, they would be strictly supervised going forward. (*Id.* at 19; **Ex. 1** at ¶¶ 18-30.)

Other experts agree, "[A]ny use of reversal treatment should be considered experimental and offered only in the context of clinical research supervised by an [IRB]."[3] But that is not what is happening right now in Colorado. Instead, Plaintiffs are championing Dr. Delgado's experimental treatment – and providing "medical care" to patients – under the guise that it is a safe and effective way to "reverse" a medication abortion when the science does not support causation or safety. Neither the General Assembly nor the Medical Board can tolerate medical providers subjecting Coloradans to experimental procedures in the clinical context, without the benefit of the safeguards of formal research, so they have now banned it. The ability to do so clearly falls within the state's broad police powers to regulate its professions. *Goldfarb*, 421 U.S. at 792. The Nursing Board's case-by-case review of abortion pill reversal reflects the complexities inherent for a board regulating both licensees that issue medical orders and licensees that are required to follow medical orders. (*See* **Ex. 2** at ¶¶ 9-12.)

[3] Grossman, 379(16) N. Eng. J. Med. at 1493.

3. Courts that have analyzed the scientific basis for Dr. Delgado's theory agree it is, at best, experimental.

Other federal courts have analyzed the scientific validity of Dr. Delgado's experimental treatment, albeit in the context of determining whether mandatory disclosures regarding the existence of Dr. Delgado's experimental treatment were constitutional. In 2019, a North Dakota federal district court struck down a state law that required abortion care providers to disclose the possibility of "abortion pill reversal." *American Med. Ass'n v. Stenehjem*, 412 F. Supp. 3d 1134 (D.N.D. 2019). On the science, the court came to the same conclusion as the Medical Board and the General Assembly, stating:

> The North Dakota law requires abortion providers to enunciate the State's viewpoint on an *unproven* medical and scientific theory, namely whether a chemical abortion can be reversed…The law also clearly interferes with the doctor-patient relationship; forces the attending physician to convey to his/her patient a state-mandated message that is *devoid of credible scientific evidence*; misinforms and misleads the patient; undermines informed consent and the standard of care; and is *arguably unethical*…The State contends there is an ongoing medical debate about whether a chemical abortion can be reversed. However, the record reveals no real, serious debate within the medical profession at the current time.

Id. at 1150-51 (emphasis added).

In 2021, an Indiana federal court also concluded Dr. Delgado's experimental theory is exactly that—a theory. Dr. Delgado testified and conceded that his studies could not prove causation, were limited due to their design, and had a greater possibility of bias than a controlled scientific trial. *All-Options, Inc. v. Attorney General of Indiana*, 546 F. Supp. 3d 754, 766-67 (S.D. Ind. 2021). There, the court

found insufficient causation between Dr. Delgado's experimental treatment and claims that it could reverse the effects of mifepristone, stating:

> The question is whether "[s]ome evidence suggests" that abortion pill reversal may have the effect of avoiding, ceasing, reversing the effects of mifepristone. In other words, is there evidence of causation? The biological principle relied upon by the State is not "[s]ome evidence" of causation; *instead, it merely supports what the medical research in the record has concluded – that further research is required.*

Id. at 768 (emphasis added).

A Tennessee federal district court reviewed a similar statute in 2021 and came to the same conclusion. *Planned Parenthood of Tennessee and North Mississippi v. Slatery*, 523 F. Supp. 3d 985 (M.D. Tenn. 2021). There, the court noted, "[N]either Dr. Delgado's research nor his biological explanation supports the idea that an abortion can be undone or negated." *Id.* at 1003. The court considered the use of the word "reverse" to misleadingly suggest that progesterone acts as an antidote to mifepristone. *Id.* And critically, the court concluded medical evidence had not yet reached the level to suggest Dr. Delgado's theory was safe and effective, in part due to "numerous flaws" in Dr. Delgado's research. *See id.*

Simply put, it is well within Colorado's police powers to prevent its licensees from subjecting its citizens to experimental treatments without adequate safeguards. That is exactly what the state and its regulatory bodies have done here, and thus Plaintiffs' motion for a preliminary injunction should be denied.

B. Plaintiffs have failed to show they are likely to succeed on the merits of their Free Exercise challenge.

Plaintiffs try to avoid this straightforward rational basis analysis by arguing that the Act and the Board's rules violate their rights under the Free Exercise Clause of the First Amendment. But the Free Exercise Clause "does not relieve an individual of the obligation to comply with a 'valid and neutral law of general applicability on the ground that the law proscribes (or prescribes) conduct that his religion prescribes (or proscribes).'" *Employment Div. of Oregon v. Smith*, 484 U.S. 872, 879 (1990) (citations omitted). If prohibiting or burdening the exercise of religion is not the object of the law, but merely an incidental effect of a generally applicable and otherwise valid law, there is no First Amendment violation. *Id.* at 878.

