IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

BELLA HEALTH AND WELLNESS et al.,

Plaintiffs,

v.

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

Defendants.

Case No. 1:23-cv-939-DDD-SKC

PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

INTRODUCTION

A new Colorado law targets women who have changed their minds about abortion, forcing them to undergo abortions they seek to avoid. In a flagrant constitutional violation, Colorado has forbidden doctors and nurses from helping these women. Health care professionals cannot give these women—or even tell them about—safe and effective treatment that is lawfully available across the country and around the world.

Five months ago, Colorado avoided a preliminary injunction by promising non-enforcement and representing to the Court that it *might* adopt rules deeming this treatment lawful by October 1. But instead of fixing the problem, it has doubled down, leaving the statutory prohibition in place and making it unprofessional conduct for doctors and nurses to assist a woman in attempting to reverse the effects of the first abortion pill. That misguided approach—openly driven by politics rather than science—both violates the Constitution and makes Colorado a national and international outlier. Indeed, the government's recent rulemaking efforts have made the constitutional violations even clearer.

During a healthy pregnancy, a woman's body naturally produces a hormone called progesterone. Progesterone supports pregnancy by thickening the uterine lining and suppressing contractions. When a woman who wants to keep her baby faces threatened miscarriage, doctors often prescribe additional progesterone to help her maintain the pregnancy. By contrast, one way to cause an abortion is to block the body's natural supply of progesterone and induce miscarriage. In fact, the FDA describes

the abortion-inducing drug mifepristone as "a drug that blocks a hormone called progesterone that is needed for a pregnancy to continue."

The decision to end a pregnancy is often stressful and complicated. Unsurprisingly, some women initially choose to take mifepristone, only to decide thereafter that they wish to remain pregnant. Other women seek medical help because they were forced to take mifepristone but wish to remain pregnant. These women sometimes seek medical help to stop the mifepristone-induced miscarriage.

Plaintiffs are experienced healthcare providers who help women by prescribing progesterone to maintain pregnancy. When a woman faces threatened miscarriage for any number of reasons—natural causes, physical trauma, or ingestion of mifepristone—Plaintiffs prescribe progesterone to help her maintain the desired pregnancy. To Plaintiffs, this help is a religious obligation—they cannot in good conscience turn their backs on a woman who seeks their help to keep her baby.

But Colorado has outlawed this practice entirely, forbidding Plaintiffs from helping even women who were forced to ingest mifepristone. It also forbids Plaintiffs from even *telling* women that such treatments exist. Thus, while Colorado claims to respect a woman's "fundamental right to continue a pregnancy," its new law actually forces women to undergo abortions they do not want.

None of this is lawful. Colorado has violated the free exercise rights of the Plaintiff healthcare providers who have a religious obligation to offer these women the same help Colorado allows to thousands of other women facing threatened miscarriage.

Colorado has violated the Free Speech Clause by censoring speech about progesterone, censoring how pro-life providers describe themselves and their services, and preventing women from even learning about their options. And it has violated the Fourteenth Amendment rights of Plaintiffs' patients to make their own medical choices.

The three Boards had an opportunity to right one of these constitutional wrongs—but instead they made it worse. None of the Boards took the statutory off-ramp of deeming abortion pill reversal a generally accepted standard of practice. Notably, the Medical Board initially proposed to investigate any complaints about abortion pill reversal on a case-by-case basis. But more than a dozen state legislators submitted a comment "express[ing] our dismay and disappointment" at the proposed rule. Two bill sponsors showed up to testify, demanding that the Boards "reconsider your draft rules" and "carefully reread the instructions" in the statute. The Medical Board promptly caved to that political pressure, abruptly abandoning the proposed rule and instead finding that using progesterone to reverse the effects of mifepristone is *not* a generally accepted standard of practice. Meanwhile, they will evaluate complaints related to any other form of abortion pill reversal on a case-by-case basis. Earlier this week, the Nursing and Pharmacy Boards disagreed in part with the Medical Board. Although they too failed to deem abortion pill reversal generally accepted, they adopted rules that purport to treat complaints about abortion pill reversal on an individualized case-by-case basis. The end result is that the statutory prohibition remains, with an added Free Exercise violation to boot because now the Boards assert

unbridled discretion for themselves when evaluating certain abortion pill reversal complaints.

None of this regulatory bobbing and weaving changes the fact that Plaintiffs need urgent relief. Since SB 23-190's enactment, numerous women have contacted Plaintiffs, asked their help, and received progesterone after taking mifepristone. Just last week, Bella received a call from a woman seeking urgent assistance in reversing the drug's effects. Bella administered supplemental progesterone, and the patient's treatment is ongoing. Numerous other abortion pill reversal patients also remain under Bella's care—including one who gave birth to a healthy baby earlier this week, and three others who are scheduled to give birth this fall.

Absent this Court's intervention, these patients risk having their care interrupted. As of October 23—when Defendants' non-enforcement promise expires—Plaintiffs will be in an impossible position: either obey the law and violate their conscience by ceasing care or break the law and risk their licenses and massive penalties.

A preliminary injunction is desperately needed to maintain the status quo as it existed prior to the case and exists right now: women should be free to change their minds after taking mifepristone, and their doctors and nurses should be free to help them.

BACKGROUND

Bella Health and Wellness. Plaintiff Bella Health and Wellness is a nonprofit, faith-based medical clinic that offers life-affirming, dignified health care to women,

men, and children from all backgrounds and faiths. Am.Compl. ¶¶30, 41. Founded in 2014 by Plaintiffs Dede Chism and Abby Sinnett, Bella offers obstetrics-gynecology care as well as family medicine, pediatrics, and functional medicine. *Id.* ¶¶41-42. Today, Bella and its 20 providers serve 20,000 patients, many of whom are financially vulnerable. *Id.* ¶¶44-45.

Progesterone. Progesterone is a naturally occurring hormone that, as the name indicates, promotes gestation. Am.Compl. ¶61. It plays an essential role in regulating female reproductive function in the uterus, ovaries, mammary glands, and brain, and it is particularly critical to achieving and maintaining a healthy pregnancy. *Id.* ¶62.

Progesterone has been used to support female fertility in a variety of ways for more than 50 years. *Id.* ¶66. It is commonly prescribed for a host of uses in obstetrics and gynecology, including treatment of recurring miscarriages, prevention of preterm birth, support of endometrial function during in vitro fertilization, treatment of absent menstrual periods, treatment of excessive blood loss during menstruation, treatment of premenstrual syndrome, and prevention of irregular thickening of the endometrium during menopause. *Id.* ¶67. All uses of supplemental progesterone except two are considered "off-label" uses. *Id.* ¶73.[1]

The FDA historically classified the drugs pregnant women might take into five

[1] The FDA has long recognized the freedom healthcare professionals enjoy to prescribe FDA-approved drugs off-label, stating that "[o]nce a [drug] product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens of patient populations that are not included in approved labeling." Am.Compl. ¶72.

risk categories (A, B, C, D, or X) to indicate the potential of a drug to cause adverse effects during pregnancy. *Id.* ¶69. Progesterone is classified as Category B—the same category as Tylenol, which is available over-the-counter and is the most commonly used pain reliever during pregnancy. *Id.* ¶70.

