

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO**

BELLA HEALTH AND WELLNESS,
DENISE “DEDE” CHISM,
ABBY SINNETT, and
KATHLEEN SANDER, on behalf of them-
selves and their patients,

Plaintiffs,

v.

PHIL WEISER, in his official capacity as
Attorney General of Colorado;
ROLAND FLORES,
AMANDA MIXON,
JENNIFER BLAIR,
BECKETT CZARNECKI,
ROBERT M. MAULITZ,
SAUGHAR SAMALI,
ALAN E. SHACKELFORD,
KIELY M. SCHULTZ,
CHRISTOPHER A. BATES,
AMY E. COLEN,
ANITA KUMAR,
DONALD LEFKOWITS,
MAIDUL MEHMUD,
KIAN MODANLOU,
SCOTT C. STRAUSS,
JULIE ANN HARPER,
PETER KENNEALEY, and
HIEN H. LY, in their official capacity as
members of the Colorado Medical Board;
BERNARD JOSEPH FRANTA,
LORI RAE HAMILTON,
KARRIE TOMLIN,
LENNY ROTHERMUND,
MACKENZIE ARMANI,
HAYLEY HITCHCOCK,
PHYLLIS GRAHAM-DICKERSON,
BRANDY VALDEZ MURPHY,
DIANE REINHARD,

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

**FIRST AMENDED
VERIFIED COMPLAINT**

**DEMAND FOR
JURY TRIAL**

NICHELE BRATTON, and
AECIAN PENDLETON, in their official capacity as members of the Colorado State Board of Nursing;
JOHN KELLNER, in his official capacity as District Attorney of the 18th Judicial District of Colorado;
MICHAEL DOUGHERTY, in his official capacity as District Attorney of the 20th Judicial District of Colorado; and
BETH McCANN, in her official capacity as District Attorney of the 2nd Judicial District of Colorado;

Defendants.

NATURE OF THE ACTION

1. A new Colorado law targets women who have changed their minds about abortion, forcing them to undergo abortions they seek to avoid.
2. Although Colorado claims to recognize the “fundamental right to continue a pregnancy,” this law, SB 23-190, actively thwarts women from making that choice, and makes it illegal for nurses and doctors to assist them or even *inform* them about their options. The law’s implementing regulations leave those prohibitions in place, making it professional misconduct for doctors and nurses to assist a woman in attempting to reverse the effects of the first abortion pill.
3. That misguided approach both violates the Constitution and makes Colorado a national and international outlier.

4. Across the country and around the world, pregnant women facing threatened miscarriages are commonly treated with progesterone—a naturally occurring and safe hormone that supports pregnancy. Progesterone helps thicken the uterine lining and suppresses uterine contractions, thereby helping a woman who makes the choice to stay pregnant carry out that choice.

5. Plaintiffs are experienced, licensed healthcare providers who regularly provide progesterone to help women facing threatened miscarriages. Collectively, they have used progesterone this way for thousands of women over several decades of practice.

6. Plaintiffs are religiously compelled to offer this treatment to women facing threatened miscarriage. They cannot in good conscience turn their backs on either their pregnant patient or the pregnancy she seeks their medical help to continue.

7. In 49 states, it remains perfectly legal for healthcare providers to provide such treatment to women who seek it. But SB 23-190 (including its new implementing regulations and through the CCPA) makes it illegal to give progesterone to one particular group: women who have changed their minds about having an abortion and instead choose to stay pregnant. If Plaintiffs persist in offering progesterone to help these patients carry out their choice, they will be “subject to discipline” by their respective licensing boards and will risk losing their licenses. And by publicizing their willingness to provide this treatment option, Plaintiffs are exposed to crushing financial penalties.

8. Some women initially begin the abortion process by taking a drug called mifepristone—which the FDA describes as “a drug that blocks a hormone called progesterone that is needed for a pregnancy to continue.” By blocking progesterone, mifepristone eventually causes an abortion by triggering a miscarriage.

9. But as the Supreme Court has long recognized, the decision to have an abortion is often a stressful one and fraught with consequences. Sometimes women change their minds about whether to follow through with an abortion. Sadly, some women are even tricked, pressured, or physically forced into taking mifepristone in the first place, including women who are victims of sex trafficking.

10. While Colorado allows Plaintiffs and other healthcare providers to use progesterone for all other women facing threatened miscarriage, SB 23-190 makes it illegal for them to offer the same treatment for women facing threatened miscarriage because they initially took mifepristone (whether willingly or not) but now want to remain pregnant. Colorado law would force these women to abort pregnancies they wish to continue.

11. After SB 23-190’s enactment, the Colorado Medical, Nursing, and Pharmacy Boards convened to consider the implementing regulations required by the statute. The statute provided that abortion pill reversal would remain unprofessional conduct unless all three Boards deem it a generally accepted standard of practice. None of the three Boards made that finding, leaving the statutory prohibition in place.

12. The Medical Board initially proposed a rule stating it would investigate any complaints about abortion pill reversal on a case-by-case basis. But the political reaction was swift and furious. More than a dozen state senators and representatives submitted a rulemaking comment “express[ing] our dismay and disappointment” in even that proposed rule. Two of the bill sponsors showed up to testify against the draft rule, demanding that the Boards “reconsider your draft rules” and “carefully reread the instructions” in the statute.

13. The Medical Board promptly caved to political pressure. During its final rulemaking hearing on August 17, the Medical Board abandoned its proposed rule. Instead, it announced that using progesterone to reverse the effects of mifepristone is *not* a generally accepted standard of practice. Meanwhile, it will treat complaints about any other form of abortion pill reversal on a case-by-case basis.

14. On September 20, the Nursing Board convened its own final rulemaking hearing. Unlike the Medical Board’s categorical approach forbidding progesterone, the Nursing Board’s rule states that it will treat complaints about *all forms* of abortion pill reversal on an individualized case-by-case basis.

15. On September 21, the Pharmacy Board convened its final rulemaking hearing. Like the Nursing Board, the Pharmacy Board rejected the Medical Board’s categorical approach, instead opting to treat complaints about all forms of abortion pill reversal on a case-by-case basis.

16. In adopting the final rule, several Pharmacy Board members expressly noted that progesterone is both safe and effective. 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.” Ex. Y at 11. As the Board Chair put it: “We know that progesterone is safe and effective no matter ... what it’s being used for.” Ex. Y at 17. The end result is a regulatory regime that leaves in place the statutory rule: In the state of Colorado, alone among the 50 states, abortion pill reversal is unprofessional conduct.

17. Since SB 23-190’s enactment, numerous women have contacted Plaintiffs, requesting their help in reversing the effects of mifepristone, and have received progesterone under Bella’s care.

18. 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 earlier this week. Three other women who received abortion pill reversal treatment under Bella’s care are scheduled to give birth this fall.

19. Just last week, yet another woman started abortion pill reversal treatment at Bella and is now under follow-up care.

20. SB 23-190 and its implementing regulations would deprive these women and others like them of the ability to exercise their fundamental right to continue their

pregnancies, leaving them at risk of being forced to undergo abortions they no longer desire.

21. SB 23-190 and its implementing regulations also force Plaintiffs to imminently choose between exercising their sincerely held religious beliefs by offering these women and their babies life-affirming health care—or facing the loss of their licenses, the loss of their malpractice insurance, and severe financial penalties.

22. No public health goal is served by denying Colorado women a treatment available in every other state even to women who have changed their minds and choose to continue their pregnancy after taking one abortion pill.

23. Colorado’s decision to single out for draconian penalties progesterone treatment to reverse an unwanted abortion violates Bella’s free exercise rights. Bella and its providers sincerely believe that they are religiously obligated to assist any woman facing a threat of miscarriage who requests their help, whether that risk arises biologically, due to physical trauma, or because she willingly or unwillingly took the first abortion pill. Colorado, in no uncertain terms, now tells them that if they choose to follow their religious beliefs, they risk losing their licenses and face crushing financial penalties. This is precisely the type of targeting and coercion prohibited by the Free Exercise Clause.

24. SB 23-190 also constitutes an egregious form of content and viewpoint discrimination. It leaves healthcare providers free to publicize any and all progesterone treatments save one—progesterone administered to reverse the effects of the first

abortion pill. And it applies only to advertisements falsely indicating the speaker provides or refers for abortion or emergency contraceptives, explicitly targeting “anti-abortion centers” for their role in the “anti-choice movement.” But the First Amendment roundly condemns any governmental attempt to play favorites in this fashion. And it likewise protects a patient’s right to receive information. Colorado cannot decide that certain topics are off limits for healthcare providers and their patients just because Colorado does not like the message that women can choose to change their minds. And Colorado cannot target and regulate speech on only one side of the abortion debate.

25. Finally, SB 23-190 will have tragic effects on any woman in Colorado who has taken mifepristone and wants help to maintain her pregnancy. The Fourteenth Amendment entitles those women to make medical decisions affecting their bodily integrity and to receive the equal protection of the laws—including laws regulating medical practices like progesterone treatment. But thanks to SB 23-190, women who have changed their minds after beginning the abortion-pill regimen—or those who were pressured or tricked into taking it in the first place—are now left out in the cold. While other women facing threatened pregnancy loss can still seek help, Colorado is now forcing abortion on women who desire to carry their pregnancies to term—and prohibiting any healthcare provider from helping them carry out that choice, or even telling them their options.

26. Without immediate relief, Plaintiffs are threatened with the loss of medical and nursing licenses for continuing to help women in need who choose to keep their pregnancies, as well as severe financial penalties merely for publicizing their willingness to help. Without immediate relief, Plaintiffs' patients will be forced to undergo abortions they would choose not to have.

JURISDICTION AND VENUE

27. This action arises under the Constitution and the laws of the United States. This Court has subject-matter jurisdiction under 28 U.S.C. §§1331 and 1343.

28. The Court has authority to issue the declaratory and injunctive relief sought under 28 U.S.C. §§2201 and 2202.

29. Venue lies in this district under 28 U.S.C. §1391(b)(1) and (2).

THE PARTIES

Plaintiffs

30. Plaintiff Bella Health and Wellness is an independent, faith-based Catholic medical center offering life-affirming, dignified health care to women, men, and children. Bella is a Colorado nonprofit corporation and a de facto association of the Christian faithful under Code of Canon Law of the Catholic Church c.299, §1. Bella maintains its primary medical campus in Englewood, Colorado, and an additional medical center in Denver, Colorado. Bella previously maintained an additional medical center in Lafayette, Colorado, which has since closed.

31. Plaintiff Denise “Dede” Chism, MSN, PNNP, is co-founder and chief executive officer of Bella. She earned her master’s degree in nursing with a specialty as a perinatal nurse practitioner from Regis University in Denver. She has worked as a nurse practitioner specializing in high-risk pregnancies for over twenty-seven years. She provides abortion pill reversal care at Bella.

32. Plaintiff Abby Sinnett, MS, WHNP, is co-founder and chief operating officer of Bella. She earned her master’s degree in science from the University of Colorado. She has eleven years’ experience as a women’s health nurse practitioner. She also has ten years’ experience as a women’s clinical preceptor, educating nurse practitioner students, certified nurse midwife students, and physician assistant students in the clinical setting. She worked as a labor and delivery nurse for seven years before becoming a nurse practitioner. She provides abortion pill reversal care at Bella.