Plaintiffs bear the burden of showing an infringement on their rights under the Free Exercise Clause by showing that Colorado has burdened their sincere religious practice pursuant to a policy that is neither neutral nor generally applicable. *Kennedy v. Bremerton Sch. Dist.*, 142 S. Ct. 2407, 2421-22 (2022). Only if Plaintiffs carry this burden do the Defendants need to show that their actions were justified. *Id.* at 2421. Plaintiffs cannot establish that the Act and the Boards' Rules are not neutral or generally applicable; therefore, rational basis review applies. *Grace United Methodist Church v. City of Cheyenne*, 451 F.3d 643, 649 (10th Cir. 2006).

Colorado has a legitimate interest in protecting the public from an experimental treatment that does not have any scientific evidence supporting its efficacy or identifying its risk to patients, and has the possibility of causing harm by

interrupting an FDA-approved two-medication regimen, as discussed in Section I(A), *supra*. Colorado's regulation of Dr. Delgado's experimental treatment is rationally related to that interest. Accordingly, Plaintiffs cannot demonstrate a likelihood of success on the merits of their Free Exercise Claims, and the motion for preliminary injunction should be denied.

1. The Act and the Boards' Rules are facially neutral.

"A law is neutral so long as its object is something other than the infringement or restriction of religious practices." *Grace United*, 451 F.3d at 649-50 (*citing Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 533 (1993)). "A law lacks facial neutrality if it refers to a religious practice without a secular meaning discernable from the language or context." *Lukumi*, 508 U.S. at 533. Plaintiffs have the burden to establish that law and regulations are not neutral. *Kennedy*, 142 S. Ct. at 2421-22.

Here, both the Act and the Boards' Rules are neutral. Section 3 of the Act makes it unprofessional conduct, or subjects a licensee to discipline, if a licensee administers, dispenses, distributes, or delivers a drug with the intent to interfere with, reverse, or halt a medication abortion. (Doc. 32-1 at ECF 4 § 3.) With respect to Plaintiffs, the Act solely concerns itself with the practice of medicine and nursing; specifically, prescribing, administering, or dispensing a certain medication to try to reverse an abortion. The Medical Board's rule, which is the only rule to expressly prohibit providing, prescribing, or giving progesterone to reverse the effects of

mifepristone, is similarly concerned only with the practice of medicine. The Nursing Board's rule, reflecting the wide variety of roles with respect to patient care, is still solely concerned with the practice of nursing. Both rules are clearly facially neutral.

2. The Act does not target religious conduct for distinctive treatment.

The next step in the neutrality analysis is to determine whether the law "targets religious conduct for distinctive treatment." *Lukumi*, 508 U.S. at 534. Here, the Act and the Rules regulate an experimental medical treatment that is not part of a religious ritual, like peyote was in *Smith*, or animal sacrifice in *Lukumi*. It is simply a tool that Plaintiffs claim helps continue pregnancies after ingesting mifepristone, despite the consensus among the general medical community that Dr. Delgado's experimental treatment does not work.

The Act and the Rules do not prohibit Plaintiffs from providing life-affirming care, providing care to women facing threatened miscarriages, or care to patients who have changed their minds after taking mifepristone. (**Ex. 1** at ¶ 14.) Instead, the Act and implementing Rules require Plaintiffs to provide life-affirming care to patients in a manner that comports with generally accepted standards of evidence-based medical and nursing practice. The Medical Board has determined Dr. Delgado's experimental treatment falls outside generally accepted standards of practice, and so they banned it. The scope of practice for nurses is complex, and so the Nursing Board has elected to assess each instance of "medication abortion reversal" on a case-by-case basis. The Act and the Rules apply to all medical professionals regardless of their

motivation. The Act and the Rules are, at most, incidental burdens on conduct motivated by religious convictions. The Act and its implementing Rules are therefore subject to rational basis review.

a. Statements made by a handful of legislators do not establish legislative intent.

Relying mostly on *Lukumi* and *Masterpiece Cakeshop*¸ Plaintiffs claim that statements made by members of the public, as well as five legislators, during the legislative and rulemaking processes demonstrate religious animus. It goes without saying that members of the public or interest groups are not legislators, and their public comments consequently provide little insight into the General Assembly's intent with the Act.