Two recent studies—the Progesterone in Recurrent Miscarriages (PROMISE) study and the Progesterone in Spontaneous Miscarriage (PRISM) study—documented the use of progesterone to treat unexplained recurrent miscarriage and early pregnancy bleeding. *Id.* ¶¶75-77. In November 2021, the United Kingdom's National Institute of Health and Care Excellence (NICE) published new guidelines, based on a research review (including the PRISM study), recommending progesterone therapy for women with early pregnancy bleeding and at least one previous miscarriage. *Id.* ¶78. NICE noted that "there was no evidence of harms for women or babies" from the use of progesterone, including "no increase in risk of stillbirth, ectopic pregnancy, congenital abnormalities or adverse drug reactions." *Id.* ¶79.

The Abortion Pill. The abortion pill refers to the use of prescribed drugs to terminate pregnancy. *Id.* ¶80. The current abortion-pill regimen consists of two drugs: mifepristone and misoprostol. *Id.* ¶81. Under the FDA-approved protocol, a woman takes mifepristone orally, followed up to 48 hours later by misoprostol. *Id.* ¶89.[2]

[2] On August 16, 2023, the Fifth Circuit held that certain changes made in 2016 by the FDA to mifepristone's risk evaluation and mitigation strategy (REMS) were likely arbitrary and capricious under the Administrative Procedure Act. *Alliance for Hippocratic Med. v. FDA*, 78 F.4th 210, 225-26, 245-46 (5th Cir. 2023). It also held that the FDA's 2021 decision "not [to] enforce an agency regulation requiring mifepristone to be prescribed and dispensed in person" was likely arbitrary and capricious. *Id.* at

Mifepristone is a progesterone antagonist, meaning it binds to (and blocks) the same intracellular receptors that progesterone would normally bind to. *Id.* ¶¶83-84. As the FDA explains, "Mifepristone is a drug that blocks a hormone called progesterone that is needed for a pregnancy to continue." *Id.* ¶84. By blocking the progesterone receptors, mifepristone causes the uterine lining to deteriorate, blocking oxygen and nutrition to the developing embryo and rendering the uterus vulnerable to contractions. *Id.* ¶86.

The second drug, misoprostol, then binds to smooth muscle cells in the uterine lining, thereby causing contractions that mechanically expel the embryo from a woman's uterus. *Id.* ¶87. Misoprostol is part of the protocol because mifepristone alone has an incomplete abortion rate of 20-40%, as determined by the end point of complete uterine expulsion. *Id.* ¶88.

Abortion Pill Reversal. Some women change their mind about terminating their pregnancies after taking mifepristone but before taking misoprostol. *Id.* ¶90. Other women did not want to take mifepristone in the first place, but rather took it under duress or because they were tricked or forced. *Id.* ¶91 & n.26.

When a woman has taken mifepristone and then wants to continue her pregnancy, providers may prescribe supplemental progesterone in an attempt to overcome the

222, 249. The Fifth Circuit's decision remains stayed pending "disposition of a petition for a writ of certiorari, if such a writ is timely sought." *Danco Labs., v. Alliance for Hippocratic Med.*, 143 S.Ct. 1075, 1075 (2023). A district judge in the Eastern District of Washington has separately enjoined the FDA from altering its REMS for mifepristone in 16 states and D.C., including Colorado. Order & Clarification, *Washington v. FDA*, No. 1:23-cv-3026 (E.D. Wash.), Dkts. 80, 91.

progesterone-blocking effects of the mifepristone. *Id.* ¶92. Administering progesterone in these circumstances is commonly known as "abortion pill reversal." *Id.* Abortion pill reversal involves administering an influx of progesterone—the hormone inhibited by mifepristone—to curb and outlast the effects of mifepristone. *Id.* ¶93. Like most other uses of progesterone, its use in abortion pill reversal is off-label. *Id.* ¶94.

The scientific literature demonstrates progesterone's ability to counteract mifepristone. *Id.* ¶95. In 1989, researchers designed a study to investigate "the role of progesterone in the maintenance of pregnancy," using groups of pregnant rats. *Id.* ¶96. After four days, only 33.3% of the rats receiving mifepristone remained pregnant, but 100% of the rats who were also given progesterone remained pregnant. *Id.*

In 2018, Dr. George Delgado published an observational case series that followed 754 pregnant women who had taken mifepristone, but had not yet taken misoprostol, and were interested in reversing mifepristone's effects. *Id.* ¶97. A total of 547 women met inclusion criteria and underwent progesterone therapy within 72 hours after taking mifepristone. *Id.* ¶98. The overall success rate—247 live births, plus four viable pregnancies lost to follow-up after 20 weeks gestation—was 48%. *Id.* The 2018 study also showed fetal survival rates of 64% for the subgroup that received progesterone intramuscularly and 68% for the subgroup that received a high dose of oral progesterone followed by daily oral progesterone until the end of the first trimester. *Id.* ¶99.

These rates compare favorably with the baseline fetal survival rate of approximately 25% if no treatment is attempted after mifepristone is administered. *Id.* ¶100.

Bella's Experience with Progesterone Therapy and Abortion Pill Reversal. Bella's general practice is to consider progesterone therapy where a pregnant woman has any of the following risk factors: prior miscarriage, bleeding in the first trimester, prior pregnancy with preterm labor or delivery, infertility, history of low luteal progesterone, and medications that block progesterone (*i.e.*, mifepristone). *Id.* ¶106. If a woman presents with one or more of these risk factors, Bella will offer progesterone therapy to reduce the risk of miscarriage and preterm birth. *Id.* ¶107.

Bella and its providers have a religious obligation to treat all women at risk of miscarriage, whether that risk arises biologically, due to physical trauma, or because the woman willingly or unwillingly ingested mifepristone. *Id.* ¶108. As a matter of conscience, Bella and its providers cannot refuse to help a woman who desires to continue her pregnancy simply because she first took mifepristone. *Id.* ¶109. Bella and its providers are thus religiously obligated to offer abortion pill reversal. *Id.*

When a woman contacts Bella seeking abortion pill reversal, a Bella provider will meet her at the clinic as soon as possible, including at nights or on weekends, or holidays. *Id.* ¶111. Bella informs each woman that the use of progesterone to attempt to reverse the effects of mifepristone is an off-label use and that success is not guaranteed. *Id.* ¶112. If the woman chooses to proceed, Bella offers progesterone therapy in an effort to counteract the effects of mifepristone. *Id.* ¶113.

Bella has treated dozens of abortion pill reversal patients who successfully maintained their pregnancies. *Id.* ¶114. Since SB 23-190's enactment, numerous women have received progesterone to counteract the effects of mifepristone under Bella's care. *Id.* ¶115. One woman—who initially received progesterone at a pregnancy center, but transferred to Bella's care within days of SB 23-190's enactment under the protection of this Court's temporary restraining order—gave birth to a healthy baby boy on September 18. *Id.* ¶116. Three more are scheduled to give birth before the end of the year. *Id.* Yet another woman started abortion pill reversal treatment at Bella just last week and is now under follow-up care. *Id.* ¶117.

Bella's Speech about its Services. Bella's website describes it as a "comprehensive, life-affirming OB-GYN practice." *Id.* ¶123. It separately describes Bella as offering a "full continuum of care and comprehensive health care at every stage of life." *Id.* ("We are a life-affirming, full-service Family Medicine and OB-GYN medical center."). Bella also describes and promotes the availability of abortion pill reversal on its website, social media accounts, and in brochures and posters describing Bella's services. *Id.* ¶125-31. Bella's website contains the following FAQ: "I took the 'abortion pill,' but I've changed my mind. Is there anything you can do?" The answer explains:

> If you've initiated a chemical abortion by taking the first abortion pill (mifepristone, also known as Mifeprex or RU-486), we may be able to save the life of your child. If we act quickly, there is a possibility we can save your baby through a safe, painless therapy known as Abortion Pill Reversal (APR). We've helped dozens of women just like you. No judgment. No questions. Just excellent medical care and complete support. We are here for you.