33. Plaintiff Kathleen Sander, MD, OB-GYN, is a board-certified obstetrician and gynecologist at Bella, where she has worked for five years. She earned her medical degree from Florida State University. She completed the four-year OB-GYN Residency Training Program at Mercy Hospital St. Louis, as well as a year-long fellowship in medical and surgical NaPro Technology at the Pope Paul VI Institute. She provides abortion pill reversal care at Bella.

34. All four Plaintiffs assert claims on behalf of themselves and their current and prospective patients.

Defendants

35. Defendant Phil Weiser is the Colorado Attorney General. Weiser “shall prosecute” complaints referred to him by the Colorado Medical Board, Colo. Rev. Stat. §12-240-125(5)(d), and the Colorado State Board of Nursing, *id.* §12-255-119(4)(d). Weiser has authority to investigate and enforce the Colorado Consumer Protection Act. *See id.* §§6-1-103, 6-1-107. Weiser is sued in his official capacity only.

36. Defendants Roland Flores, Jr., Amanda Mixon, Jennifer Blair, Beckett Czarnecki, Robert M. Maulitz, Saughar Samali, Alan E. Shackelford, Kiely M. Schultz, Amy E. Colen, Peter Kennealey, Anita Kumar, Donald J. Lefkowitz, Maidul (May) Mehmud, Kian A. Modanlou, Scott C. Strauss, Christopher A. Bates, Julie Ann Harper, and Hien (Adam) H. Ly are members of the Colorado Medical Board.¹ As members of the Colorado Medical Board, they exercise investigative, adjudicative, and disciplinary authority over licensees, certificants, and registrants with respect to Colorado Revised Statutes, title 12, article 240. *See* Colo. Rev. Stat. §12-240-125. These Defendants are sued in their official capacity only.

37. Defendants Bernard Joseph Franta, Lori Rae Hamilton, Karrie Tomlin, Lenny Rothermund, Hayley Hitchcock, Mackenzie Armani, Phyllis Graham-Dickerson, Brandy Valdez Murphy, Diane Reinhard, Nichele Bratton, and Aecian Pendleton

¹ As described in Defendants’ Notice of Substitution of Parties, Defendants Anita Kumar and Donald J. Lefkowitz are no longer members of the Colorado Medical Board, but will be substituted by their successors when those successors are named. Dkt. 82, *see also* Fed. R. Civ. P. 25(d).

are members of the Colorado State Board of Nursing.² As members of the Colorado State Board of Nursing, they exercise investigative, adjudicative, and disciplinary authority over licensees, certificants, and registrants with respect to Colorado Revised Statutes, title 12, article 255. *See id.* §§12-255-119. These Defendants are sued in their official capacity only.

38. Defendant John Kellner is District Attorney of the 18th Judicial District of Colorado. The 18th Judicial District includes Arapahoe County, where Bella's primary medical campus is located. Kellner has authority to investigate and enforce the Colorado Consumer Protection Act. *See id.* §§6-1-103, 6-1-107. Kellner is sued in his official capacity only.

39. Defendant Michael Dougherty is District Attorney of the 20th Judicial District of Colorado. The 20th Judicial District includes Boulder County, where Bella operated at the Lafayette medical center from in or about 2017 to on or about July 27, 2023. Dougherty has authority to investigate and enforce the Colorado Consumer Protection Act. *See id.* §§6-1-103, 6-1-107. Dougherty is sued in his official capacity only.

40. Defendant Beth McCann is District Attorney of the 2nd Judicial District of Colorado. The 2nd Judicial District includes Denver County, where Bella's Denver

² As described in Defendants' Notice of Substitution of Parties, Defendant Hayley Hitchcock is no longer a member of the Colorado State Board of Nursing, but will be substituted by her successor when that successor is named. Dkt. 82, *see also* Fed. R. Civ. P. 25(d).

medical center is located. McCann has authority to investigate and enforce the Colorado Consumer Protection Act. *See id.* §§6-1-103, 6-1-107. McCann is sued in her official capacity only.

FACTUAL ALLEGATIONS

Bella Health and Wellness

41. Bella Health and Wellness is a nonprofit, faith-based medical clinic that offers life-affirming, dignified health care to men, women, and children from all backgrounds and faith traditions. Bella is one of Denver's leading multi-specialty medical practices, offering obstetrics-gynecology care as well as family medicine, pediatrics, and functional medicine.

42. The inspiration for Bella arose in 2012, when mother and daughter nurse practitioners, Dede Chism and Abby Sinnett, were on a medical mission in the Andes Mountains of Peru. On that mission trip, Dede and Abby became convinced that everyone has a story, every life should be protected, and every person deserves to know they are made good. They ultimately discerned the Holy Spirit's call to open a Catholic medical clinic for women in the Denver metropolitan area.

43. In December 2014, Dede and Abby opened Bella Natural Women's Care, the first comprehensive, life-affirming OB-GYN practice in Colorado. In 2016, Bella began also offering care to men and children. In 2020, Bella instituted full family medicine and primary care under a new mission name, Bella Health and Wellness.

44. Today, Bella has 20 providers and over 20,000 registered patients. A significant percentage of Bella's patients are financially vulnerable and receive Medicaid, Emergency Medicaid, or free care.

45. Bella currently practices out of two clinics, with the medical center in Englewood, Colorado as its primary campus. Bella also partners with Catholic Charities to provide medical services to women at Marisol Health Clinic in Denver, Colorado.

46. Bella previously partnered with Catholic Charities to provide medical services to women at the Marisol Health Clinic in Lafayette, Colorado. Bella ceased operations at the Lafayette center on or about July 27, 2023, shortly before the clinic closed.

47. Bella is organized as an association of the Christian faithful under Code of Canon Law of the Catholic Church c.299, §1, for religious, public, charitable, or educational purposes, to promote health and the social welfare of the Catholic community (not to the exclusion of others). As an association of the Christian faithful under canon law, Bella "strive[s] in a common endeavor to foster a more perfect life, to promote public worship or Christian doctrine, or to exercise other works of the apostolate such as initiatives of evangelization, works of piety or charity, and those which animate the temporal order with a Christian spirit." Code of Canon Law of the Catholic Church c.298, §1.

48. Bella is a nonprofit corporation organized in the state of Colorado under section 501(c)(3) of the Internal Revenue Code.

49. Bella is included in the federal group tax exemption of the Roman Catholic Church. It is listed in the Official Catholic Directory—which lists all agencies, instrumentalities, and the educational, charitable, and religious institutions operated by the Roman Catholic Church in the United States—under the Archdiocese of Denver.

50. Bella's Articles of Incorporation authorize it to promote, establish, conduct, and maintain activities:

- (a) To provide spiritual, emotional, educational, charitable, and financial support of human dignity in accordance with the social teachings of the Magisterium of the Catholic Church, the Ethical and Religious Directives of the United States Conference of Catholic Bishops;
- (b) To support the ministry of the local Archbishop in a way that is consistent with its mission and possibilities; to govern all efforts in accord with good stewardship, fidelity to Catholic teaching on matters of faith and morals; to conduct its work in conformity with Civil and Canon laws; and to cooperate with all relevant archdiocese policies and procedures;
- (c) To promote and protect life from natural conception to natural death;
- (d) To deliver, and support the delivery of, charitable health services consistent with the teachings of the Catholic Church;
- (e) To assist the poor in their basic health care needs;
- (f) To promote a Catholic culture, spiritual life and strong relationship with the Lord Jesus among members, volunteers, and workers of the Corporation through spiritual retreats, religious services, liturgical rites and celebrations, lectures, talks, discussion groups and other similar activities;
- (g) To develop religious formation programs concerning the teachings of the Catholic Church on human dignity, women's health, and the gift of sexuality; [and]
- (h) To promote the religious freedom of all citizens and the protection of moral conscious for patients and physicians concerning health care[.]

51. Bella operates with the blessing of Archbishop Samuel Aquila of the Archdiocese of Denver.

52. Bella exists to make people whole—body, mind, and soul—by practicing medicine that honors the innate dignity of every person. Bella and its providers believe that they are entrusted to continue the healing ministry of Jesus Christ. They approach all health care with compassion and reverence, guided by the words of St. Pope John Paul II: “A person’s rightful due is to be treated as an object of love, not as an object for use.”

53. Consistent with its religious mission, Bella and its providers and staff follow the Ethical and Religious Directives for Catholic Health Care Services issued by the United States Conference of Catholic Bishops (available at <https://perma.cc/KAS3-JXAK>). Under the Directives, “The Church’s moral teaching on health care nurtures a truly interpersonal professional-patient relationship. This professional-patient relationship is never separated, then, from the Catholic identity of the health care institution.” *Id.* at 13. The “free exchange of information” that results from the relationship between the professional health care provider and the patient “must avoid manipulation, intimidation, or condescension.” *Id.*

54. All providers employed by Bella sign a “Provider Ethical Agreement.” Ex. A. The Agreement explains that “[p]roviders and staff of Bella have agreed to follow the Ethical and Religious Directives for Catholic Health Care Services as issued by the United States Conference of Catholic Bishops.” By signing the Agreement, Bella’s

providers “agree to identify treatment plans that work in cooperation with the body and that do not alter healthy natural processes.”

55. Each patient of Bella signs a “Practice Agreement.” Ex. B. The Agreement states Bella’s commitment “to provide comprehensive, life-affirming health care with dignity and compassion” and “to offer[] you medical solutions that respect your dignity, preserve your integrity, and work in cooperation with your body.” The Agreement explains, “This means that we do not offer contraception, sterilizations, or abortions but rather promote and provide natural fertility awareness that is scientifically validated.”

56. Bella and its providers believe that pregnancy and childbirth are beautiful and natural processes. They are devoted to honoring the dignity of the women they serve and promoting respect for their unborn children.

57. Bella and its providers are committed to providing the best possible care to all pregnant women, including women who are experiencing threatened miscarriage, regardless of the cause of that threat.

58. Thus, Bella’s commitment to respecting the dignity of its patients extends to women who take the first drug in the abortion-pill regimen but then decide to continue their pregnancies.

59. Consistent with its commitment to honor the dignity of their patients and provide life-affirming health care, Bella offers progesterone therapy to pregnant women

experiencing threatened miscarriage—including women who have taken the first abortion pill and then choose to continue their pregnancies.

60. The use of progesterone to treat women who change their minds after taking the first abortion pill is commonly known as “abortion pill reversal.”

Progesterone

61. Progesterone is a naturally occurring hormone that is named for its promotion of gestation.³

62. Progesterone plays an essential role in regulating female reproductive function in the uterus, ovaries, mammary glands, and brain. It is particularly critical to the achievement and maintenance of a healthy pregnancy.⁴

63. During the first ten weeks of pregnancy, progesterone is naturally secreted by the corpus luteum (*i.e.*, the remnants of the ovarian follicle that enclosed a developing ovum) while the placenta develops. It is then secreted by the placenta during the remainder of pregnancy.⁵

³ See W. M. Allen et al., *Nomenclature of Corpus Luteum Hormone*, 136 *Nature* 303, 303 (1935), <https://perma.cc/DV4P-W5BL> (discussing identification of the “progestational hormone”).

⁴ See generally Lucie Kolatorova et al., *Progesterone: A Steroid with Wide Range of Effects in Physiology as Well as Human Medicine*, 23 *Int’l J. Molecular Scis.*, July 2022, <https://perma.cc/V3JE-CGXF>.

⁵ Jessie K. Cable & Michael H. Grider, *Physiology, Progesterone*, StatPearls Publishing (Michael H. Grider ed., 2022), <https://perma.cc/VB6D-JY72>.