What is more, courts are cautioned against attempting to consider the "subjective motivation of the lawmakers" as "it is virtually impossible to determine the singular 'motive' of a collective legislative body, and this Court has a long tradition of refraining from such inquiries." *Lukumi*, 508 U.S. at 558 (Scalia, J., concurring) (cleaned up). As the Supreme Court has recognized, courts should not:

> void a statute that is, under well-settled criteria, constitutional on its face, on the basis of what fewer than a handful of Congressmen said about it. What motivates one legislator to make a speech about a statute is not necessarily what motivates scores of others to enact it, and the stakes are sufficiently high for us to eschew guesswork. We decline to void essentially on the ground that it is unwise legislation which Congress had the undoubted power to enact and which could be reenacted in its exact form if the same or another legislator made a 'wiser' speech about it.

United States v. O'Brien, 391 U.S. 367, 383-84 (1968).

Further, the comments Plaintiffs claim show animus, which did little more than point out that many anti-abortion centers are religiously affiliated, are incomparable to those made in *Lukumi*. In *Lukumi*, the Hialeah City Council passed a complex web of ordinances specifically designed to ban ritual animal sacrifice because practitioners of the Santeria religion announced they were opening a church in town. *Lukumi*, 508 U.S. at 525-530. In the Santeria faith, animal sacrifice is a principal form of devotion. *Id.* at 524. The city crafted regulations to effectively ban *only* ritual sacrifice performed by practitioners of Santeria, leaving the door open to both secular slaughter and kosher slaughter. *Id.* at 535-37.

The city council was unequivocal in its intentions, passing a resolution that stated, "certain religions may propose to engage in practices which are inconsistent with public morals." *Id.* at 535. Various city officials told the city council that Santeria was a sin, demonic, and asked the council "not to permit this Church to exist." *Id.* at 541-42. The Court found these comments, and others like it, as evidence that "the object of the ordinances" was to "target animal sacrifice by Santeria worshippers because of its religious motivation." *Id.* at 542.

The contrast between the legislative history here and that in *Lukumi* could not be starker. Here, the comments made by legislators, when viewed in context, show their concern was not the suppression of a religious rite. Rather, their goal was to protect patient autonomy for those seeking abortion care, to prohibit deceptive advertising practices, and to stop the "dangerous and unregulated" practice of using

progesterone to "reverse" a medication abortion. Their comments certainly do not warrant striking down a law "that is, under well-settled criteria, constitutional on its face, on the basis of what fewer than a handful of Congressmen said about it." *O'Brien*, 391 U.S. at 383-84.

b. Statements made by the adjudicatory bodies—the Medical Board and Nursing Board—reveal only a concern for science.

Plaintiffs' reliance on *Masterpiece Cakeshop* is misplaced because they have presented no evidence of any animus by the Boards. As the Supreme Court noted, *Masterpiece Cakeshop* is decidedly different from *Lukumi* because it involved statements made "by an adjudicatory body deciding a particular case." *Masterpiece Cakeshop v. Colorado C.R. Comm'n*, 138 S. Ct. 1719, 1730 (2018). *Masterpiece Cakeshop* involved litigation before the Colorado Civil Rights Commission (Commission) related to a charge of discrimination against a baker who refused to make a wedding cake for a same-sex couple due to his sincerely held religious beliefs. *See id.* at 1724-26. During the adjudicatory process, commissioners described the baker's First Amendment argument as "one of the most despicable pieces of rhetoric that people can use." *Id.* at 1729. Commissioners even compared the baker's "sincerely held religious beliefs to defenses of slavery and the Holocaust." *Id.* The Court ultimately overturned the Commission's decision because their statements "cast doubt on the fairness and impartiality of the Commission's adjudication of [the baker's] case." *Id.* at 1730.

Notably absent from Plaintiffs' Amended Complaint or Motion for a Preliminary Injunction are any allegations surrounding statements from members of the Boards. At most, Plaintiffs insinuate that the Medical Board "caved to political pressure" when it modified its proposed rule to ban Dr. Delgado's experimental treatment. (*See* Doc. 94 at ¶ 13.)

But Plaintiffs' own selected *excerpts* from the Medical Board's rulemaking hearing show that was not the reason for the modification whatsoever. One board member noted, "[M]ost, if not all, of the written and verbal testimony" discussed using progesterone to reverse the effects of mifepristone and misoprostol. (Doc. 90-24 at ECF 4). Another board member suggested "it would be helpful to have some language added to this rule about the specific example that everyone is talking about." (Doc. 90-24 at ECF 5). These comments make it clear that the Medical Board did not "cave" to political pressure—it instead modified the rule to make its stance on Dr. Delgado's experimental treatment clear to its licensees because his theory is heavily implicated by Section 3 of the Act.