Id. ¶126.

Colorado Medical and Nursing Licensing Regimes. As "regulators" of their respective professions, the Colorado Medical Board and the Colorado State Board of Nursing "may investigate, hold hearings, and gather evidence in all matters related to the exercise and performance of [their] powers and duties." Colo. Rev. Stat. §12-20-403(1). Each Board may discipline licensees who engage in "conduct that constitutes grounds for discipline or unprofessional conduct." *Id.* §12-20-404(1). If a Medical Board investigation "discloses facts that warrant further proceedings by formal complaint," the complaint "shall be referred" to the AG, who then "shall prosecute those charges." *Id.* §12-240-125(4)(c)(V), (5)(d); *see also id.* §12-255-119(3)(c)(V), (4)(d) (AG "shall prosecute" complaints referred by Nursing Board). Complaints regarding a licensee's conduct "may be made" to either Board "by any person or may be initiated by an inquiry panel of the board on its own motion." Colo. Rev. Stat. §§12-240-125(4)(a)(I) (Medical Board); *id.* §12-255-119(3)(a)(II).

Colorado Consumer Protection Act. The Colorado Consumer Protection Act (CCPA) makes it a "deceptive trade practice" to "knowingly or recklessly make[] a false representation as to the characteristics, … uses, [or] benefits … of goods, [or]

services," Colo. Rev. Stat. §6-1-105(1)(e), or to "knowingly or recklessly engage[] in any unfair, unconscionable, deceptive, deliberately misleading, false, or fraudulent act or practice," *id.* §6-1-105(1)(rrr). The AG and the state's district attorneys are "concurrently responsible" for CCPA enforcement, *id.* §6-1-103, and can seek a civil penalty of up to $20,000 for each violation, *id.* §6-1-112(1)(a). Private parties who are "actual or potential consumer[s]" and are injured by a deceptive practice can also sue. *Id.* §6-1-113(1)(a). They can seek damages for the greater of $500, the "amount of actual damages sustained," or three times that amount if bad-faith conduct is established by clear and convincing evidence, plus attorneys' fees and costs, *id.* §6-1-113(2).

Colorado Senate Bill 23-190. On April 14, 2023, Governor Jared Polis signed into law Senate Bill 23-190, which took effect immediately.

Section 1 of SB 23-190 declares that "anti-abortion centers" are the "ground-level presence of a well-coordinated anti-choice movement" and engage in "deceptive advertising tactics to target and acquire clients." §1(1)(a), (d)-(e). It specifically accuses "anti-abortion centers" of "go[ing] so far as to advertise medication abortion reversal, a dangerous and deceptive practice that is not supported by science or clinical standards." *Id.* §1(1)(f).

Section 1's final subsection then targets both the provision of abortion pill reversal and the speech of those who wish to publicize it. It does this by "declar[ing] that" CCPA Section 6-1-105(1)(e) and (1)(rrr) "appl[y] to … advertising for or providing or offering to provide or make available medication abortion reversal." §1(3).

Section 2 targets speech by those who do not provide or refer for abortion or emergency contraceptives, providing that it is a "deceptive trade practice" to "make[] or disseminate[] to the public … any advertisement that indicates that the person provides abortions or emergency contraceptives, or referrals for abortions or emergency contraceptives, when the person knows or reasonably should have known … that the person does not provide those specific services." §2(2); Colo. Rev. Stat. §6-1-734.

Finally, Section 3 of SB 23-190 bans abortion pill reversal treatment outright, making it "unprofessional conduct" for a licensee to "provide[], prescribe[], administer[], or attempt[] medication abortion reversal in this state." SB 23-190 §3(2); Colo. Rev. Stat. §12-30-120. It adds that abortion pill reversal is "unprofessional conduct"—*unless* the Colorado Medical Board, the Board of Nursing, and Board of Pharmacy, "in consultation with each other," adopt "rules finding that it is a generally accepted standard of practice to engage in medication abortion reversal" by October 1, 2023. SB 23-190 §3(2)(a)-(b).

Legislative Record. SB 23-190's debate shows the law is specifically designed to target religious organizations that offer abortion alternatives, including abortion pill reversal. Am.Compl. ¶¶159-61, 153. The bill's sponsors stated that SB 23-190 will "crack down" on these "anti-abortion centers," which were described as "ideologically-driven" and "fake clinics," *Id.* ¶¶159-62, 165.

The bill's sponsors levied a host of accusations about such organizations, claiming they "trad[e] on the goodwill of legitimate medicine to defraud patients," *id.* ¶161,

"tak[e] advantage of vulnerable populations," *id.* ¶163, tell "outright [lies]," *id.* ¶167, and engage in "intimidation," "delay tactics," "disinformation," and "shame," *id.* ¶161, 164, 167. Finally, the sponsors accused religious organizations—"the only ones that can prescribe abortion pill reversal," *id.* ¶162—of causing "harm" to pregnant women through a "life-threatening" and "dangerous" procedure, *id.* ¶¶162, 165.

The repeated claim that abortion pill reversal is "dangerous" rested largely on the testimony of Dr. Mitchell Creinin, an OB-GYN who has served as a paid consultant for the distributor of mifepristone. *Id.* ¶176. Creinin claimed that abortion pill reversal is a "medical fraud," a conclusion he based on a failed randomized trial he conducted in 2019 to test the "efficacy and safety" of abortion pill reversal. *Id.* ¶177.

Creinin's study was intended to enroll 40 pregnant women divided into two control groups: one receiving mifepristone followed by progesterone and the other receiving mifepristone followed by a placebo. *Id.* ¶178. But only 12 women were enrolled in the study, and only 10 women ultimately completed it. *Id.* Creinin testified that "[w]e had to stop the study after 12 women were enrolled because three of the women had such significant bleeding that had to be rushed to the emergency room or they called in an ambulance," which he described as "incredibly rare[,] more than rare." *Id.* ¶179. He then immediately had to clarify that of those three women, "two of the people had received placebo and one had received progesterone." *Id.*

But Creinin failed to disclose that "no intervention was needed" for the one woman who had received progesterone and went to the emergency department. *Id.* ¶180. By

contrast, the two women in the placebo group who went to the emergency room both "required emergency suction aspiration abortions" because "they had retained products and … they were bleeding significantly, severely bleeding. One of them required a blood transfusion because her hemoglobin dropped significantly." *Id.* ¶181.

Creinin ultimately testified that "my study was inconclusive as far as showing whether or not the [progesterone] treatment might work" and conceded that "it's always possible" that abortion pill reversal could be effective. *Id.* ¶¶179, 183. He also admitted that no U.S. jurisdiction has ever made a finding of professional misconduct based on abortion pill reversal. *Id.* ¶184.

The sponsors of SB 23-190 identified the terms "comprehensive" and "full range" of services (or similar terms) as deceptive advertising when used by a pro-life provider. *Id.* ¶171. For example, Senator Marchman described "anti-abortion center[s]" as "faith-based organizations that *pose as a comprehensive reproductive healthcare clinic*." *Id.* ¶172. Senator Winter claimed that "many anti-abortion centers are *purposefully misleading about offering* unbiased, medically-based … *comprehensive healthcare*. … [A]nti-abortion clinics should not act as though they offer a *full range of reproductive healthcare*." *Id.* ¶173.

Procedural History. On April 14, 2023, hours after SB 23-190's signing, Plaintiffs sued and moved for a temporary restraining order and preliminary injunction. Dkt.7. This Court entered a temporary restraining order that night. Dkt.8.