64. Progesterone prepares the endometrium (the tissue lining the uterus) to allow implantation and stimulates glands in the endometrium to secrete nutrients for the embryo.⁶

65. Later in pregnancy, progesterone plays a role in the relaxation of smooth muscle cells, promoting uterine relaxation and suppressing uterine contractions prior to delivery.⁷

66. Progesterone has been used to support female fertility in a variety of ways for more than 50 years.⁸

67. Progesterone is commonly prescribed for a host of uses in obstetrics and gynecology, including pregnancy support in patients with a history of recurrent miscarriages, prevention of preterm birth, support of endometrial function during in vitro fertilization, treatment of absent menstrual periods (secondary amenorrhea), treatment of excessive blood loss during menstruation, treatment of premenstrual syndrome, and prevention of irregular thickening of the endometrium (endometrial hyperplasia) during menopause.⁹

⁶ See Arri Coomarasamy et al., *PROMISE: first-trimester progesterone therapy in women with a history of unexplained recurrent miscarriages – a randomised, double-blind, placebo-controlled, international multicentre trial and economic evaluation*, Health Tech. Assessment, May 2016, at 1, <https://perma.cc/4BZH-NUUN>.

⁷ See N.E. Simons et al., *The long-term effect of prenatal progesterone treatment on child development, behaviour and health: a systematic review*, 128 Brit. J. of Obstetrics & Gynaecology 964, May 2021, <https://bit.ly/3Ky7SGD>.

⁸ See Gian Carlo Di Renzo et al., *Progesterone: History, facts, and artifacts*, 69 Best Practice & Rsch. Clinical Obstetrics & Gynaecology 2 (2020), <https://bit.ly/3ZH1uAU>.

⁹ See Kolatorova et al., *supra* note 4.

68. Progesterone received FDA approval in 1998 for use in treating irregular thickening of the endometrium (endometrial hyperplasia) in post-menopausal women.¹⁰

69. The FDA historically classified the drugs pregnant women might take into five risk categories (A, B, C, D, or X) to indicate the potential of a drug to cause adverse effects during pregnancy.

70. Progesterone is classified as a “Category B” drug for pregnant women—in the same category as Tylenol, the most commonly used pain reliever during pregnancy.¹¹

71. Healthcare professionals may lawfully prescribe or use a prescription drug both for uses suggested on the FDA-approved labeling, *i.e.*, “on-label uses,” and for uses not prescribed, recommended, or suggested on the FDA-approved labeling, *i.e.*, “off-label uses.” Off-label use of prescription drugs is a widespread and accepted practice in health care.¹²

72. 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

¹⁰ FDA, Approval Letter (Dec. 16, 1998), <https://perma.cc/M7T7-VSDL>.

¹¹ FDA, Prometrium Label, at 19, <https://perma.cc/CR46-2FTS>; *Prometrium Prescribing Information*, Drugs.com, <https://perma.cc/RDN3-WNQ8>; *see also* Emily Oster, *Expecting Better* 169 (2016) (“Other than prenatal vitamins, probably the most common Category B drug is Tylenol,” which is “the most commonly used pain reliever during pregnancy.”).

¹² *See, e.g.*, Agata Bodie, Cong. Rsch. Serv., R45792, Off-Label Use of Prescription Drugs 10 (2021), <https://perma.cc/T35U-H8KD> (estimating that off-label prescriptions make up as much as 38% of doctor-office prescriptions in the United States (collecting sources)); *see also, e.g.*, *Wash. Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000) (“[I]t is undisputed that the prescription of drugs for unapproved uses is commonplace in modern medical practice and ubiquitous in certain specialties.”).

approved for marketing, a physician may prescribe it for uses or in treatment regimens of patient populations that are not included in approved labeling.”¹³

73. All uses of supplemental progesterone except for two—treatment of endometrial hyperplasia and secondary amenorrhea—are considered “off-label” uses.

74. Obstetricians frequently prescribe drugs for off-label uses during pregnancy.

75. Two recent studies evaluated the use of progesterone to treat unexplained recurrent miscarriage or early pregnancy bleeding.

76. The first study, known as the Progesterone in Recurrent Miscarriages (PROMISE) study, evaluated more than 800 women with unexplained recurrent miscarriages in 45 hospitals in the United Kingdom and the Netherlands. It found a 2.5% greater live birth rate among the women who received progesterone therapy, but concluded there was no “significant difference” in the rate of live births with the use of progesterone.¹⁴ There was also no increased risk of birth defects.

77. The second study, known as the Progesterone in Spontaneous Miscarriage (PRISM) study, followed over 4,000 women at 48 hospitals in the United Kingdom and found a 3% greater live birth rate among the women who received progesterone therapy. The study found no “significantly higher incidence of live births” among all

¹³ Citizen Petition Regarding the Food and Drug Administration’s Policy on Promotion of Unapproved Uses of Approved Drugs and Devices; Request for Comments, 59 Fed. Reg. 59,820, 59,821 (Nov. 18, 1994) (quoting 12 FDA Drug Bulletin, Apr. 1982, at 5, <https://perma.cc/A5UJ-C5YL>); *see also Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 350 (2001) (explaining that “‘off-label’ usage ... is an accepted and necessary corollary of the FDA’s mission to regulate ... without directly interfering with the practice of medicine”).

¹⁴ Coomarasamy et al., *supra* note 6.

women who received progesterone therapy. But it did identify a differential benefit among women with prior miscarriages, showing a 15% greater live birth rate among women with early pregnancy bleeding and three or more prior miscarriages. It also found no increased risk of birth defects.¹⁵

78. In November 2021, the UK's National Institute of Health and Care Excellence (NICE) published new guidelines, based on a review of recent studies (including the PRISM study), recommending progesterone therapy for women with early pregnancy bleeding and at least one previous miscarriage.¹⁶

79. NICE specifically 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.”¹⁷

The Abortion Pill

80. The abortion pill, also known as “medication abortion,” “medical abortion,” or “chemical abortion,” refers to the use of prescribed drugs to terminate pregnancy, as opposed to surgical abortion.

¹⁵ Arri Coomarasamy et al., *A Randomized Trial of Progesterone in Women with Bleeding in Early Pregnancy*, 380 New Eng. J. Med. 1815 (2019), <https://bit.ly/3m0dXCl>.

¹⁶ *Ectopic pregnancy and miscarriage: diagnosis and initial management*, National Institute for Health and Care Excellence (NICE) (updated Nov. 24, 2021), <https://perma.cc/Y9TE-KCY5> (Guideline NG126, Recommendation 1.5.2).

¹⁷ *Ectopic pregnancy and miscarriage: diagnosis and initial management*, National Institute for Health and Care Excellence (NICE), 16 (November 2021), <https://perma.cc/4W4X-Q95Y> (Guideline NG126 Update).

81. Despite the common term “the abortion pill,” the current abortion-pill regimen consists of two drugs: (1) mifepristone (marketed originally as “RU-486” and now as “Mifeprex”), and (2) misoprostol.

82. Mifepristone is a synthetic steroid developed in the 1980s by a research team led by Etienne-Emile Baulieu at the French pharmaceutical company Roussel-Uclaf.¹⁸

83. Mifepristone is a progesterone antagonist, meaning that it binds to—and blocks—the same intracellular receptors as progesterone.¹⁹

84. As the FDA explains, “Mifepristone is a drug that blocks a hormone called progesterone that is needed for a pregnancy to continue.”²⁰

85. As Baulieu put it, the progesterone receptors are like a keyhole, and mifepristone is the “false key” that fits the lock but cannot open it.²¹

86. By blocking the progesterone receptors, mifepristone causes the uterine lining to deteriorate, blocking oxygen and nutrition to the developing embryo and eventually

¹⁸ See generally *The Antiprogesterin Steroid RU 486 and Human Fertility Control* (Etienne-Emile Baulieu & Sheldon J. Segal eds., 1985), <https://bit.ly/3zyNvTs>.

¹⁹ See *id.* at 276 (“Our results confirm that RU 486 behaves as a progesterone antagonist at the receptor level.”).

²⁰ FDA, Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation, <https://perma.cc/5XDY-Q4T3>.

²¹ Cristine Russell, *Chemical Found by French Could Lead to Monthly Birth Control Pill*, Washington Post (Apr. 20, 1982), <https://perma.cc/6VA5-5ZXJ>.

resulting in detachment of the embryo from the endometrium. It also softens the cervix and renders the uterus vulnerable to contractions.²²

87. The second drug in the abortion-pill regimen, misoprostol, binds to smooth muscle cells in the uterine lining, thereby causing contractions that mechanically expel the embryo from a woman's uterus, thereby completing the abortion process.

88. 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.²³ A recent scoping review indicates that the continuing pregnancy rate after ingesting mifepristone alone is generally 25% or less for gestational ages of up to 49 days.²⁴

89. The FDA approved the two-drug abortion-pill regimen in 2000. Under the approved protocol, a woman takes mifepristone orally, followed up to 48 hours later by misoprostol.²⁵

Abortion Pill Reversal

90. Some women change their mind about terminating their pregnancies after taking mifepristone but before taking misoprostol.

²² Mary L. Davenport et al., *Embryo Survival After Mifepristone: A Systematic Review of the Literature*, 32 Issues L. & Med. 3 (2017), <https://bit.ly/3ZBFfMN>.

²³ Mitchell D. Creinin et al., *Medical abortion in early pregnancy*, in *Management of Unintended and Abnormal Pregnancy: Comprehensive Abortion Care* 112 (Blackwell Publishing Ltd. 2009), <https://perma.cc/3YPB-DL4C>.

²⁴ Paul L.C. DeBeasi, *Mifepristone Antagonization with Progesterone to Avert Medication Abortion: A Scoping Review*, *The Linacre Quarterly* (July 2023), <https://bit.ly/48knDuJ>.

²⁵ FDA, Summary Review for Regulatory Action (Mar. 29, 2016), <https://perma.cc/F468-UFEJ>.

91. Other women do not want to take mifepristone in the first place, but rather take it under duress or because they were tricked or forced.²⁶

92. When a woman has taken mifepristone (willingly or not) and then wants to keep her pregnancy, it no longer makes sense for her to take misoprostol. So, halting the abortion pill process starts with the patient not taking misoprostol. Healthcare providers may then prescribe progesterone in an attempt to overcome the progesterone-blocking effects of the mifepristone and maintain the pregnancy. Administering progesterone in these circumstances is known as “abortion pill reversal.”