Reviewing Plaintiffs' excerpts of the rulemaking hearing as a whole, it is clear the Medical Board modified its proposed rule to prohibit Dr. Delgado's experimental treatment only because it was "the subject of a lot of tests" and they "presently understand" it as "a concerning practice." (Doc. 90-24 at ECF 10.) Medical Board members left the door open to new scientific advances, suggesting that if "new therapies happen… then I think we amend [the] rule, and you can do that." (Doc. 90-

24 at ECF 10.) One board member explicitly pointed out that "the act itself is not a problem. It's the use of this particular [ ] drug in this case." (Doc. 90-24 at ECF 12.) The members were quite explicit, stating, "[T]hat's kind of my thought…the statement really that the board does not and will not treat medication abortion reversal as a per se act of unprofessional conduct." (Doc. 90-24 at ECF 27.) The comments made by Medical Board members make it clear—the issue is that Dr. Delgado's experimental treatment is unsupported by scientific literature. Religion never entered the conversation.

3. The Act and the implementing Rules are generally applicable.

"A government policy will fail the general applicability requirement if it 'prohibits religious conduct while permitting secular conduct that undermines the government's asserted interests in a similar way,' or if it provides "a mechanism for individualized exemptions.'" *Kennedy*, 142 S. Ct. at 2422. "A law also lacks general applicability if it prohibits religious conduct while permitting secular conduct that undermines the government's asserted interests in a similar way." *Fulton v. City of Philadelphia, Pennsylvania*, 141 S. Ct. 1868, 1877 (2021).

Here, the Act and the Rules are generally applicable. The law categorically prohibits prescribing a medication in an attempt to reverse a medication abortion. And the Medical Board's implementing rule more specifically prohibits use of progesterone in an attempt to reverse the effects of mifepristone. There are no exceptions to the law or rule, secular or otherwise. The law does not "invite the

government to consider the particular reasons for a person's conduct" because the conduct is banned under all circumstances. *Fulton*, 141 S. Ct. at 1877.

Plaintiffs attempt to carry their burden by characterizing other uses of progesterone as a comparable secular activity. (Doc. 92 at ECF 22-25.) However, Plaintiffs' argument ignores the fact that in the practices of medicine and nursing, each off-label use of a medication is analyzed individually on both its risk and intended benefit. (**Ex. 1** at ¶ 36, 37; **Ex. 2** at ¶ 14.) One cannot simply look at progesterone in a vacuum—the drug must be considered in the context of the condition for which it may be indicated. Here, the use of progesterone after mifepristone is incomparable to other potential off-label uses of progesterone specifically because there is neither scientific evidence demonstrating that it can achieve its intended benefit, nor is there scientific evidence assessing its potential risk to patients. (**Ex. 1** at ¶¶ 22, 30, 31, 33, 34, 38, 39, 40; **Ex. 2** at ¶ 14.) It is specifically the lack of scientific evidence about the potential risks posed by this experimental treatment, whose efficacy has yet to be established that prompted Colorado to enact legislation and regulation of its use. For that reason, it is incomparable to other uses of progesterone for which there is a reliable, scientifically supported indication for its use.

Plaintiffs also claim the Boards' Rules are not generally applicable because they believe the Rules contain "a formal mechanism for granting exceptions" to SB 23-190, or in the case of the Medical Board, any form of medication abortion reversal

other than one performed using progesterone. (Doc. 92 at ECF 30-31.) This argument also fails because the Rules do not provide a mechanism for individualized exceptions at all. Rather, the Rules reflect that the "generally accepted standards of medical practice" present a mixed question of law and fact, and whether certain conduct comports with the standard of care varies depending upon the circumstances of each case. *State Bd. of Med. Examiners v. McCroskey,* 880 P.2d 1188, 1193 (Colo. 1994). This is not an individualized exception whereby the government weighs the particular *reasons* for a person's conduct. It is instead a reflection that the science could change, and a scientifically validated, evidence-based method of reversing mifepristone's effects could become standard of care. And if that happens, the standard of care changes for every licensee regardless of their secular or religious motivation.

Nothing makes this distinction more evident than the comments of the Medical Board members during rulemaking. One member noted, "[n]ew therapies happen… then I think we amend [the] rule, and you can do that." (Doc. 90-24 at ECF 10.) Another explicitly pointed out that "the act itself is not a problem. It's the use of this particular [ ] drug in this case." (Doc. 90-24 at ECF 12.) As such, Plaintiffs cannot carry their burden to show the law and its implementing regulations are not generally applicable.

With respect to the Nursing Board's rule, it has a very good reason to conduct a case-by-case analysis of each complaint alleging medication abortion reversal,

rather than blanketly prohibiting Dr. Delgado's experimental treatment like the Medical Board did. Unlike the Medical Board, the Nursing Board's licensees practice at all levels of patient care from prescribing to assisting in activities of daily living, and thus will have different levels of knowledge and participation in this kind of treatment. (**Ex. 2** at ¶¶ 8-12.) Other than advanced practice nurses with prescriptive authority, who can prescribe medications, most of the Nursing Board's licensees do not have discretion to ignore treatment orders. (**Ex. 2** at ¶ 11-12.)