At the preliminary injunction hearing on April 24, Samuel Delp, Senior Program Director for the Division of Professions and Occupations in the Colorado Department of Regulatory Agencies, testified that he was not aware of any prior complaints by women who said they were injured by abortion pill reversal or of any prior complaints against a doctor or nurse related to abortion pill reversal. Dkt.51 at 42:10-17; *see also id.* at 63:14-16. Natalie Hanlon Leh, Chief Deputy Attorney General for the Colorado Department of Law, similarly testified that she had never heard any complaints from women who said they had been harmed by abortion pill reversal. *Id.* at 76:16-19. And the government promised not to enforce SB 23-190 at all over the past five months.

Following the hearing, the Court declined to enter a preliminary injunction given the State's assurances that it would not enforce SB 23-190 until the rulemaking process had concluded. Dkt.48.

SB 23-190 Rulemaking. On June 5, 2023, the three Boards held a joint stakeholder meeting to gather "stakeholder feedback" about SB 23-190's implementation. Am.Compl. ¶188.

Before that meeting, Plaintiffs submitted a public comment describing the scientific evidence that abortion pill reversal is safe and effective, and also explaining "why the claims about abortion pill reversal in SB 23-190 are unsupported by credible medical data." *Id.* ¶189. Dozens of Colorado doctors and nurses filed public comments and testified in support of abortion pill reversal at the June 5 hearing. *Id.* ¶190. Several women who sought and received abortion pill reversal treatment—and who went on

to deliver healthy babies—also submitted comments urging the Boards not to deprive other women of the ability to change their minds about abortion. *Id.* ¶191. On the other side, a handful of opponents of abortion pill reversal also submitted comments. *Id.* ¶192. These included a two-page letter from Dr. Mitchell Creinin reiterating his testimony that abortion pill reversal is "misleading" and "medical fraud." *Id.*

The Medical Board issued a proposed rule that would not treat abortion pill reversal as *per se* unprofessional conduct but instead address complaints on a case-by-case basis. *Id.* ¶193. The text of that proposed rule stated that "[t]he Board will not treat medication abortion reversal as a *per se* act of unprofessional conduct." *Id.* ¶194. "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 medical practice." *Id.*

The political backlash was swift, furious, and effective. Three bill sponsors of SB 23-190—along with more than a dozen other state legislators—submitted a comment "express[ing] our dismay and disappointment in the proposed 'draft' rules to SB190." *Id.* ¶195. New Era Colorado—the self-described "leading voice for young people in Colorado politics"—submitted more than 100 form letters urging the Board to declare that abortion pill reversal is unprofessional conduct. *Id.* ¶197.

Meanwhile, Plaintiffs submitted a second comment urging the Boards to conclude, in line with all credible medical data, that abortion pill reversal is a generally accepted standard of practice. *Id.* ¶198. Numerous other Colorado doctors submitted comments supporting that same conclusion. *Id.*

At the second joint stakeholder meeting on August 4, two of the bill sponsors of SB 23-190 testified against the draft rules. *Id.* ¶199. Representative McCormick stated that because abortion pill reversal is "particularly harmful" the "General Assembly has called it out as unprofessional conduct for you in law." *Id.* ¶200. She asked the Boards to "reconsider your draft rules" and "carefully reread the instructions" in the statute. *Id.* Senator Winter stated that "I just wan[t] [to] make it incredibly clear what the legislative intent was because I don't think these draft rules meet legislative intent." *Id.* ¶201. She further insisted that the draft rule "is not what we wanted. That's not legislative intent. That's actually the reverse of the legislative intent." *Id.*

At its final hearing on August 17, the Medical Board abruptly reversed course. *Id.* ¶202. It now announced that "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." *Id.* But "[f]or other conduct that could meet the definition of medication abortion reversal, the Board will investigate such deviation on a case-by-case basis." *Id.*

On September 20, the Nursing Board convened its own final rulemaking hearing. It disagreed with the Medical Board, *id.* ¶204, declining to treat abortion pill reversal as *per se* unprofessional conduct. Instead, it will examine abortion pill reversal complaints on a case-by-case basis. *Id.* ¶204-05.

On September 21, the Pharmacy Board convened its final hearing. *Id.* ¶206. It followed the Nursing Board's approach, opting to treat complaints about *all* forms of abortion pill reversal on a case-by-case basis. One Pharmacy Board member recounted that "we dispense a lot of …. bioidentical progesterone from my pharmacy …. [I]t's not dangerous to the patient as far as what I've seen." *Id.* ¶207. And the Board Chair stated, "[w]e know that progesterone is safe and effective no matter …. what it's being used for." *Id.* ¶207.

Although the Board rules are effective on October 1, all Defendants have agreed to a non-enforcement period expiring at 12:00 a.m. on October 24, 2023. Dkt.88.

Harm to Bella and its Patients. Because of SB 23-190 and its implementing regulations, Bella is unable to help pregnant women who seek abortion pill reversal without putting its providers' medical licenses at risk. Am.Compl. ¶210. If a woman calls Bella after October 23 seeking abortion pill reversal, Bella and its providers will be forced to choose between complying with SB 23-190 and following their conscience and core religious commitments to help that woman and her unborn child. *Id.*

This harm is no speculation; it is imminent. Just last week, Bella received a call from a woman seeking urgent assistance in reversing the effects of mifepristone. *Id.*

¶211. Bella administered supplemental progesterone, and that patient's treatment is ongoing. *Id.* Numerous other abortion pill reversal patients also remain under Bella's care—including one who gave birth to a healthy baby earlier this week, and three more who are scheduled to give birth this fall. *Id.* ¶¶116, 211. If Bella follows its religious obligations and continues providing abortion pill reversal treatment after October 23, its providers risk losing their licenses. *Id.* ¶¶212-13. If they comply, they will have been coerced by the state to abandon their deep convictions, and their patients will irreparably lose the opportunity to continue their pregnancies. *Id.* ¶213.

Because of SB 23-190, Bella is also unable to publicize abortion pill reversal without risking ruinous financial penalties—up to $20,000 per violation. *Id.* ¶¶215-19; *see* Colo. Rev. Stat. §6-1-103. Bella has already been chilled from speaking about abortion pill reversal once before—when it was forced to strip information from its website and social media accounts prior to filing this lawsuit. *Id.* ¶216. Absent this Court's intervention, Bella's speech will again be chilled by SB 23-190's draconian penalties as soon as the State's non-enforcement promise expires. *Id.* ¶217.

Because of SB 23-190, Bella also risks draconian penalties and damages if it continues to describe itself as a "full-service" practice or as providing "comprehensive" or "full continuum" care. *Id.* ¶221. Bella believes that these terms accurately describe the care it provides—but it will be forced to alter how it describes itself to potential patients because of the statute's sweeping prohibition on any advertisement that "indicat[es]" that a person provides abortions. *Id.*

And because of SB23-190, Bella's current and prospective patients who take mifepristone and then decide to continue their pregnancies will be deprived of access to information and progesterone therapy—for the sole reason that they took mifepristone, willingly or unwillingly, before seeking medical help to preserve their pregnancies. *Id.* ¶222. That flatly contradicts SB 23-190's own declaration that women have the "fundamental right to continue a pregnancy." §1(1)(a).