93. The basic biochemical premise of abortion pill reversal is that the function of a receptor antagonist (*i.e.*, mifepristone) can be inhibited by increasing the concentration of the receptor agonist (*i.e.*, progesterone).²⁷ Abortion pill reversal therefore

²⁶ See, *e.g.*, Fernella Wedderburn, *Man Admits to Giving Unsuspecting Ex-Girlfriend Abortion Pill*, Barbados Today (Sept. 14, 2023), <https://perma.cc/DM5D-SBGB>; *Schaghticoke man accused of drugging pregnant woman, causing miscarriage*, WRGB (July 5, 2023), <https://perma.cc/BH9C-NZ4P>; Lauren Aratani, *Texas man faces charges for allegedly slipping abortion drug in wife's drink*, Guardian (Nov. 14, 2022), <https://perma.cc/8NJD-3SSF>; *Civil servant guilty of spiking drink with abortion drug*, BBC News (May 3, 2022), <https://perma.cc/U43C-C2VU>; Andy Wells, *NHS nurse struck off for supplying abortion pills to man who 'force-fed' them to pregnant partner*, Yahoo (Sept. 23, 2021), <https://perma.cc/G88T-AXHX>; *Fukuoka man tricked pregnant teen girlfriend into taking abortion medication*, Tokyo Reporter (Mar. 1 2021), <https://perma.cc/7BJQ-LTRJ>; Kevin Murphy, *Abortion-drug dealer pleads guilty, linked to Grand Rapids man accused of poisoning pregnant woman's drink*, Wis. Rapids Trib. (Mar. 5, 2020), <https://perma.cc/4JSV-AJ64>; Kristine Phillips, *A doctor laced his ex-girlfriend's tea with abortion pills and got three years in prison*, Wash. Post (May 19, 2018), <https://perma.cc/W7QM-Q9VZ>; Loulla-Mae Eleftheriou-Smith, *Man forced ex-girlfriend to miscarry after secretly feeding her abortion pills in a smoothie*, Independent (Mar. 13, 2015), <https://perma.cc/KJF4-E9VX>; Lateef Mungin, *Man pleads guilty to tricking pregnant girlfriend into taking abortion pill*, CNN (Sept. 10, 2013), <https://perma.cc/RT4R-6LLL>.

²⁷ See generally Barbara J. Pleuvry, *Receptors, agonists and antagonists*, 5 Neurosurgical Anaesthesia and Intensive Care, Pharmacology 350 (2004), <https://bit.ly/439IXR4>.

involves administering an influx of progesterone—the same hormone inhibited by mifepristone—to curb and outlast, or outcompete, the effects of the mifepristone.

94. Like most other uses of supplemental progesterone, the use of progesterone in abortion pill reversal is an off-label use.

95. The scientific literature demonstrates the ability of progesterone to counteract mifepristone.

96. In 1989, researchers designed a study to investigate “the role of progesterone in the maintenance of pregnancy” by using groups of pregnant rats.²⁸ After four days, only 33.3% of the rats who received mifepristone remained pregnant, but 100% of the rats who were given progesterone in addition to mifepristone remained pregnant.

97. 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.

98. A total of 547 women met inclusion criteria and underwent progesterone therapy within 72 hours after taking mifepristone.²⁹ The overall success rate—247 live

²⁸ Shingo Yamabe et al., *The Effect of RU486 and Progesterone on Luteal Function During Pregnancy*, 65 *Folia Endocrinologica Japonica* 497 (1989), <https://perma.cc/FY3C-ADAD>.

²⁹ George Delgado et al., *A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone*, 33 *Issues L. & Med.* 21, 24-25 (2018), <https://bit.ly/3ENB8VZ>. The 2018 study followed a 2012 case report, also published by Drs. Delgado and Davenport, that followed seven women who had taken mifepristone and then received progesterone therapy after “[seeking] assistance to block the mifepristone effects.” George Delgado et al., *Progesterone use to reverse the effects of mifepristone*, 46 *Annals Pharmacotherapy* 1723, 1723 (2012), <https://perma.cc/3Z7Q-JBRT>. Four of the six women who completed the study were able to carry their pregnancies to term.

births, plus four viable pregnancies lost to follow-up after 20 weeks gestation—was 48%.³⁰

99. The 2018 study showed even higher success rates when the patients were divided into treatment subgroups. It 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.³¹

100. The survival rates in the 2018 study compare favorably with the baseline fetal survival rate of approximately 25% if no treatment is attempted after mifepristone is administered.³²

101. Notably, the 2018 study found no increased risk of birth defects after progesterone therapy. And the rate of preterm delivery was 2.7%, compared with a 10% average in the general population in the United States.³³

102. In the case of a woman choosing to stop the abortion-pill process after taking mifepristone, the 2018 study recommended a protocol to reverse the effects of mifepristone by administering progesterone, either orally or by intramuscular injection.

³⁰ Delgado et al., *A Case Series*, *supra* note 29, at 25-26.

³¹ *Id.* at 26.

³² Paul L.C. DeBeasi, *Mifepristone Antagonization with Progesterone to Avert Medication Abortion: A Scoping Review*, *The Linacre Quarterly* (July 2023), <https://bit.ly/48knDuJ>; *see also* Delgado et al., *A Case Series*, *supra* note 29, at 26; Davenport et al., *supra* note 22.

³³ Delgado et al., *A Case Series*, *supra* note 29, at 26.

tion, “as soon as possible” after taking mifepristone, followed by supplemental progesterone until the end of the first trimester (if taken orally) or for a series of additional intramuscular injections.

103. Since the outset of this litigation, two additional studies have been published that further strengthen the evidence that abortion pill reversal is safe and effective.

104. One of those studies is a rat study, published in July 2023, indicating “a clear progesterone-mediated reversal of an initiated mifepristone-induced termination in a rat model at first-trimester human equivalent.”³⁴ The other is a scoping review, also published in July 2023, that shows “no increased maternal or fetal risk from using bioidentical progesterone in early pregnancy,” and concludes that “mifepristone antagonization with progesterone is a safe and effective treatment.”³⁵

Bella’s Experience with Progesterone Therapy and Abortion Pill Reversal

105. Because progesterone is used to treat so many conditions affecting the female reproductive system, it is one of the most common prescriptions written by Bella providers in its OB-GYN practice.

106. 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

³⁴ Christina Camilleri & Stephen Sammut, *Progesterone-mediated reversal of mifepristone-induced pregnancy termination in a rat model: an exploratory investigation*, 13 Scientific Reports 10942 (2023), <https://perma.cc/4SAL-DDP3>.

³⁵ Paul L.C. DeBeasi, *Mifepristone Antagonization with Progesterone to Avert Medication Abortion: A Scoping Review*, The Linacre Quarterly (July 2023), <https://bit.ly/48knDuJ>.

first trimester, prior pregnancy with preterm labor or delivery, infertility, history of low luteal progesterone, and medications that block progesterone activity (*i.e.*, mifepristone).

107. 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. Bella's practice is to prescribe bioidentical progesterone, so named because its chemical structure is identical to natural progesterone.

108. Bella and its providers have an ethical and 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.

109. 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. Consistent with their core religious beliefs in human dignity, Bella and its providers are religiously obligated to offer abortion pill reversal so long as they have the means and ability to do so.

110. When a woman contacts Bella seeking abortion pill reversal, Bella's practice is to prioritize her timely care. Bella's website explains that she should "please call our office right away," and then provides a backup phone number to call "overnight or on the weekend." Ex. C at 2.

111. After receiving a phone call from a woman seeking abortion pill reversal, a Bella provider will meet the woman at the clinic as soon as possible, including at night or on weekends or holidays.

112. 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.

113. If the woman chooses to maintain her pregnancy and wants to proceed with abortion pill reversal, then Bella offers progesterone therapy, just as in any other circumstance involving risk of miscarriage where progesterone therapy is indicated.

114. Bella has treated dozens of abortion pill reversal patients who successfully maintained their pregnancies.

115. Since SB 23-190's enactment, numerous women have contacted Plaintiffs, requesting their help in reversing the effects of mifepristone, and have received progesterone under Bella's care.

116. One of these women—who started abortion pill reversal the same week SB 23-190 was passed, under the protection of this Court's temporary restraining order—gave birth to a healthy baby on September 18. Three more are scheduled to give birth before the end of the year.

117. Just last week, yet another woman started abortion pill reversal treatment at Bella and is now under follow-up care.

118. Bella and its providers are intimately involved with their patients' health care and thus share an inherently close relationship with their patients.

119. Bella's patients have a strong interest in keeping their personal reproductive health care decisions private.

120. In addition, Bella's prospective abortion pill reversal patients face a hindrance or obstacle in asserting their own rights. Among other things, they do not know sufficiently far in advance that they will seek that service and therefore cannot identify themselves and sue ex ante. Once those patients can identify themselves, they are in a race against time to access this care before the unwanted abortion takes place.

Bella's Speech About Its Services

121. Bella publicizes its services in a variety of media.

122. The homepage of Bella's website states, "At Bella Health + Wellness, we take a mission approach to medicine and serve all people, no matter their life circumstances, with high-quality care that honors their dignity. We believe that patients should be heard, providers should demonstrate medical conscience, and all people can be made whole." The homepage goes on to state that "[w]e are proud to be one of Denver's leading multi-specialty clinic[s] offering full OB-GYN care with a specialization in NaPRO Technologies, Family Primary Care including Pediatrics, and Functional Medicine." Ex. D at 2.

123. Bella's website describes it as a "comprehensive, life-affirming OB-GYN practice." Ex. E at 2. It separately describes Bella as offering a "full continuum of care

and comprehensive health care at every stage of life.” Ex. F at 4; *see also id.* (“We are a life-affirming, full-service Family Medicine and OB-GYN medical center.”).

124. Bella’s website and social media generally do not include express disclaimers that it does not provide services related to abortion or contraception. Bella generally refrains from providing these disclaimers because it wishes to create an open, welcoming environment to all women seeking care. Bella and its providers believe that such disclaimers send a judgmental and condemning message to any women who have previously had an abortion or used contraception.

125. Bella’s website affirms its commitment to “save mothers and babies through sound medical counseling and Abortion Pill Reversal.” Ex. C at 3.

126. Bella’s website contains the following FAQ: “I took the abortion pill, but I’ve changed my mind. Is there anything you can do to help?” 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.” Ex. C at 1.

127. The FAQ also makes clear that Bella will “cover all costs associated with an Abortion Pill Reversal, should finances be an issue.” *Id.* at 3.

128. Bella has publicly described its experience with abortion pill reversal in the *Denver Catholic*. See *WATCH: One woman's abortion pill reversal story from Bella Health and Wellness*, Denver Catholic (Mar. 10, 2023), <https://bit.ly/3U67kec>.

129. Bella has also described and promoted the availability of abortion pill reversal on its social media accounts, including on Facebook and Instagram. Ex. G at 1-8.

130. Posters and other brochures describing Bella's services, including abortion pill reversal, have also been placed in a variety of churches in the area served by Bella. Ex. G at 11-12.

131. Each Bella patient also receives a welcome packet containing a card that lists Bella's services, including abortion pill reversal. Ex. G at 9-10.

Reproductive Health Equity Act

132. On April 4, 2022, Governor Jared Polis signed into law the Reproductive Health Equity Act (RHEA). See H.B. 22-1279, 73rd Gen. Assemb., Reg. Sess. (Co. 2022), <https://perma.cc/9U3B-8UXR>.

133. RHEA declares that “[a] pregnant individual has a fundamental right to continue a pregnancy and give birth or to have an abortion and to make decisions about how to exercise that right.” Colo. Rev. Stat. §25-6-403(2).

134. To secure that right, RHEA makes it unlawful for a “public entity” to “[d]eny, restrict, interfere with, or discriminate against an individual’s fundamental right ... to continue a pregnancy and give birth or to have an abortion in the regulation or provision of benefits, facilities, services, or information,” or to “[d]eprive,

through prosecution, punishment, or other means, an individual of the individual's right to act or refrain from acting during the individual's own pregnancy based on the potential, actual, or perceived impact on the pregnancy, the pregnancy's outcomes, or on the pregnant individual's health." *Id.* §25-6-404.