Consequently, had the Nursing Board adopted a final rule with a categorical ban of Dr. Delgado's experimental treatment like the Medical Board did, the Nursing Board might have put its licensees on the horns of an unsolvable dilemma: either violate the rule or ignore a medication order—both of which could subject a nurse to discipline. It is unsurprising, then, that the Nursing Board elected to adjudicate all instances of medication abortion "reversal" on a case-by-case basis even though the relevant standard of care is no different for advanced-practice nurses with prescriptive authority and physicians. (**Ex. 2** at ¶ 10.)

C. Plaintiffs fail to show they are likely to succeed on the merits of their Due Process Clause challenge.

1. The Act and Rules do not impede a patient's right to refuse medical care.

Colorado law protects the right to continue or terminate a pregnancy. Colo. Rev. Stat. § 25-6-403(2). And it is beyond dispute that a competent person has a constitutionally protected interest in refusing unwanted medical treatment. *Cruzan*

v. Director, 497 U.S. 261, 278 (1990). Plaintiffs claim the Act and Rules "force" abortions on women in violation of the Fourteenth Amendment.

Simply put, Plaintiffs' Fourteenth Amendment claim is nothing more than a strawman claim. Neither the Act nor the implementing Rules force women to undergo abortions. The Act and the Rules do not compel a patient to take misoprostol if they have changed their minds in the very rare circumstances where that happens. And the Act does not change the fact that any abortion care provider must obtain robust informed consent prior to prescribing the mifepristone or misoprostol. The decision to continue or terminate a pregnancy belongs only to the patient, and this Act does nothing but reinforce that truth.

But the right to continue or terminate a pregnancy does not mean a patient has a constitutional right to mandate which medications they receive to treat a particular illness, regardless of the science. The Boards are each charged with regulating their respective healing arts, and that includes prohibiting its licensees from practicing unsafe medicine that fails to meet generally accepted standards of care. Colo. Rev. Stat. §§ 12-240-102, 12-255-102. Consequently, Plaintiffs' Fourteenth Amendment claim has no merit.

D. Plaintiffs are unlikely to succeed on the merits of their challenges to Sections 1 and 2 of the Act.

Plaintiffs also seek to enjoin Sections 1 and 2 of the Act on the ground that they violate their First Amendment rights by discriminating based on content and

viewpoint. (*See* Doc. 92 at ECF 35-38.)[4] Plaintiffs are unlikely to succeed on the merits, for three reasons: (1) Section 1 does not create any substantive law and is not subject to an injunction; (2) Plaintiffs have not established a credible threat of enforcement as to Section 2; and (3) even if they were subject to any credible threat of enforcement, Plaintiffs are unlikely to succeed on their claim that Section 1 or Section 2 violate the First Amendment.[5]

1. Plaintiffs cannot enjoin a legislative declaration.

Plaintiffs argue that "Section 1 creates a targeted prohibition on deceptive trade practices." (Doc. 92 at 36.) Section 1, however, does not create any prohibition on any conduct. Section 1 is a legislative declaration. It "finds and declares" that the CCPA's "prohibition on deceptive trade practices applies to" advertising or providing "medication abortion reversal." (Doc. 32-1 at ECF 3 § 1.) But such legislative declarations are not substantive law. They are at most used to construe ambiguous statutes. *See* Colo. Rev. Stat. § 2-4-203(1)(g); *see also* Antonin Scalia & Brian A. Garner, *Reading Law: The Interpretation of Legal Texts* 217 (Thomson/West 2012) (legislative preamble is "an aside" and "*not* part of the congressionally legislated . . . set of rights and duties."). But "[w]hen a statute is unambiguous, courts generally apply the plain and ordinary meaning of terms without examining the legislative declaration." *People in Interest of T.B.*, 452 P.3d 36, 43 (Colo. App. 2016). No Colorado

[4] Plaintiffs' motion does not seek an injunction on the ground that Section 2 is void for vagueness.
[5] The arguments that follow closely mirror those raised in the Attorney General's Motion to Dismiss, Doc. 68.

court has found "deceptive trade practice" to be ambiguous, so there is no credible argument that Section 1 will be used to interpret that phrase.