LEGAL STANDARD

A preliminary injunction is warranted when an applicant shows (1) a likelihood of success on the merits, (2) irreparable harm absent relief, (3) the balance of equities weighs in its favor, and (4) the injunction is in the public interest. *Planned Parenthood of Kan. v. Andersen*, 882 F.3d 1205, 1223 (10th Cir. 2018). "[I]n First Amendment cases, the likelihood of success on the merits will often be the determinative factor." *Hobby Lobby v. Sebelius*, 723 F.3d 1114, 1145 (10th Cir. 2013) (en banc), *aff'd sub nom.*, *Burwell v. Hobby Lobby*, 573 U.S. 682 (2014).

ARGUMENT

I. Plaintiffs are likely to succeed on the merits.

Plaintiffs are likely to succeed on the merits because Colorado's effort to ban abortion pill reversal through SB 23-190, its implementing regulations, and the CCPA violates the Free Exercise Clause, the Free Speech Clause, and the Fourteenth Amendment. Colorado cannot come close to satisfying its burdens under strict scrutiny.

A. Colorado's ban on abortion pill reversal violates the Free Exercise Clause.

At its core, this case is about Plaintiffs' religious obligation to help women who desire to continue their pregnancies after taking the first abortion pill. SB 23-190 squarely prohibits Bella from offering progesterone therapy in these circumstances. A law is subject to strict scrutiny under the Free Exercise Clause when it is "not 'neutral'" or "generally applicable." *Ashaheed v. Currington*, 7 F.4th 1236, 1243 (10th Cir. 2022). SB 23-190 fails both requirements.

Not generally applicable. "[L]aws burdening religious practice must be of general applicability." *Church of the Lukumi Babalu Aye v. City of Hialeah*, 508 U.S. 520, 542 (1993). A law fails general applicability if it "treat[s] *any* comparable secular activity more favorably than religious exercise," *Tandon v. Newsom*, 141 S.Ct. 1294, 1296 (2021) (per curiam), or "prohibits religious conduct while permitting secular conduct that undermines the government's asserted interests in a similar way," *Fulton v. City of Philadelphia*, 141 S.Ct. 1868, 1877 (2021); *see also Denver Bible Church v. Azar*, 494 F.Supp.3d 816, 833 (D. Colo. 2020) (laws violate the First Amendment where they "treat religious institutions less favorably than some secular institutions"). "[W]hether two activities are comparable … must be judged against the asserted government interest that justifies the regulation at issue." *Tandon*, 141 S.Ct. at 1296. Importantly, the comparability analysis "is concerned with the *risks* various activities pose," not the "reasons why" people engage in them. *Id.* (emphasis added).

There is no question that Section 3 and its implementing regulations, as well as Section 1 (on its own and through the CCPA) "burden [Plaintiffs'] religious practice." *Lukumi*, 508 U.S. at 542. Consistent with their commitment to the dignity of human life, Plaintiffs must provide life-affirming medical care to women at risk of miscarriage. As a matter of conscience, Plaintiffs cannot refuse to administer progesterone to a woman who desires to continue her pregnancy simply because she took mifepristone. Plaintiffs are therefore religiously obligated to offer the abortion pill reversal that Colorado now outlaws.

Under *Tandon*, a single exemption for a "comparable secular activity" is enough to defeat general applicability. 141 S.Ct. at 1296. Here, SB 23-190 makes no attempt to regulate a laundry list of off-label uses of progesterone, much less outright prohibit them. Nor do the regulations or the CCPA prohibitions implemented by Section 1. Colorado's purported interest in prohibiting that religious exercise is in protecting women from "a dangerous and deceptive practice that is not supported by science or clinical standards." SB 23-190 §1(1)(f). But abortion pill reversal is simply supplemental progesterone. And there are many off-label uses of progesterone—including treatment of recurring miscarriages, prevention of preterm birth, and support of endometrial function during IVF treatment—all of which remain legal in Colorado, and all of which "undermine[]" Colorado's purported interest "in a similar way to a hypothetical religious exemption." *Lowe v. Mills*, 68 F.4th 706, 714-15 (1st Cir. 2023)

(plaintiffs stated free exercise claim based on a policy that permitted medical but not religious exemptions from vaccine requirement).

Nor can Colorado point to the "reasons why" the progesterone is administered to bolster its alleged interest. *See Tandon*, 141 S.Ct. at 1296. What matters is the "risk[]." *Id.*; *FCA v. SJUSD*, No. 22-15827, 2023 WL 5946036, at *18 (9th Cir. Sept. 13, 2023) (en banc) (faulting government for focusing on "reasons why" it treated secular activity more favorably than religious activity, rather than the "risks" of the two activities). And the risk of administering progesterone—the naturally occurring hormone that regulates female reproductive function and maintains pregnancy—is minimal (if any). The FDA has said as much, placing progesterone in the same risk category as Tylenol—the most commonly used pain reliever during pregnancy.

SB 23-190 fails general applicability for a second, independent reason: its implementing regulations contain "a formal mechanism for granting exceptions [that] 'invites' the government to decide which reasons for not complying with the policy are worthy of solicitude." *Fulton*, 141 S.Ct. at 1879. And as the en banc Ninth Circuit just stated, "the mere existence of government discretion is enough to render a policy not generally applicable." *FCA*, 2023 WL 5946036, at *15-17 (finding that school district's "discretion to grant individualized exemptions" from its student group antidiscrimination policy "on an ad hoc basis" rendered the policy not generally applicable.); *see also, e.g.*, *Dahl v. Board of Trustees*, 15 F.4th 728, 733 (6th Cir. 2021) (per curiam) (university vaccine policy "not generally applicable" because the "University retains

discretion to extend exemptions in whole or in part"). That's because "a system of exceptions … undermines the [State's] contention that its [regulations] can brook no departures." *Fulton*, 141 S.Ct. at 1882.

So too here. The Medical Board's rule explicitly states that using progesterone to counteract mifepristone's effects is categorically declared not to "meet generally accepted standards of medical practice," but any other form of abortion pill reversal will be evaluated "on a case-by-case basis." Dkt.78. The Nursing and Pharmacy Boards' rules are even clearer, providing them with unbridled discretion *to evaluate all* forms of abortion pill reversal on a case-by-case basis. Am.Compl. ¶241. Colorado's creation of a "system of individual exemptions, made . . . at the 'sole discretion' of the [Boards]" is a clear-cut violation of *Fulton*, and thus triggers struct scrutiny, 141 S. Ct. at 1878-99.

This lack of general applicability is compounded by SB 23-190's overall focus on "anti-abortion centers," §1(1)(c)-(f), and its imposition of targeted deceptive practices rules (only related to one side of the abortion issue), §2(2), and information bans (only related to one use of progesterone), §§1(3), 3(2). Colorado cannot plausibly claim to be regulating generally. For all these reasons, SB 23-190 is not a generally applicable law. It is therefore subject to strict scrutiny, which it fails. *Infra* Section I.E.

Not neutral. The government is "obliged under the Free Exercise Clause to proceed in a manner neutral toward and tolerant of [religious actors'] religious beliefs." *Masterpiece Cakeshop v. Colorado C.R. Comm'n*, 138 S.Ct. 1719, 1731 (2018). Even

"slight suspicion[s]" of religious intolerance or "subtle departures from neutrality" violate the Free Exercise Clause. *Id.*; *Lukumi*, 508 U.S. at 534. SB 23-190 fails neutrality because it is the product of overt animus toward religious adherents, *see Masterpiece*, 138 S.Ct. at 1731, and thereby creates a "religious gerrymander," *see Lukumi*, 508 U.S. at 535.