135. RHEA defines "[p]ublic entity" as

the state, the judicial department of the state, any county, city and county, municipality, school district, special improvement district, and every other kind of district, agency, instrumentality, or political subdivision thereof organized pursuant to law and any separate entity created by intergovernmental contract or cooperation only between or among the state, county, city and county, municipality, school district, special improvement district, and every other kind of district, agency, instrumentality, or political subdivision thereof.

Id. §24-10-103(5); *see id.* §25-6-402(3).

136. RHEA's substantive provisions are based on a series of legislative declarations, including that "Colorado voters have demonstrated that they trust individuals to make their own ethical decisions about abortion care based on what is best for their health and their families," HB 22-1279 §1(1)(f), and that "[p]olitically motivated, medically inappropriate restrictions on health care have no place in our statutes or our medical offices," *id.* §1(1)(g).

Colorado Medical and Nursing Licensing Regimes

137. The Colorado Medical Board was created by the Colorado Medical Practice Act and comprises 17 members appointed by the Governor. Colo. Rev. Stat. §12-240-105. The State Board of Nursing was created by the Nurse and Nurse Aid Practice Act and comprises 11 members appointed by the Governor. *Id.* §§12-255-101, 105.

Each Board is funded by legislative appropriations and cash funds derived from regulated entities and federal funding. *See* Colo. Rev. Stat. §12-20-103.

138. As “regulator[s]” of their respective professions, the Colorado Medical Board and State Board of Nursing “may investigate, hold hearings, and gather evidence in all matters related to the exercise and performance of [its] powers and duties” over their respective “particular profession or occupation.” Colo. Rev. Stat. §12-20-403(1).

139. Each Board may discipline licensees who engage in “conduct that constitutes grounds for discipline or unprofessional conduct.” *Id.* §12-20-404(1). Such disciplinary actions can include, save certain statutory exemptions, issuing a letter of admonition; placing a licensee, certificant, or registrant on probation; imposing an administrative fine; or denying, refusing to renew, revoking, or suspending the license, certification, or registration of an applicant, licensee, certificant, or registrant. *Id.*

140. The Colorado Medical Board has authority to investigate, conduct hearings, and impose disciplinary action for statutory violations, including, *inter alia*, a suspension or revocation of license to practice medicine and a fine of up to \$5,000 per violation. *Id.* §12-240-125(5)(c)(III). If a Medical Board investigation “discloses facts that warrant further proceedings by formal complaint,” the complaint “shall be referred” to the attorney general, who then “shall prosecute those charges.” *Id.* §12-240-125(4)(c)(V), (5)(d).

141. The Colorado State Board of Nursing has authority to investigate, conduct hearings, and impose disciplinary action for statutory violations, including, *inter alia*,

suspension, revocation, or nonrenewal of a license to practice nursing and a fine between \$250 and \$1,000 per violation. *Id.* §12-255-119(4)(c)(III). If a Board of Nursing investigation discloses “facts ... that warrant further proceedings by formal complaint,” the Board “should ... refer[]” the matter to the attorney general, who then “shall prosecute” the complaint. *Id.* §12-255-119(3)(c)(V).

142. Complaints regarding a licensee’s conduct “may be made” either to the Colorado Medical Board or the State Board of Nursing “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).

143. The Colorado Medical Board rules provide that “the relationship between a provider and a patient is fundamental and is not to be constrained or adversely affected by any considerations other than what is best for the patient.” Colorado Medical Board Policy 40-03, Policy Statement Regarding the Provider/Patient Relationship (rev. Aug. 20, 2015).

144. Where “[p]revailing models of medical practice” result in “an inappropriate restriction of the provider’s ability to practice quality medicine” and “creat[e] negative consequences for the patient,” “[i]t is the expectation of the Board that providers take those actions they consider necessary to assure that the procedures in question do not adversely affect the care that they render to their patients.” *Id.*

Colorado Consumer Protection Act

145. 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] services,” *Colo. Rev. Stat.* §6-1-105(1), (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).

146. A deceptive trade practice under the CCPA “requires a *false statement of fact* that either induces the recipient to act or has the capacity to deceive the recipient.” *Renfro v. Champion Petfoods USA, Inc.*, 25 F.4th 1293, 1301-02 (10th Cir. 2022) (quoting *Rhino Linings USA, Inc. v. Rocky Mt. Rhino Lining, Inc.*, 62 P.3d 142, 144 (Colo. 2003)).

147. The CCPA defines “[a]dvertisement” as “the attempt by publication, dissemination, solicitation, or circulation, visual, oral, or written, to induce directly or indirectly any person to enter into any obligation or to acquire any title or interest in any property.” *Colo. Rev. Stat.* §6-1-102(1).

148. The attorney general and the district attorneys of the judicial districts of Colorado are “concurrently responsible” for CCPA enforcement. *Id.* §6-1-103.

149. The attorney general and the district attorneys may bring a civil action under the CCPA seeking imposition of a civil penalty of up to \$20,000 per violation. *Id.* §6-1-112(1)(a). “[A] violation of any provision shall constitute a separate violation with respect to each consumer or transaction involved.” *Id.*

150. Private parties who are “actual or potential consumer[s]” and are injured by a deceptive practice can also sue under the CCPA. *Id.* §6-1-113(1)(a). Private claimants can seek damages for the greater of \$500, the “amount of actual damages sustained,” or three times that amount “if it is established by clear and convincing evidence that such person engaged in bad faith conduct,” in addition to the claimant’s attorneys’ fees and costs. *Id.* §6-1-113(2).

Colorado Senate Bill 23-190

151. On April 14, 2023, Governor Jared Polis signed into law Senate Bill 23-190, a bill for an act “[c]oncerning policies to make punishable deceptive actions regarding pregnancy-related services.” SB 23-190 was one of three bills in the so-called “Safe Access to Protected Health Care” legislative package. The full text of SB 23-190 is attached as Ex. H.

152. SB 23-190 took effect immediately upon signature.

153. Section 1 of SB 23-190 declares, among other things, 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 “[a]nti-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.” §1(1)(f).

154. Section 1’s final subsection then makes clear that SB 23-190, both on its own and through the CCPA, targets those who wish to publicize or provide abortion

pill reversal. It “declare[s]” that Section 6-1-105(1)(e) and (1)(rrr)—two of the CCPA’s prohibitions on deceptive trade practices—“appl[y] to disseminating or causing to be disseminated false advertising relating to the provision of abortion or emergency contraceptive services, or referrals for those services, and *advertising for or providing or offering to provide or make available medication abortion reversal*.” §1(3) (emphasis added); *see* Colo. Rev. Stat. §§6-1-105(1)(e); 6-1-105(1)(rrr).

155. Section 2 of SB 23-190 specially targets speech by those who do not provide or refer for abortion or emergency contraceptives. Specifically, it adds a new provision to the CCPA 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); *see* Colo. Rev. Stat. §6-1-734.

156. Section 3 of SB 23-190 bans abortion pill reversal treatment, making it “unprofessional conduct” for a licensee to “provide[], prescribe[], administer[], or attempt[] medication abortion reversal in this state.” §3(2); *see* Colo. Rev. Stat. §12-30-120.

157. Section 3 defines “[m]edication abortion” as “an abortion conducted solely through the use of one or more prescription drugs.” §3(1)(b). It separately defines

“[m]edication abortion reversal” as “administering, dispensing, distributing, or delivering a drug with the intent to interfere with, reverse, or halt a medication abortion.” §3(1)(c).

158. The statute provided a single mechanism to undo its prohibition on abortion pill reversal. Under Section 3, abortion pill reversal is “unprofessional conduct”—unless the Colorado Medical Board, the State Board of Nursing, and the State 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. §3(2)(a)-(b).

Legislative Record³⁶

159. The debate surrounding SB 23-190 shows that it targets religious organizations in Colorado that offer alternatives to abortion, including abortion pill reversal.

160. Senator Janice Marchman, one of the bill’s sponsors, stated that SB 23-190 will “crack down on anti-abortion centers,” Ex. I at 5, 7 (Press Conference, Mar. 9, 2023), which she described as “fake clinics,” *id.* at 2, 4, 6, 8; Ex. J at 2. She explained that the bill’s reference to “anti-abortion centers” referred to “faith-based organizations” that offer alternatives to abortion in Colorado. Ex. J at 1 (Senate Judiciary Hearing, Mar. 15, 2023).

³⁶ Citations to legislative sessions in this section are to unofficial transcripts that have been transcribed by a third party. Recordings of the sessions can be found at <https://leg.colorado.gov/watch-listen>.

161. Marchman lamented that “Colorado has more than 50 religious-based” organizations “that encourage women to keep their babies or link them with adoption agencies,” Ex. J at 3, and she accused these “ideologically-driven” religious organizations of “trad[ing] on the goodwill of legitimate medicine to defraud patients” by “us[ing] disinformation, intimidation, shame, and delay tactics to withhold essential and time-sensitive reproductive healthcare” and by “lur[ing] people in and steer[ing] them away from abortion,” Ex. I at 6; Ex. J at 2-3.

162. Marchman also stated that these “fake clinics” were “the only ones that can prescribe abortion pill reversal.” Ex. K at 3,4 (Senate Second and Third Reading, Mar. 20, 2023). And she argued that these “fake clinics” must be stopped from offering this “life-threatening” procedure. Ex. I at 6.

163. Senator Faith Winter, the bill’s other Senate sponsor, accused faith-based organizations of “taking advantage of vulnerable populations” by “purposely target[ing] young people, low-income communities, rural communities, and communities of color.” Ex. J at 5.

164. Representative Elisabeth Epps, one of the bill’s House sponsors, levied similar charges, accusing “fake clinics” of us[ing] “free pregnancy tests,” ultrasounds, and prenatal care as “disinformation, intimidation and delay tactics” and faulting “fake clinics” for “advertis[ing] in languages other than English specifically to target immigrant communities.” Ex. I at 8-9.

165. Epps stated that such organizations employ “rhetoric” telling women that “you are less or incomplete or broken because of the status of your uterus.” Ex. M at 15 (House Third Reading, Mar. 30, 2023). And she called abortion pill reversal “dangerous,” claiming that it causes “harm” to pregnant women, Ex. I at 10, and that taking progesterone to reverse an abortion is as effective as taking “a Tylenol or a Viagra or a juju bean” to achieve the same effect. Ex. M at 16.

166. According to Epps, when it comes to abortion pill reversal and other services provided by religious organizations, “there’s not room for nuance.” Ex. M at 6.

167. Representative Karen McCormick, the bill’s other House sponsor, accused these religious organizations of engaging in a “bait and switch,” Ex. M at 2, by “fool[ing] or deceiv[ing] or ... outright [lying] to” their patients. *Id.* at 3. According to McCormick, “religiously affiliated” organizations offer information that is “riddled with ... guilt-inducing anti-abortion ... messages.” *Id.* at 13.

168. Representative Stephanie Vigil lamented how “explicitly religious” organizations are “deeply integrated” in the “a massive, well-funded, and very intentional movement” known as the “anti-choice movement.” Ex. M at 12.

169. These and other accusations caused Sen. James Smallwood, Jr. to describe the bill as “as close to pure vitriolic dribble that I’ve ever seen” in seven years as a legislator, and to comment that “the sheer lack of even thinly veiled neutrality is just appalling.” Ex. K at 5.

170. Bill sponsors explained that SB 23-190 would “prohibit” advertising for abortion pill reversal and “define it as a deceptive trade practice.” Ex. J at 2 (Marchman); *see also* Ex. J at 4-5 (Winter). Representative Epps similarly explained that SB 23-190 “prohibits the use of deceptive advertising by these centers and that limits what they market, what they want us to believe is an abortion reversal pill.” Ex. I at 10.