Section 1 expresses the General Assembly's understanding of what constitutes a deceptive trade practice, but the legislature did not change or alter any law. If the legislature had wanted to create a statute making "advertising for or providing ... medication abortion reversal" unlawful under the CCPA, it would have done so. In the 2022 legislative session, for example, the legislature expressly amended the CCPA to add new violations in seven different bills.[6] It chose not to do so here. Plaintiffs are therefore not likely to succeed on their claim that Section 1 violates any of their rights.[7]

2. Plaintiffs have not established a credible threat of enforcement as to Section 2.

Section 2 amends the CCPA to clarify that a person engages in a deceptive trade practice when the person advertises that they provide abortions or emergency contraceptives when the person "knows or reasonably should have known" that they do not actually provide "those specific services." (Doc. 32-1 at ECF 3 § 2 (adding Colo. Rev. Stat. § 6-1-734(2))). But Plaintiffs have made clear that they do not advertise abortions or emergency contraceptives, the only conduct that Section 2 targets. Under these circumstances, Plaintiffs lack standing to challenge Section 2 and so cannot

[6] H.B. 22-1099, H.B. 22-1242, H.B. 22-1287, S.B. 22-205, H.B. 22-1031, H.B. 22-1284, H.B. 22-034, 73rd Gen. Assemb., 2nd Reg. Sess. (Colo. 2022).

[7] To the extent Plaintiffs' argument that Section 1 violates the right of their patients to receive information, that argument fails for these same reasons.

obtain a preliminary injunction against it. *See Arizonans for Official English v. Arizona*, 520 U.S. 43, 67 (1997) (injury must exist at "all stages" of a lawsuit) (quotation omitted); *see also Kan. Health Care Ass'n v. Kan. Dep't of Soc. and Rehab. Servs.*, 958 F.2d 1018, 1021-23 (10th Cir. 1992) (reversing and vacating preliminary injunction because plaintiffs lacked standing).

For standing to exist, a plaintiff must prove they have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). To establish injury in fact, the plaintiff must show that he or she suffered "an invasion of a legally protected interest" that is "concrete and particularized" and "actual or imminent[.]" *Lujan v. Defenders of Wildlife,* 504 U.S. 555, 560 (1992). The touchstone of this inquiry is whether a plaintiff suffers concrete harm: "no concrete harm, no standing." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2200 (2021). The plaintiff bears the burden of proof on each element. *Spokeo*, 578 U.S. at 338.

In a narrow category of cases, a plaintiff who fears enforcement of a challenged law may seek pre-enforcement review, as Plaintiffs do here. *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158-59 (2014) ("*SBA List*"). But to preserve the concrete harm requirement, pre-enforcement challenges are limited to those cases where enforcement is "certainly impending, or there is a substantial risk that the harm will occur." *Id.* at 158 (quotations omitted); *Baker v. USD 229 Blue Valley*, 979 F.3d 866,

873 (10th Cir. 2020). Without a credible threat of imminent enforcement, the mere presence of an unconstitutional statute "does not entitle anyone to sue, even if they allege an inhibiting effect on constitutionally protected conduct prohibited by the statute.'" *Mink v. Suthers*, 482 F.3d 1244, 1253 (10th Cir. 2007) (quotation omitted).

Thus, to maintain a pre-enforcement challenge, a plaintiff "must typically demonstrate (1) an intention to engage in conduct arguably affected with a constitutional interest but proscribed by the challenged statute, and (2) that 'there exists a credible threat of prosecution thereunder.'" *Colo. Outfitters Ass'n v. Hickenlooper*, 823 F.3d 537, 545 (10th Cir. 2016) (quotation omitted). Plaintiffs' challenge to Section 2 fails on both elements.

As to the first element, Section 2 of the Act does not proscribe Plaintiffs' desired conduct. Section 2 is narrow. It clarifies that it constitutes a deceptive trade practice for a person to advertise that they provide abortions or emergency contraceptives when the person knows or reasonably should have known that they do not provide those services. Even before the Act existed, the CCPA made false representations about such services unlawful. Colo. Rev. Stat. § 6-1-105(1)(e), (1)(rrr). The Act simply added more specificity in the context of abortions and emergency contraceptives and permits additional civil penalties for violating the more specific prohibition in § 6-1-734. *See* Colo. Rev. Stat. § 6-1-112 (providing civil penalties for *each* violation of the CCPA).

But Plaintiffs have made clear that, in their opinion, there is no question that they are complying with the CCPA and that they do not advertise care they do not provide. (*See* Doc. 68-2 at ECF 5-6, 16:25-17:1 ("No, we do not advertise anything regarding abortion care.")). Plaintiffs therefore do not intend to engage in conduct proscribed by Section 2.

The absence of the first element alone deprives Plaintiffs of standing. But the second element is also absent because Plaintiffs face no credible threat of enforcement. Plaintiffs do not allege they violate Section 2 or have any intention of doing so. Plaintiffs also identify no history of either the CCPA or the Act being enforced against similar clinics or practitioners. *See SBA List*, 573 U.S. at 164.