The Supreme Court has also long recognized that government hostility to religion can be "masked, as well as overt." *Id.* at 534. To determine whether a law is neutral, courts must "survey meticulously," *id.*, all evidence of a law's purpose for religious animus, such as "the legislative or administrative history, including contemporaneous statements made by members of the decisionmaking body." *Masterpiece*, 138 S.Ct. at 1731. Such animus can demonstrate that a law was "enacted 'because of', not merely 'in spite of,' [its] suppression of … religious practice." *Lukumi*, 508 U.S. at 540.

The legislative record here raises far more than a "slight suspicion" of animosity, *Masterpiece*, 138 S.Ct. at 1731, instead making clear that SB 23-190 was enacted "because of" religious conduct, *Lukumi*, 508 U.S. at 540. The bill's sponsors expressly stated that their intent was to target "faith-based" organizations offering and advertising abortion pill reversal. *Supra* at p.15. Their disdain for such organizations manifests time and again in the legislative record, where the bill's sponsors and proponents refer to such organizations as "fake clinics" and accuse them of "sham[ing] women"; engaging in "delay tactics," "disinformation," and "intimidation"; and "harm[ing]" women by offering them the "life-threatening" procedure of abortion pill

reversal, despite the data saying otherwise. *Supra* at pp.13-14. And when the Medical Board failed to initially heed these warnings, the same sponsors "ma[d]e it incredibly clear what the legislative intent was" behind SB 23-190, reprimanding the Board's members for not doing "what [the legislature] wanted" and telling them to "carefully reread the instructions" and to "stop and limit" this singular use of progesterone. *Supra* at p.18.

Taken together and separately, these statements demonstrate that the legislators intended to send a clear and unequivocal message to those motivated by their religion to offer life-affirming care in Colorado: compromise your beliefs or close your doors. *See New Hope Fam. Servs. v. Poole*, 966 F.3d 145, 168 (2d Cir. 2020) (finding similar statements sufficient to state a free exercise claim). Moreover, repeatedly impugning the motivations of religious adherents as intentionally employing deceitful disinformation campaigns and delay tactics amounts neither to "tolerance" nor "neutral objectivity." *Meriwether v. Hartop*, 992 F.3d 492, 512-13 (6th Cir. 2021) (finding statements about religion being "oppress[ive]" and "primarily motivated out of fear" sufficient to state a free exercise claim); *see also Ashaheed*, 7 F.4th at 1244 (complaint alleged religious animus based on allegations of "Sergeant Currington's dismissive attitude, threats, and differential treatment of non-Muslims").

Unsurprisingly, the government's focus on religious providers of abortion pill reversal means that "the burden of the [law], in practical terms, falls on [religious] adherents but almost no others." *Lukumi*, 508 U.S. at 535-36. "[S]trong evidence" of a

religious gerrymander occurs when "the effect of [the] law in its real operation" makes it "evident" that the law "target[s]" religion. *Id.* at 535. That's because "[t]he principle that government, in pursuit of legitimate interests, cannot in a selective manner impose burdens only on conduct motivated by religious belief is essential to the protection of the rights guaranteed by the Free Exercise Clause." *Id.* at 543; *see also Trinity Lutheran Church of Columbia v. Comer*, 137 S.Ct. 2012, 2019 (2017) (government may not "target the religious for special disabilities based on their religious status" (cleaned up)).

Here, the targeted scope of SB 23-190's prohibition on offering abortion pill reversal makes clear that "almost the only conduct subject to [the law] is the religious exercise" of faith-based providers offering life-affirming care through this service. *Lukumi*, 508 U.S. at 535. Colorado has chosen to regulate providing one and only one progesterone treatment—abortion pill reversal—which, according to the bill's sponsors, is used "only" by "faith-based organizations." Am.Compl. ¶¶160-62. Healthcare providers can continue using progesterone in any other circumstance and for any other reason. Thus, once SB 23-190's "operation is considered," it is clear that it "achieve[s] [the] result" of prohibiting religious conduct while leaving comparable conduct untouched. *Lukumi*, 508 U.S. at 535. This is precisely the type of "religious gerrymander" condemned by *Lukumi*. *See id.* at 535-36 (striking down a law that permits "almost all killings of animals except for religious sacrifice").

Colorado's blatant religious targeting ends the analysis. Courts must "set aside such policies without further inquiry," *Kennedy v. Bremerton Sch. Dist.*, 142 S.Ct. 2407, 2422 n.1 (2022) (cleaned up), because they are "plainly unconstitutional." *Colorado Christian Univ. v. Weaver*, 534 F.3d 1245, 1260 (10th Cir. 2008). "After all, government action motivated by religious animus cannot be 'narrowly tailored to advance' 'a compelling governmental interest.'" *Ashaheed*, 7 F.4th at 1244-45. SB 23-190 is therefore invalid for non-neutrality, even without strict scrutiny.

B. SB 23-190 violates the Free Speech Clause by discriminating based on content and viewpoint.

The Supreme Court has recently reaffirmed that the First Amendment prohibits the government—specifically, the state of Colorado—from "excising certain ideas or viewpoints from the public dialogue." *303 Creative v. Elenis*, 143 S.Ct. 2298, 2313 (2023). Section 1, both on its own and through the CCPA, and Section 2 of SB 23-190 do precisely this by regulating speech based on its content and viewpoint. They are thus "presumptively unconstitutional" and subject to strict scrutiny. *See NIFLA v. Becerra*, 138 S.Ct. 2361, 2371 (2018).

"Both content- and viewpoint-based speech restrictions are presumptively invalid." *Pahls v. Thomas*, 718 F.3d 1210, 1229 (10th Cir. 2013). A law is content-based if it "on its face draws distinctions based on the message a speaker conveys" or if it "cannot be justified without reference to the content of the regulated speech, or [was] adopted by the government because of disagreement with the message the speech conveys." *Reed v. Town of Gilbert*, 576 U.S. 155, 163-64 (2015) (cleaned up). A law is

viewpoint based if it "targets not subject matter, but particular views taken by speakers on a subject." *Rosenberger v. Rector & Visitors of Univ. of Va.*, 515 U.S. 819, 829 (1995). SB 23-190 is both.

SB 23-190 is facially content-based because it applies only to speakers who discuss certain topics. Section 1 creates a targeted prohibition on deceptive trade practices that applies only to speakers who advertise one particular message by offering to provide abortion pill reversal. §1(3)(b). By contrast, a speaker who advertises the *abortion pill* is not subject to the law. Because Section 1, both on its own and through the CCPA, "singles out specific subject matter for differential treatment," it is content-based. *Reed*, 576 U.S. at 169. So too for Section 2, which applies only to speakers whose advertisements "indicate[]" that they provide or refer for abortion or emergency contraceptives. §2(2). Because this provision "requires enforcement authorities to examine the content of the message that is conveyed to determine whether a violation has occurred," it is content-based. *Animal Legal Def. Fund v. Kelly*, 9 F.4th 1219, 1228 (10th Cir. 2021) (cleaned up).

Even if SB 23-190 were facially content-neutral—it is not—it is content-based because Colorado enacted it out of disagreement with the message conveyed by "anti-abortion centers." §1(1)(c)-(f); *see Reed*, 576 U.S. at 164; *see also Ward v. Rock Against Racism*, 491 U.S. 781, 791 (1989) ("The government's purpose is the controlling consideration."). SB 23-190 claims that "anti-abortion centers"—healthcare providers

and pregnancy centers that do not provide or refer for abortion or emergency contraceptive services—"use deceptive advertising tactics" and "go so far as to advertise medication abortion reversal, a dangerous and deceptive practice that is not supported by science or clinical standards." §1(1)(e)-(f). And its sponsors decried them as "fake clinics," accusing them of "sham[ing]" women and spreading "disinformation." *Supra* at pp.13-14. Because SB 23-190 is "targeted at specific subject matter" and was enacted due to "'disagreement' with its message," it is "content based even if it does not discriminate among viewpoints." *Reed*, 576 U.S. at 167, 169.