171. Bill sponsors also identified the terms “comprehensive” and “full range” of services (or similar terms) as deceptive advertising when used by pro-life providers.

172. For example, Senator Marchman described “anti-abortion center[s]” as “faith-based organizations that *pose as a comprehensive reproductive healthcare clinic.*” Ex. J at 2 (emphasis added).

173. 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.*” Ex. J at 5 (emphasis added); *see also* Ex. M at 1 (McCormick) (“Comprehensive reproductive care includes the following: access to contraception, emergency [c]ontraception ... [and] abortion or referral for abortion[.]”); Ex. L at 1 (McCormick) (similar).

174. Representative McCormick insisted that “[c]omprehensive reproductive care includes [] access to contraception, emergency contraception, . . . *abortion [and] referral for abortion.*” Ex. M at 2 (emphasis added); *see also* Ex. L at 2 (similar). She

claimed that anti-abortion centers falsely “give consumers the impression that they offer *full reproductive care*.” Ex. L at 2 (emphasis added).

175. Legislators opposed to SB 23-190 repeatedly noted that its proponents offered no testimony that any woman in Colorado had been harmed by progesterone treatment of any kind—including abortion pill reversal—nor that any medical licensing board has ever taken action against a healthcare professional for offering abortion pill reversal. *See* Ex. N at 3 (House Third Reading, Apr. 1, 2023) (statement of Rep. Gabe Evans); *id.* at 5 (statement of Rep. Stephanie Luck); *id.* at 8 (statement of Rep. Bob Marshall).

176. To support their statements about abortion pill reversal, the bill’s proponents offered testimony from Dr. Mitchell Creinin, an OB-GYN who has served as a paid consultant of Danco Laboratories, the distributor of mifepristone in the United States. Ex. J at 7-16.³⁷

177. Creinin described abortion pill reversal as “medical fraud.” Ex. J at 6. He based this conclusion on a failed randomized trial he conducted in 2019 to test the “efficacy and safety” of abortion pill reversal.³⁸

³⁷ *See, e.g.,* Kelly Cleland & Mitchell D. Creinin et al., *Significant Adverse Events and Outcomes After Medical Abortion*, 121 *Obstetrics & Gynecology* 166, 171 (2013), <https://perma.cc/DNJ2-L7VJ> (disclosing that Creinin receives compensation from the company that sells Mifeprex as its sole product).

³⁸ Mitchell D. Creinin et al., *Mifepristone Antagonization With Progesterone to Prevent Medical Abortion: A Randomized Controlled Trial*, 135 *Obstetrics & Gynecology* 158 (2020), <https://perma.cc/8LPN-NSKK>.

178. Creinin's study was intended to enroll 40 pregnant women to be divided into two control groups: one group receiving mifepristone followed by progesterone, and the other group receiving mifepristone followed by a placebo. But only 12 women were enrolled in the study, and only 10 women ultimately completed it.

179. 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." Ex. J at 11. He then immediately had to clarify that of those three women, "two of the people had received placebo and one had received progesterone." *Id.* He ultimately testified that "my study was inconclusive as far as showing whether or not the [progesterone] treatment might work." Ex. J at 13.

180. What Creinin's testimony failed to disclose, however, was that "[n]o intervention was needed" for the one woman who had received progesterone and went to the emergency department. Ex. L at 6.

181. By contrast, the two women receiving placebo in Creinin's study "required emergency suction aspiration abortions. They needed secondary surgical abortions because they had retained products and because they were bleeding significantly, severely bleeding. One of them required a blood transfusion because her hemoglobin dropped significantly." Ex. L at 6.

182. These clarifications about the outcomes of the three affected women in Creinin's study came to light through the testimony of Dr. George Delgado. Delgado

also testified about the results of his 2018 study that documented fetal survival rates up to 64-68% for women who received progesterone within 72 hours of taking mifepristone. *See* Ex. L at 4-9; *see supra* ¶¶97-102.

183. Creinin admitted that, even under his view, “it’s always possible” that abortion pill reversal could become effective, Ex. J at 14, and that “the FDA does not require randomized control trials for drug approval.” Ex. L at 12.

184. Creinin also admitted that no jurisdiction in the United States has ever made a finding that a medical healthcare provider engaged in professional misconduct for administering abortion pill reversal. Ex. J at 14-15.

185. Creinin opined that progesterone should not be used to treat miscarriage, since in his view progesterone “does nothing to increase the likelihood of them having another continuing pregnancy.” Ex. J at 11-12; Ex. L at 10.

Procedural History

186. 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.

187. On April 24, this Court held a hearing on Plaintiffs’ preliminary injunction motion. Dkt. 46. 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 at 4.

SB 23-190 Rulemaking

188. On June 5, 2023, the Colorado Medical Board, Board of Nursing, and Board of Pharmacy held a joint stakeholder meeting to gather “stakeholder feedback regarding the implementation of [Colorado Senate Bill 23-190.” Ex. O at 2; June 5, 2023 Joint Stakeholder Meeting, <https://bit.ly/46omD6K>.

189. Prior to the June 5 meeting, Plaintiffs submitted a public comment explaining “why there is good scientific reason to believe that abortion pill reversal is safe and effective and why the claims about abortion pill reversal in SB 23-190 are unsupported by credible medical data.” Ex. P at 2. Plaintiffs also attached an appendix containing the numerous medical journal articles cited in their comment. Written Stakeholder Comments, at 238-779, <https://perma.cc/53ZP-HBKF>.

190. Dozens of Colorado doctors and nurses filed public comments and made oral statements in support of abortion pill reversal at the June 5 hearing. *See, e.g.*, Written Stakeholder Comments, at 166-69, 209-15, <https://perma.cc/53ZP-HBKF>. These doctors and nurses explained the scientific evidence that abortion pill reversal is safe and effective. They also expressed alarm that SB 23-190 represents an unprecedented intrusion on patient choice and medical freedom.

191. Several women who sought and received abortion pill reversal treatment after taking the first abortion pill—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.* at 217-18, 878; *see also id.* at 1055-56.

192. On the other side, a handful of opponents of abortion pill reversal also submitted comments. These included a two-page submission from Dr. Mitchell Creinin reiterating his testimony in the Colorado legislature that abortion pill reversal is “misleading” and “medical fraud.” *Id.* at 223-25.

193. On July 14, the Medical Board filed a notice of proposed rulemaking in accordance with the Colorado Administrative Procedure Act, including the text of a proposed rule implementing SB 23-190. Dkt. 73; Ex. Q.

194. The proposed rule did not find that abortion pill reversal is unprofessional conduct. It instead stated that “[t]he Board will not treat medication abortion reversal as a per se act of unprofessional conduct. 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.” Ex. Q at 11.

195. Three bill sponsors of SB 23-190—along with more than a dozen other state senators and representatives—submitted a comment “express[ing] our dismay and disappointment in the proposed ‘draft’ rules to SB190.” Written Stakeholder Comments, at 1238, <https://perma.cc/53ZP-HBKF>. The legislators emphasized their “frustration” that the draft rule “would have the opposite effect” of their intent in passing SB 23-190—which was to “stop and limit the harm” caused by abortion pill reversal. *Id.*

196. Dozens of organizations that endorsed SB 23-190 also submitted a comment “express[ing] our disappointment in the draft rules” and insisting that abortion pill reversal is unprofessional conduct. *Id.* at 1222-29.

197. 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 “because I believe it is my right to receive safe and well-studied health care treatments to protect my physical and mental health in the state of Colorado.” *Id.* at 1069-1188.

198. At the same time, Bella and its providers submitted a second rulemaking comment urging the Boards to conclude, in line with all credible medical data, that abortion pill reversal is a generally accepted standard of practice. Ex. T. Numerous other Colorado doctors submitted comments asking the Boards to reach that same conclusion. *See, e.g.,* Written Stakeholder Comments, at 1020-21, 1045-50, <https://perma.cc/53ZP-HBKF>.

199. At the second joint stakeholder meeting on August 4, two of the bill sponsors of SB 23-190 showed up to testify against the draft rules.

200. 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.” Ex. U at 7; August 4, 2023 Joint Stakeholder Meeting, at 16:03-16:16, <https://bit.ly/3ZwYAjR>. She asked the Boards to “reconsider your draft rules”

and “carefully reread the instructions” in the statute. Ex. U at 7; August 4, 2023 Joint Stakeholder Meeting, at 17:14-17:21, <https://bit.ly/3ro0KG0>.

201. Senator Winter similarly 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.” Ex. U at 11; August 4, 2023 Joint Stakeholder Meeting, at 27:53-28:03, <https://bit.ly/46kziYC>. 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,” and she asked the Boards to “hold up legislative intent on what was actually passed.” Ex. U at 11; August 4, 2023 Joint Stakeholder Meeting, at 29:16-29:30, <https://bit.ly/3PMCSVU>.

202. At the final rulemaking hearing on August 17, the Medical Board abruptly reversed course. Ex. V. at 2-4. 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.” Dkt. 78. 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.*

203. Meanwhile, the State Board of Nursing proposed a draft rule that was materially identical to the Medical Board’s proposed rule, and thus did not purport to treat abortion pill reversal as a *per se* act of unprofessional conduct. Ex. R.

204. The Nursing Board held its final rulemaking hearing on September 20, 2023. *See* Ex. W. No sponsors of SB 23-190 testified at that hearing—and the Nursing Board adopted (with one minor modification) the rule it had originally proposed. Ex. X.

205. Thus, the Nursing Board’s rule will not treat providing progesterone to counteract the effects of mifepristone as a *per se* act of unprofessional conduct, but will instead evaluate complaints about all forms of abortion pill reversal on an individualized case-by-case basis.

206. On September 21, the Pharmacy Board convened its final rulemaking hearing. The Pharmacy Board also rejected the Medical Board’s categorical approach, instead opting to treat complaints about all forms of abortion pill reversal on a case-by-case basis.

207. Notably, several Pharmacy Board members expressly stated that progesterone is both safe and effective. 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.” Ex. Y at 11. As the Board Chair put it: “We know that progesterone is safe and effective no matter ... what it’s being used for.” Ex. Y at 17.

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

Harm to Bella and its Patients

209. The harm inflicted by SB 23-190 and its implementing regulations on Bella, its providers, and the women they serve is massive and imminent.

210. 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. If a woman calls Bella seeking abortion pill reversal after the Defendants' non-enforcement agreement expires, 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 by offering abortion pill reversal.

211. This harm is far from speculative. Just last week, Bella received a call from a woman seeking urgent assistance in reversing the effects of mifepristone. 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.

212. Before SB 23-190 and its implementing regulations, Bella could have freely exercised its religious obligations to continue providing life-affirming care to these patients and the children they wish to carry to term. And those patients could have freely received medication that may allow them to exercise their "fundamental right" to maintain their pregnancies.

213. Now Bella's providers stand on the brink of losing their licenses and facing ruinous fines if they follow their sincerely held beliefs by continuing to offer life-affirming care to these patients and their children. And if they bow under the weight of the state's pressure, their patients will forever lose their ability to attempt to undo a deeply significant decision that is fraught with personal consequences.

214. Because in Colorado abortion pill reversal is now unprofessional conduct—and not a generally accepted standard of practice—Bella also risks the loss of its malpractice insurance, jeopardizing the future existence of the practice altogether.