The closest Plaintiffs come to alleging a credible fear of enforcement is their interpretation of certain legislator statements that advertising "comprehensive" services indicates the provider offers abortion-related services. (*See* Doc. 92 at ECF 26). These statements in the legislative history are far from sufficient to create a credible threat of enforcement. First, legislators do not make enforcement decisions. Second, Plaintiffs disagree with the statements and has expressly testified that it tries to make clear what services it does and does not offer—including by advertising "comprehensive, *life-affirming* health care." (Doc. 1-2 at 2; Doc. 1-3 at 5; *see* 68-2 at ECF 8, 35:5-10 (emphasizing "honesty and transparency" in Plaintiffs' statements)). And finally—and most critically—the Attorney General has already disavowed enforcement of Section 2 for this statement, standing alone. (Doc. 68-2 at ECF 19,

103:22-23 ("[T]hat statement in and of itself is not going to be the basis for any sort of action under here.")). A prosecutor's disavowal of this type is strong evidence that Plaintiffs face no credible threat of enforcement. *See, e.g., Winsness v. Yocom*, 433 F.3d 727, 732-33 (10th Cir. 2006); *D.L.S. v. Utah*, 374 F.3d 971, 975 (10th Cir. 2004).

At bottom, Plaintiffs' claimed fear of Section 2 being enforced against them is "imaginary or speculative." *Babbit v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979) (quotations omitted). Plaintiffs therefore lack standing and so are unlikely to succeed on the merits of their challenge to Section 2.

3. *Plaintiffs are unlikely to succeed on the merits of their First Amendment claim.*

Even if Plaintiffs had standing to maintain a challenge to Section 1 or Section 2, they are not likely to succeed on the merits of any such challenge. Plaintiffs argue that Section 2 is not viewpoint neutral. (Doc. 68-2 at ECF 11-12, 92:23-93:17.) The First Amendment's "core requirement of viewpoint neutrality" applies "even though the statute regulates otherwise unprotected speech." *Chaker v. Crogan*, 428 F.3d 1215, 1226 (9th Cir. 2005) (citing cases). So the Act may nonetheless be subject to heightened scrutiny if it favors some messages or speakers at the expense of others. *R.A.V. v. City of St. Paul*, 505 U.S. 377, 383-84, 386 (1992).

The Act does not do so. The law does not pick ideological winners for any underlying message related to abortion or contraception—businesses remain entirely free to support or criticize these treatments so long as their advertisements are truthful. *E.g.*, *R.A.V.*, 505 U.S. at 383 (prohibiting only fighting words *against* racial

equality); *Chaker*, 428 F.3d at 1215 (prohibiting only false speech *critical* of law enforcement). Nor does the application of Section 2 depend whatsoever on the speaker's motives. *See Animal Legal Def. Fund v. Kelly*, 9 F.4th 1219 (10th Cir. 2021) (prohibiting lying to gain control of an animal facility with *intent to damage* the enterprise). The Act's prohibition on false advertising applies whether a business misrepresents its care for money or for ideological reasons. Nor does the Act turn on the speaker's identity. The law applies equally to a secular clinic as to Plaintiffs. If, for example, a Planned Parenthood clinic offers only wellness checkups, it is also prohibited by Section 2 from advertising that it provides abortion services.

Plaintiffs argue that Section 2 is "facially content based" because it applies only to speakers who advertise abortion pill reversal. (Doc. 92 at ECF 36.) Of course, other subsections of the CCPA already prohibit such false advertising. Colo. Rev. Stat. § 6-1-105(1)(e), (1)(rrr). But regardless, there is no "First Amendment principle that [a] prohibition of constitutionally proscribable speech cannot be 'underinclusiv[e].'" *R.A.V.*, 505 U.S. 377, 387 (1992). That is because the very reason the speech is unprotected—the various harms caused by fraud—"form[s] the basis of distinction within the class." *Id.* at 388. It is the province of the legislative branch to make judgments about where "the risk of fraud" is most severe. *Id.* Many laws prohibit fraud in certain contexts or about certain subjects. 18 U.S.C. § 1001 (false statements to government officer). None would survive Plaintiffs' impossible standard.

Plaintiffs next argue that even if the law is *facially* neutral, it is nevertheless content based, presumably because it was "adopted by the government because of disagreement with the message the [regulated] speech conveys." *Reed v. Town of Gilbert*, 576 U.S. 155, 163-64 (2015) (internal citation omitted). But the regulated speech here is *false advertising*, not any particular message about abortion. As shown above, the Act prohibits false advertising about abortion regardless of whether that advertising is made in support of abortion rights or against them.