But SB 23-190 *does* discriminate among viewpoints, making the First Amendment violation here "all the more blatant." *Rosenberger*, 515 U.S. at 829. Section 1 makes clear that SB 23-190 explicitly targets the views of "[a]nti-abortion centers" for their role in the "anti-choice movement." §1(1)(d). It effectuates that targeting by prohibiting (on its own and through the CCPA) advertising or counseling patients in connection with abortion pill reversal. §1(3)(b). Section 1 thus plainly discriminates against the viewpoint that progesterone treatment can reverse the effects of the first abortion pill. Healthcare providers are free to advertise and discuss with patients any and every progesterone treatment except to reverse the effects of the first abortion pill.

Section 2 is infected with the same constitutional flaw. It prohibits false advertising only of speakers who do not provide or refer for abortion or emergency contraceptives, while leaving deceptive advertising of those who *do* provide abortion and con-

traceptive services untouched. Just as with Section 1, then, Section 2 "targets … particular views taken by speakers on a subject." *Rosenberger,* 515 U.S. at 829. Because SB 23-190 "facilitate[s] speech on only one side of the abortion debate," it is "a clear form of viewpoint discrimination." *McCullen v. Coakley*, 573 U.S. 464, 485 (2014).

The Supreme Court "has stressed the danger of content-based regulations 'in the fields of medicine and public health, where information can save lives.'" *NIFLA*, 138 S.Ct. at 2374. Colorado may not like that women change their mind about abortion or may not believe that progesterone can reverse the effect of the first abortion pill. But it "may not burden the speech of others in order to tilt public debate in a preferred direction." *Sorrell v. IMS Health*, 564 U.S. 552, 578-79 (2011); *see First Nat'l Bank of Bos. v. Bellotti*, 435 U.S. 765, 785-86 (1978). As a content- and viewpoint-based restriction of speech, SB 23-190 is "presumptively unconstitutional" and subject to strict scrutiny, *NIFLA*, 138 S.Ct. at 2371, which it fails, *infra* Section I.E.

C. SB 23-190 violates the First Amendment right to receive information.

SB 23-190 is also invalid because it deprives Bella's current and prospective patients of their constitutional right to receive information. In particular, the law violates the First Amendment—and robs these women of their ability to make an informed choice—by stopping them from viewing advertising and speaking with their providers about using progesterone to reverse the effects of the first abortion pill.

It is "well established" that the First Amendment "protects the right to receive information and ideas." *Stanley v. Georgia*, 394 U.S. 557, 564 (1969); *accord Doe v.*

City of Albuquerque, 667 F.3d 1111, 1118-20 (10th Cir. 2012) (compiling cases). That right is particularly important in the abortion context, where the Supreme Court has long recognized the potential for under-informed decision-making to cause "devastating psychological consequences." *Planned Parenthood v. Casey*, 505 U.S. 833, 882 (1992), *overruled on other grounds by Dobbs v. Jackson Women's Health Org.*, 142 S.Ct. 2228 (2022). Absent the ability to receive information about progesterone therapy to reverse the effects of the first abortion pill, women who want to choose to remain pregnant will instead be forced to undergo an abortion they have not chosen.

The restriction here is entirely content- and viewpoint-based. Women are permitted to see advertisements for drugs to help them choose abortion. And they are permitted to see advertisements for all manner of uses of progesterone. But they are forbidden from receiving only one message: that progesterone might help them if they choose to continue their pregnancy after taking an abortion pill. That is content and viewpoint discrimination, and it fails strict scrutiny. *Infra* Section I.E.

D. SB 23-190 violates the Fourteenth Amendment right of pregnant women not to be forced to undergo or continue an abortion.

The Constitution protects the right to refuse "unwanted medical treatment," *Cruzan v. Director*, 497 U.S. 261, 278 (1990), and the right "to bodily integrity," *Washington v. Glucksberg*, 521 U.S. 702, 720 (1997) (citing *Rochin v. California*, 342 U.S. 165 (1952)). That includes the "right to decide independently, with the advice of [her] physician, to acquire and to use needed medication." *Whalen v. Roe*, 429 U.S. 589, 603 (1977). And it specifically includes the right to procreate—to decide "whether to bear

or beget a child" and to do so "free from unwarranted governmental intrusion." *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972); *see also Dobbs*, 142 S.Ct. at 2280 ("It is hard to see how we could be clearer" that *Dobbs* does not "cast doubt" on *Eisenstadt*).

Colorado purports to respect these rights—recognizing a "fundamental right to continue a pregnancy" with which state public entities are forbidden to "interfere," Colo. Rev. Stat. §§25-6-403(2), 25-6-404(1)—but SB 23-190 does the opposite. By making it illegal to help women who either willingly or unwillingly ingested mifepristone and choose to keep their babies, Colorado is actively thwarting women's decisions about "whether to bear or beget" a child and making it illegal for them to access safe FDA-approved medications to try to prevent an abortion they do not wish to have. In so doing, Colorado has violated the Fourteenth Amendment's Due Process Clause.

E. The government cannot carry its burden under strict scrutiny.

Because SB 23-190 infringes free exercise and free speech rights, and because it violates the Fourteenth Amendment, it must survive strict scrutiny—"the most demanding test known to constitutional law." *City of Boerne v. Flores*, 521 U.S. 507, 534 (1997). The government bears the burden, and therefore "face[s] the daunting task of establishing that the requirement was narrowly tailored to advance a compelling governmental interest." *Axson-Flynn v. Johnson*, 356 F.3d 1277, 1294 (10th Cir. 2004).

No compelling interest. There is no prospect that the government can demonstrate that their laws actually further a compelling government interest in preventing the publicizing or provision of abortion pill reversal, let alone an "exceedingly persuasive" one. *SFFA v. Harvard Coll.*, 143 S.Ct. 2141, 2168 (2023).

First, given that Colorado has never used any of its existing tools to punish anyone for using abortion pill reversal, Defendants have not shown an "actual problem in need of solving." *Brown v. Entertainment Merchs. Ass'n*, 564 U.S. 786, 799 (2011) (cleaned up). Indeed, the State's own witnesses testified at the preliminary injunction hearing that they had never even heard of any complaints related to abortion pill reversal. *Supra* at p.16. The legislative and rulemaking history are equally devoid of documented danger, revealing no evidence of a single Colorado woman harmed by taking progesterone at all, much less because she took progesterone to counteract mifepristone. Am.Compl. ¶175. And consistent with the State's testimony at the preliminary injunction hearing, the legislative and rulemaking record fails to include even one instance in which either the Medical Board or the Nursing Board has so much as admonished a single provider for providing progesterone for this purpose. *Id.* Where Colorado itself has not used any of its regulatory tools whatsoever—and has professed under oath it has never so much as heard of such a harm—it is difficult to imagine how Defendants could expect this Court to suddenly deem that interest *compelling* five months later. Nor can Defendants show their laws are "actually necessary" to serve that interest. *Brown*, 564 U.S. 786, 799.