215. SB 23-190 separately subjects Bella to liability if it continues publicizing abortion pill reversal, as it has done in a variety of media over the years.

216. Prior to filing this lawsuit, in light of the potentially crippling penalties imposed by SB 23-190, Bella was forced to remove any mention of abortion pill reversal from its website and social media accounts. After this Court entered a temporary restraining order, Bella restored information about abortion pill reversal to its website and social media accounts. Bella has since maintained that information on its website and social media accounts under the protection of this Court's order memorializing the State's agreement not to enforce SB 23-190 pending the conclusion of the rule-making.

217. Bella will once again be forced to remove any mention of abortion pill reversal from its website and social media accounts as soon as the Defendants' non-enforcement promise expires.

218. In addition, Bella will be forced to remove any brochures and handouts that mention abortion pill reversal from its office and incur the costs of reprinting those materials free from any mention of abortion pill reversal. Materials describing Bella's services including abortion pill reversal are also already on display at many third-party locations such as churches.

219. Because Section 1 expressly applies the CCPA's prohibitions on deceptive practices to abortion pill reversal—and because the Colorado legislature has declared abortion pill reversal to be unprofessional conduct—Bella can no longer continue publicizing abortion pill reversal without risking public and private enforcement actions and ruinous financial penalties.

220. Bella desires to continue publicizing abortion pill reversal but will be chilled from doing so as soon as the Defendants' promise of non-enforcement expires because of SB 23-190 and its implementing regulations.

221. 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. Bella believes that these terms accurately describe the care it provides, but it will be chilled from using them because of Section 2's sweeping prohibition on any advertisement "indicat[ing] ... that the person provides abortions or emergency contraceptives, or referrals for abortions or emergency contraceptives." SB 23-190 § 2(2).

222. Every day that Bella is forced to remain silent about abortion pill reversal, women in Colorado are deprived of information about highly qualified and local doctors and nurses who would help them if they have willingly or unwillingly taken mifepristone. Absent an injunction, these women may miss the critical window needed to effectuate their choice to continue their pregnancies, and Bella will miss the opportunity to help them.

CLAIMS FOR RELIEF

Count I

42 U.S.C. § 1983

Violation of U.S. Const. Amend. I: Free Exercise Clause Not Generally Applicable

223. All preceding paragraphs are incorporated by reference.

224. “[L]aws burdening religious practice must be of general applicability.” *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 542 (1993).

225. 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).

226. “[W]hether two activities are comparable for purposes of the Free Exercise Clause must be judged against the asserted government interest that justifies the regulation at issue.” *Id.* The comparability analysis “is concerned with the *risks* various activities pose,” not the “reasons why” people engage in those activities. *Id.* (emphasis added).

227. Consistent with their underlying commitment to the dignity of every human life, Plaintiffs must provide life-affirming medical care to every woman at risk of miscarriage—whether that risk arises biologically, due to physical trauma, or because she has willingly or unwillingly ingested the first abortion pill. As a matter of conscience, Plaintiffs cannot refuse to administer progesterone to a woman who desires to continue her pregnancy simply because she first took mifepristone. Plaintiffs are therefore religiously obligated to offer abortion pill reversal.

228. Colorado’s asserted interest in prohibiting abortion pill reversal is to protect women from “a dangerous and deceptive practice that is not supported by science or clinical standards.” SB 23-190 §1(1)(f).

229. But abortion pill reversal is nothing more than supplemental progesterone. And there are a multitude of off-label uses of progesterone, which has been widely prescribed to women—including pregnant women—for more than 50 years.

230. Yet Section 3 and its implementing regulations, as well as Section 1 (on its own and through the CCPA) make no attempt to regulate—much less outright prohibit—the off-label use of progesterone (or any other drug) in any other circumstance. That omission renders SB 23-190 and its regulations not generally applicable.

231. SB 23-190 and its implementing regulations thus trigger strict scrutiny.

232. Colorado has no compelling interest in prohibiting the use of progesterone for abortion pill reversal.

233. Colorado has not selected the least restrictive means to further any governmental interest.

234. Bella, its providers, and the women they serve have suffered and will suffer irreparable harm absent injunctive and declaratory relief against Defendants.

Count II

42 U.S.C. § 1983

Violation of U.S. Const. Amend. I: Free Exercise Clause Not Generally Applicable

235. All preceding paragraphs are incorporated by reference.

236. “[L]aws burdening religious practice must be of general applicability.” *Lukumi*, 508 U.S. at 542.

237. A law fails general applicability if it contains “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 v. City of Philadelphia*, 141 S.Ct. 1868, 1879 (2021) (cleaned up).

238. This is so “*regardless whether any exceptions have been given*,” *id.* at 1879, because the mere existence of discretion “undermines the [State’s] contention that its [regulations] can brook no departures,” *id.* at 1882 (emphasis added).

239. SB 23-190 and its implementing regulations expressly contain such a discretionary system of exemptions.

240. The Medical Board’s rule states categorically that using progesterone to counteract mifepristone’s effects does not “meet generally accepted standards of medical practice,” while any other form of abortion pill treatments will be evaluated “on a case-by-case basis.” Dkt. 78.

241. The Nursing and Pharmacy Board regulations afford them unbridled discretion *to evaluate all* forms of abortion pill reversal on a case-by-case basis. Ex. X at 2; Ex. Z at 1.

242. SB 23-190 and its regulations thus trigger “the strictest scrutiny.” *Fulton*, 141 S.Ct. at 1881.

243. Colorado has no compelling interest in prohibiting the use of progesterone for abortion pill reversal.

244. Colorado has not selected the least restrictive means to further any governmental interest.

245. Bella, its providers, and the women they serve have suffered and will suffer irreparable harm absent injunctive and declaratory relief against Defendants.

Count III

42 U.S.C. § 1983

Violation of U.S. Const. Amend. I: Free Exercise Clause Not Neutral

246. All preceding paragraphs are incorporated by reference.

247. 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, Ltd. v. Colo. C.R. Comm’n*, 138 S.Ct. 1719, 1731 (2018).

248. “Government fails to act neutrally when it proceeds in a manner intolerant of religious beliefs or restricts practices because of their religious nature.” *Fulton*, 141 S.Ct. at 1877.

249. Laws are not neutral when they accomplish a “religious gerrymander.” *Lukumi*, 508 U.S. at 535.

250. A religious gerrymander occurs when “the burden of the [law], in practical terms, falls on [religious] adherents but almost no others.” *Id.* at 536.

251. A law is also not neutral when “the legislative or administrative history, including contemporaneous statements made by members of the decisionmaking body” demonstrate animus toward religion. *Masterpiece*, 138 S.Ct. at 1731.

252. When “‘official expressions of hostility’ to religion accompany laws or policies burdening religious exercise,” courts must “‘set aside’ such policies without further inquiry.” *Kennedy v. Bremerton Sch. Dist.*, 142 S.Ct. 2407, 2422 n.1 (2022) (quoting *Masterpiece*, 138 S.Ct. at 1732).

253. SB 23-190 and its implementing regulations are not neutral with regard to religion.

254. SB 23-190's legislative history, rulemaking history, and narrow application demonstrate that defendants have proceeded in a manner intolerant of religious beliefs.

255. SB 23-190 and its regulations lack a religious exemption, despite the fact that both the legislature and the Boards were well aware of healthcare providers who feel a religious obligation to provide abortion pill reversal.

256. SB 23-190 and its regulations create a religious gerrymander by targeting a subset of religiously motivated actors while failing to pursue the same alleged state interest against those who provide, prescribe, and administer progesterone off-label for uses other than abortion pill reversal.

257. SB 23-190 and its regulations thus "violate the State's duty under the First Amendment not to base laws or regulations on hostility to a religion or religious viewpoint." *Masterpiece*, 138 S.Ct. at 1731.

258. A strict scrutiny defense is not even available for a non-neutral law, *Kennedy*, 142 S.Ct. at 2422 n.1, and Defendants could not satisfy strict scrutiny in any event because they lack a compelling interest and the law is not narrowly tailored.

259. Bella, its providers, and the women they serve have suffered and will suffer irreparable harm absent injunctive and declaratory relief against Defendants.

Count IV

42 U.S.C. § 1983

**Violation of U.S. Const. Amend. I: Free Speech Clause
Content and Viewpoint Discrimination**

260. All preceding paragraphs are incorporated by reference.

261. Under the First Amendment, “governments have ‘no power to restrict expression because of its message, its ideas, its subject matter, or its content.’” *Nat’l Inst. of Fam. & Life Advocs. v. Becerra (NIFLA)*, 138 S.Ct. 2361, 2371 (2018) (quoting *Reed v. Town of Gilbert*, 576 U.S. 155, 163 (2015)).

262. 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*, 576 U.S. at 163-64 (cleaned up); *see also City of Austin v. Reagan Nat’l Advert. of Austin, LLC*, 142 S.Ct. 1464, 1471 (2022) (“A regulation of speech is facially content based under the First Amendment if it targets speech based on its communicative content—that is, if it applies to particular speech because of the topic discussed or the idea or message expressed.” (cleaned up)).

263. Viewpoint discrimination is “an egregious form of content discrimination,” in which “the government 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). A law is viewpoint based “when the specific motivating ideology or the opinion or perspective of the speaker is the rationale for the restriction.” *Id.*

264. Content-based laws “are presumptively unconstitutional and may be justified only if the government proves that they are narrowly tailored to serve compelling state interests.” *Reed*, 576 U.S. at 163.

265. Even within a proscribed category of speech, the government may not engage in content or viewpoint discrimination within that proscribed category. *R.A.V. v. City of St. Paul*, 505 U.S. 377, 384 (1992) (“[T]he government may proscribe libel; but it may not make the further content discrimination of proscribing *only* libel critical of the government.”).

266. Section 1, both on its own and through the CCPA, and Section 2 of SB 23-190 turn on the content and viewpoint of speech by targeting speech restrictions at “anti-abortion centers,” §1(1).

267. Section 1, both on its own and through the CCPA, punishes advertising for abortion pill reversal and prohibits Plaintiffs and others from counseling patients in connection with abortion pill reversal.

268. Section 2 prohibits false advertising only of speakers who do not provide or refer for abortion or emergency contraceptives.

269. Thus, Section 1, both on its own and through the CCPA, and Section 2 are content-based because, “on [their] face,” each “draws distinctions based on the message a speaker conveys” and “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*, 576 U.S. at 163-64 (cleaned up).

270. Section 1, both on its own and through the CCPA, and Section 2 are also viewpoint-discriminatory because each “targets ... particular views taken by speakers on a subject.” *Rosenberger*, 515 U.S. at 829.

271. Because Section 1, both on its own and through the CCPA, and Section 2 turn on the content and viewpoint of a person’s speech and were enacted out of disagreement with the message of “anti-abortion centers,” SB 23-190 and its implementing regulations content and viewpoint based and presumptively unconstitutional.

272. Colorado has no compelling interest in targeting the speech of life-affirming OB-GYN medical providers and pro-life pregnancy centers that do not provide or refer for abortion or emergency contraceptives.

273. Colorado has no compelling interest in prohibiting Plaintiffs from publicizing the availability of abortion pill reversal.

274. Colorado has no compelling interest in prohibiting Plaintiffs from counseling women in connection with abortion pill reversal.