The statements Plaintiffs point to in the Act's legislative declaration and by individual legislators do not change matters. The statement it quotes in the Act's legislative declaration states only that "*some* anti-abortion centers use deceptive advertising[.]" (Doc. 32-1 at ECF 2 § 1(e) (emphasis added for word omitted at Resp. 15)). This statement describes a concern about a particular locus of fraud, not disagreement with any protected message. And statements by individual legislators that are found nowhere in the legislative text do not justify invalidating a validly enacted law. Legislative history is full of statements concerning a legislator's view of the facts, the necessity of the law, or the issues of the day. They are irrelevant to understanding the purpose of the unambiguous Act. *See, e.g.*, *Conroy v. Aniskoff*, 507 U.S. 511, 519 (1993) (Scalia, J., concurring) (relying on legislators' statements is "the equivalent of entering a crowded cocktail party and looking over the heads of the guests for one's friends").

Plaintiffs also argue that Section 2 is not viewpoint neutral because it applies to "only one side of the abortion debate." (Doc. 92 at ECF 32) (quotations omitted). But legislators are not required to identify every possible problem when they pass laws about a subject matter, even one that is politically charged. "[A] State may choose to regulate [ ] advertising in one industry but not in others, because the risk of fraud ... is in its view greater there." *R.A.V.*, 505 U.S. at 388-89 (internal citation omitted). And so long as the law's prohibitions do not discriminate on the basis of viewpoint, a regulation "may address some offensive instances and leave other, equally offensive, instances alone." *Id.* at 390.

Just so here. Unfair and deceptive practice acts frequently contain subparts addressed to specific wrongful acts that the legislature believes are particularly prevalent or harmful. The CCPA contains many such provisions; from falsely representing the need for radon mitigation (Colo. Rev. Stat. § 6-1-105(1)(*ll*)) to falsely claiming to possess an academic degree (Colo. Rev. Stat. § 6-1-707). The CCPA does not specifically ban every possible misrepresentation on these topics and these provisions apply only to a subset of businesses or persons.

Section 2 is designed to prevent harm caused by the false advertising of two medical treatments that are time-sensitive such that truthful advertising is critical for patients. The law does not ban false advertising of all possible medical treatments (including other medical treatments related to pregnancy) but it does not have to. And while Plaintiffs are correct that Section 2 applies only to those business that

don't offer abortions and emergency contraception, that is not evidence of viewpoint discrimination. Just as Colo. Rev. Stat. § 6-1-105(1)(*ll*) applies only to businesses that offer radon mitigation, such selectivity occurs simply because those are the entities that *could* commit the fraud with which the legislature was concerned, not because those entities hold any particular views or speak any particular messages. *See R.A.V.*, 505 U.S. at 389-90.

In short, Section 2 applies to providers who speak pro-abortion messages or anti-abortion messages. It applies whether providers make misrepresentations for money or for ideology. And it does not prevent any provider from expressing views on "the abortion debate," (Doc. 92 at ECF 32), whatever they may be. The law prohibits only fraudulent speech about the services a business provides—a long-standing target of consumer protection laws.

II. Plaintiffs will not suffer irreparable harm absent a preliminary injunction.

Generally, the irreparable harm element of a preliminary injunction collapses with the first in constitutional claims. *See Free the Nipple-Fort Collins v. City of Fort Collins, Colorado*, 916 F.3d 792, 805 (10th Cir. 2010). Therefore, because there is no likelihood of establishing a constitutional violation, there is no irreparable harm.

III. The balance of the equities and public interest weigh heavily in Colorado's favor.

The last two factors, the balance of equities and the public interest, "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). Colorado's legislature has declared what it believes to be the public interest by passing the Act, and it is in a better position than Plaintiffs or this Court to determine the public interest. *See Fish v. Kobach*, 840 F.3d 710, 755 (10th Cir. 2016) ("our democratically elected representatives are in a better position than this Court to determine the public interest"); *accord Thompson v. Dewine*, 959 F.3d 804, 812 (6th Cir. 2020) ("giving effect to the will of the people by enforcing the laws they and their representatives enact serves the public interest"). Therefore, this factor also weighs against a preliminary injunction.

IV. CONCLUSION

For these reasons, Plaintiffs' motion for a preliminary injunction should be denied.

Respectfully submitted this October 3, 2023.

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing pleading complies with the type-volume limitation set forth in Judge Domenico's Practice Standard III(A)(1) and this Court's minute order expanding the word limit to 10,000 words (Doc. 93).

CERTIFICATE OF SERVICE

I hereby certify that on October 3, 2023, I served a true and complete copy of the foregoing **STATE DEFENDANTS' RESPONSE TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION** upon all parties herein by e-filing with the CM/ECF system maintained by the court and/or email.

s/Amanda Diaz
Amanda Diaz