Second, SB 23-190 is vastly underinclusive, in that it does not reach the majority of situations in which pregnant women take progesterone to ward off threatened miscarriage. Nor does it address countless other examples of off-label drug use (like mifepristone itself). A government fails to show a compelling interest "when [a law] leaves appreciable damage to that supposedly vital interest unprohibited." *Lukumi*, 508 U.S. at 547; *see also Yellowbear v. Lampert*, 741 F.3d 48, 60 (10th Cir. 2014) (Gorsuch, J.) ("A law's underinclusiveness … can raise with it the inference that the government's claimed interest isn't actually so compelling after all.").

Third, the response of Colorado's own purported experts in the field belies any claim that anything remotely approaching a compelling interest exists here. If the interest in saving women from abortion pill reversal were so strong, and the science so clear, then why did two of the three regulators tasked with implementing SB 23-190 decide it was not necessary to categorically declare the practice to be unprofessional conduct? The State cannot pretend to have a compelling interest in prohibiting a practice its own regulators called "safe and effective." Am.Compl. ¶207.

SB 23-190 was purportedly enacted to protect women from the "dangerous" and "deceptive" practice of abortion pill reversal. §1(1)(f). But if Colorado were truly concerned about patient safety, it would prohibit *all* off-label uses of the hormone, rather than singling out abortion pill reversal for disfavored treatment. And its regulators would agree on how to treat the practice. Instead, the legislature has left every other use of progesterone completely untouched, while the Nursing and Pharmacy Boards

purport to treat abortion pill reversal just like any other complaint of unprofessional conduct. It is hard to imagine a clearer example of a law that "leaves appreciable damage to [a] supposedly vital interest unprohibited" by failing to regulate conduct "that endangers [the government's] interest[] in a similar or greater degree." *Lukumi*, 508 U.S. at 543, 547.

Nor can Defendants hide behind the single failed randomized trial conducted by Dr. Creinin discussed in the legislative history. Dr. Creinin, who has served as a paid consultant to the distributor of mifepristone, has admitted his test was "inconclusive" and that progesterone treatment "might work." *See supra* at p.15. Although Creinin stopped his inconclusive study early because three women were sent to the emergency room with significant bleeding—which Creinin called "incredibly rare"—two of the three women had not received progesterone at all (they were in the placebo group), and the one who had received progesterone required "no intervention." If anything, Creinin's study shows harm from the one pill he gave women that is designed to cause bleeding—mifepristone (which of course Colorado does *not* seek to regulate here)—rather than the progesterone offered to counteract it.

Defendants have equally failed to carry their burden of proffering an interest compelling enough to justify Section 2's prohibition on "indicat[ing] that the person provides abortions or emergency contraceptives, or referrals for abortions or emergency contraceptives." §2(2); Colo. Rev. Stat. §6-1-734. Indeed, Natalie Hanlon Leh, who oversees the Consumer Protection Section, Dkt. 51 at 65, testified that Section 2 did

nothing at all. According to Leh, the "authority" to prosecute such violations "was already there" under pre-existing CCPA prohibitions, which have "long prohibited false representations about services." *Id.* at 67-68. Thus, Section 2 does not "add[] anything that was not already a part of the statute." *Id.* at 68. The State cannot explain how it could possibly have a legitimate compelling interest in enacting a provision fully duplicative of pre-existing law.

Not Narrowly Tailored. Nor can Defendants plausibly carry their burden of showing that SB 23-190 is narrowly tailored to any valid interest, much less a compelling one. First, the same underinclusivity that dooms the compelling interest argument also forecloses narrow tailoring, because a law that is "underinclusive in substantial respects" demonstrates an "absence of narrow tailoring" that "suffices to establish [its] invalidity." *Lukumi*, 508 U.S. at 546. Moreover, Defendants would need to demonstrate—with evidence—that their myriad other existing laws to protect patients, regulate medical practice, and prevent false advertising have somehow been ineffective. *See, e.g.*, *McCullen*, 573 U.S. at 494 (law failed even intermediate scrutiny where "the Commonwealth has not shown that it seriously undertook to address the problem with less intrusive tools readily available to it"). They have not even attempted to do so.

II. The remaining preliminary injunction factors favor relief.

As Plaintiffs have shown that SB 23-190 violates the First Amendment, the remaining preliminary injunction factors "present little difficulty." *Citizens United v. Gessler*, 773 F.3d 200, 218 (10th Cir. 2014).

Irreparable harm. By establishing a likelihood of success on the merits of their First and Fourteenth Amendment claims, Plaintiffs have also shown that they and their patients will suffer irreparable harm absent a preliminary injunction. *See, e.g., Planned Parenthood Ass'n of Utah v. Herbert*, 828 F.3d 1245, 1263 (10th Cir. 2016) (concluding that "the likelihood that [plaintiff] will suffer a violation of its First Amendment rights … , standing alone, gives rise to an irreparable injury"). That's because "the loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S.Ct. 63, 67 (2020) (cleaned up). The alternative to the loss of those freedoms is another irreparable harm: the loss of their licenses, the loss of their malpractice insurance, and severe financial penalties. Am.Compl. ¶21; *see Husky Venture v. B55 Invs.*, 911 F.3d 1000, 1012 (10th Cir. 2018) ("a threat to trade or business viability may constitute irreparable harm" (cleaned up)); *DTC Energy Grp. v. Hirschfeld*, 912 F.3d 1263, 1271 (10th Cir. 2018) (recognizing "loss of customers, loss of goodwill, and further erosion of … competitive position" as the relevant to irreparable harm). That doesn't even speak to the harms of Plaintiffs' patients: women who would

otherwise seek and receive this medical help will be forced to undergo or continue abortions that they would choose not to have—a harm than can never be remedied.

Balance of Equities and Public Interest. The balance of the equities and public interest also favor Plaintiffs. In a suit against the government, these factors "merge." *Nken v. Holder*, 556 U.S. 418, 435 (2009). Both are satisfied here. "When a law is likely unconstitutional, the interests of those the government represents, such as [consumers,] do not outweigh a plaintiff's interest in having its constitutional rights protected." *Hobby Lobby*, 723 F.3d at 1145 (cleaned up). Indeed, "it is always in the public interest to prevent the violation of a party's constitutional rights." *Id.* And Colorado simply "does not have an interest in enforcing a law that is likely constitutionally infirm." *Chamber of Com. of U.S. v. Edmondson*, 594 F.3d 742, 771 (10th Cir. 2010). Nor could Colorado have an interest in violating its own law declaring a fundamental right to continue a pregnancy—with which no public entity can interfere.

CONCLUSION

This Court should grant a preliminary injunction barring Defendants from enforcing SB 23-190.

Dated: September 22, 2023

Respectfully submitted,

/s/ Mark L. Rienzi

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CERTIFICATE OF CONFERENCE

Pursuant to Local Civil Rule 7.1(a), I hereby certify that, on September 22, 2023, counsel for Plaintiffs, Rebekah P. Ricketts, informed Defendants' counsel of Plaintiffs' intent to file this motion. Defendants' counsel indicated that all Defendants oppose the motion.

/s/ Mark L. Rienzi
Mark L. Rienzi

CERTIFICATE OF COMPLIANCE

Plaintiffs have submitted an unopposed motion requesting leave to file this brief in excess of the Court's word limitations. I hereby certify that this brief contains 9,976 words. As to all other matters, I hereby certify that the foregoing pleading complies with the type-volume limitation set forth in Judge Domenico's Practice Standard III(A)(1).

/s/ Mark L. Rienzi
Mark L. Rienzi

CERTIFICATE OF SERVICE

I hereby certify that on September 22, 2023, I electronically filed the foregoing Motion for a Preliminary Injunction with the Clerk of Court via CM/ECF, which will provide electronic copies to counsel of record.

/s/ Mark L. Rienzi
Mark L. Rienzi