275. Colorado has not selected the least restrictive means to further any government interest.

276. Section 1, both on its own and through the CCPA, and Section 2 have chilled and will chill Bella’s speech about abortion pill reversal, and about itself and its services, under threat of severe financial penalties.

277. Bella, its providers, and the women they serve have suffered and will suffer irreparable harm absent injunctive and declaratory relief against Defendants.

Count V

42 U.S.C. § 1983

**Violation of U.S. Const. Amend. I: Free Speech Clause
Patients' Right to Receive Information**

278. All proceeding paragraphs are incorporated by reference.

279. The First Amendment protects not only the right to disseminate information but also the “reciprocal right to receive” information. *Va. State Bd. of Pharm. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 757 (1976); *see also Island Trees Union Free Sch. Dist. No. 26 v. Pico*, 457 U.S. 853, 867 (1982) (“[T]he right to receive ideas is a necessary predicate to the *recipient's* meaningful exercise of his own right[] of speech”).

280. A patient’s right to engage freely in conversations with her doctor is a corollary to the constitutional right to refuse “unwanted medical treatment,” *Cruzan v. Director*, 497 U.S. 261, 278 (1990), as well as the right “to bodily integrity,” *Washington v. Glucksberg*, 521 U.S. 702, 720 (1997) (citing *Rochin v. California*, 342 U.S. 165 (1952)), which underlies the doctrine of informed consent, *see Schloendorff v. Soc’y of N.Y. Hosp.*, 105 N.E. 92, 92 (N.Y. 1914) (Cardozo, J.).

281. By banning publicizing, providing, administering, or attempting abortion pill reversal, Section 1, both on its own and through the CCPA, and Section 3 of SB 23-190 and its implementing regulations, force women to undergo abortions that they want to avoid. They do so by depriving pregnant women who have taken mifepristone

the right to receive from Plaintiffs information on the full range of treatment options available, including the use of progesterone as abortion pill reversal.

282. SB 23-190 and its implementing regulations are content- and viewpoint-based restrictions on speech subject to strict scrutiny.

283. Colorado has no compelling interest in depriving women of information about abortion pill reversal and thereby forcing women to undergo abortions that they want to avoid.

284. Colorado has no compelling interest in targeting life-affirming OB-GYN medical providers and pro-life pregnancy centers that publicize abortion pill reversal.

285. Colorado has no compelling interest in targeting life-affirming OB-GYN medical providers and pro-life pregnancy centers that attempt abortion pill reversal by administering progesterone.

286. Colorado has not selected the least restrictive means to further any government interest.

287. Plaintiffs' current and prospective patients have suffered and will suffer irreparable harm absent injunctive and declaratory relief against Defendants.

Count VI

42 U.S.C. § 1983

Violation of U.S. Const. Amend. XIV: Due Process Clause Patients' Right to Medical Treatment

288. All proceeding paragraphs are incorporated by reference.

289. The Constitution protects a person's right to refuse "unwanted medical treatment," *Cruzan*, 497 U.S. at 278, and one's right "to bodily integrity," *Glucksberg*, 521 U.S. at 720 (citing *Rochin*, 342 U.S. at 165).

290. The Constitution further protects a person's "right to decide independently, with the advice of his physician, to acquire and to use needed medication." *Whalen v. Roe*, 429 U.S. 589, 603 (1977).

291. These rights include a woman's fundamental right not to be forced to undergo or continue an abortion against her will.

292. By prohibiting providing progesterone as abortion pill reversal, Section 3 of SB 23-190 and its regulations violate these rights.

293. By prohibiting publicizing or providing progesterone as abortion pill reversal, Section 1 of SB 23-190, both on its own and through the CCPA, fosters in current and prospective patients an incomplete understanding of medical alternatives, thereby distorting their assessment of the relative risks and benefits of available therapies and their medical decision-making process as a whole.

294. SB 23-190's prohibition on progesterone as abortion pill reversal necessarily subverts patient autonomy and destroys the possibility of authentic patient consent.

295. SB 23-190 and its implementing regulations are subject to strict scrutiny.

296. Colorado has no compelling interest in banning publicizing or providing progesterone as abortion pill reversal.

297. Colorado has not selected the least restrictive means to further any government interest.

298. Colorado's prohibition on publicizing or providing progesterone to women who change their minds about abortion fails rational basis review.

299. Plaintiffs' current and prospective patients have suffered and will suffer irreparable harm absent injunctive and declaratory relief against Defendants.

Count VII

42 U.S.C. § 1983

Violation of U.S. Const. Amend. XIV: Equal Protection Clause Patients' Right to Medical Treatment

300. All preceding paragraphs are incorporated by reference.

301. Under the Equal Protection Clause of the Fourteenth Amendment, a State may not "deny to any person within its jurisdiction the equal protection of the laws." U.S. Const. amend. XIV, §1.

302. SB 23-190 and its implementing regulations deny women who have changed their minds about proceeding with an abortion the equal protection of the laws because, unlike all other women who face threatened miscarriage, these laws deny them the ability to receive progesterone.

303. Colorado lacks any compelling interest in denying these women the progesterone treatment that is available to other women facing threatened miscarriage.

304. Colorado has not chosen a narrowly tailored approach to pursuing its goals.

305. Colorado's law fails even rational basis review.

306. Plaintiffs’ current and prospective patients have suffered and will suffer irreparable harm absent injunctive relief and declaratory relief against Defendants.

Count VIII

42 U.S.C. § 1983

Violation of U.S. Const. Amend. XIV: Due Process Clause Void for Vagueness

307. All preceding paragraphs are incorporated by reference.

308. Under the Due Process Clause of the Fourteenth Amendment, a state statute “is void for vagueness if its prohibitions are not clearly defined.” *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972).

309. The void-for-vagueness doctrine requires that a statute define the prohibition “with sufficient definiteness that ordinary people can understand what conduct is prohibited and in a manner that does not encourage arbitrary and discriminatory enforcement.” *Kolender v. Lawson*, 461 U.S. 352, 357 (1983) (collecting cases).

310. The vagueness of speech regulations “raises special First Amendment concerns because of its obvious chilling effect on free speech.” *Reno v. ACLU*, 521 U.S. 844, 871-72 (1997).

311. Section 2 of SB 23-190 is unconstitutionally vague.

312. Section 2 of SB 23-190 offers no standards or guidelines on what sort of advertisement “indicates” that a person “provides abortions or emergency contraceptives, or referrals for abortions or emergency contraceptives.”

313. Section 2 of SB 23-190 does not give a person of ordinary intelligence a reasonable opportunity to know what is prohibited.

314. A person of ordinary intelligence does not know whether a medical practice's advertising of full OB-GYN care "indicates" that the practice "provides abortions or emergency contraceptives, or referrals for abortions or emergency contraceptives" or whether pro-life descriptors like "life-affirming" negate any such potential indication.

315. Section 2 of SB 23-190 fails to provide adequate standards or guidelines to govern the actions of those authorized to enforce the Colorado Consumer Protection Act and thus encourages arbitrary and discriminatory enforcement.

316. The lack of adequate standards or guidelines leaves those authorized to bring enforcement actions free to do so based on their personal predilections or for discriminatory purposes, including disapproval of the beliefs, viewpoint, or messages of a particular speaker.

317. The vagueness of Section 2 has an actual chilling effect on Bella's speech.

318. The vagueness of Section 2 renders SB 23-190 unconstitutionally vague.

319. Bella has suffered and will suffer irreparable harm absent injunctive and declaratory relief against Defendants.

PRAYER FOR RELIEF

Wherefore, Plaintiffs request that the Court:

a. Issue a preliminary injunction and permanent injunction prohibiting Defendants, their agents and employees, and all those acting in concert with them, from enforcing Section 1 of SB 23-190 (on its own and through the CCPA), Section 2 of SB 23-190, and Section 3 of SB 23-190 and its implementing regulations against Plaintiffs and all those acting in concert with them;

b. Declare that SB 23-190 and its implementing regulations are unconstitutional both on their face and as applied to Plaintiffs and their current and prospective patients;

c. Declare that:

1. Section 3 of SB 23-190 and its implementing regulations, and Section 1 of SB 23-190 (on its own and through the CCPA), violate the Free Exercise Clause of the First Amendment to the United States Constitution because they are not generally applicable;
2. SB 23-190 and its implementing regulations violate the Free Exercise Clause of the First Amendment to the United States Constitution because they are not neutral;
3. Section 1 of SB 23-190 (both on its own and through the CCPA) and Section 2 of SB 23-190 violate the Free Speech Clause of the First

Amendment to the United States Constitution by discriminating against Plaintiffs based on the content and viewpoint of their speech;

4. The phrases “comprehensive, life-affirming OB-GYN practice,” “comprehensive, life-affirming health care,” “comprehensive healthcare,” “full continuum of care,” and “full-service Family Medicine and OB-GYN medical center,” do not constitute an “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,” and thus do not violate the CCPA;
5. SB 23-190 and its implementing regulations violate the Due Process Clause of the Fourteenth Amendment to the United States Constitution by denying Plaintiffs’ patients their right to medical treatment and their right not to undergo an abortion against their will;
6. SB 23-190 and its implementing regulations violate the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution by discriminating against women who have changed their minds about going through with an abortion;

7. Section 2 of SB 23-190 violates the Due Process Clause of the Fourteenth Amendment to the United States Constitution by being impermissibly vague;

d. Issue a preliminary injunction and permanent injunction prohibiting Defendants, their agents and employees, and all those acting in concert with them, from taking any enforcement action under Section 3 of SB 23-190 and its implementing regulations and/or Section 1 of SB 23-190 (either on its own and through the CCPA), against Plaintiffs and all those acting in concert with them based on their provision of abortion pill reversal;

e. Issue a preliminary injunction and permanent injunction prohibiting Defendants, their agents and employees, and all those acting in concert with them from taking any enforcement action under Section 2 of SB 23-190, against Plaintiffs and all those acting in concert with them, based on the Plaintiffs' use of the phrases "comprehensive, life-affirming OB-GYN practice," "comprehensive, life-affirming health care," "comprehensive healthcare," "full continuum of care," and "full-service Family Medicine and OB-GYN medical center" to describe their healthcare practice;

f. Issue a preliminary injunction and permanent injunction prohibiting Defendants, their agents and employees, and all those acting in concert with them from taking any enforcement action under Section 1 of SB 23-190 (on its own and through the CCPA) against Plaintiffs and all those acting in concert with them based on the language of Plaintiffs' "Abortion Pill Reversal" webpage. *See* Ex. C.

- g. Award nominal damages in the amount of \$1.00 against Defendants.
 - h. Award Plaintiffs reasonable attorneys' fees and costs under 42 U.S.C. §1988;
- and
- i. Award such other relief as the Court may deem equitable, just, and proper.

JURY DEMAND

Plaintiffs demand a trial by jury of all issues so triable.

Dated: September 22, 2023

Respectfully submitted,

/s/ Mark L. Rienzi

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*Admitted only in Texas. Supervised by a
member of the D.C. Bar.

VERIFICATION

I am over the age of 18 and am a Plaintiff in this action. I declare under penalty of perjury, pursuant to 28 U.S.C. § 1746, that I have read the foregoing FIRST AMENDED VERIFIED COMPLAINT, and the factual allegations thereof, and that to the best of my knowledge the facts alleged therein are true and correct.

Executed on Sept 22, 2023

A handwritten signature in blue ink, reading "Denise Chism", written over a horizontal line.

Denise Chism