

Written Testimony of Catherine Glenn Foster, M.A., J.D. President & CEO, Americans United for Life In Support of HB 23-1150 Submitted to the House Committee on Health & Insurance

Dear Chair Daugherty and Members of the Committee:

I serve as President & CEO of Americans United for Life (AUL), America's original and most active pro-life legal advocacy organization. Founded in 1971, two years before the Supreme Court's decision in *Roe v. Wade*, AUL has dedicated over 50 years to advocating for comprehensive legal protections for human life from fertilization to natural death. AUL attorneys are highly regarded experts on the Constitution and legal issues touching on abortion and are often consulted on various bills, amendments, and ongoing litigation across the country.¹ For five decades, AUL's staff, supporters, and partners have worked tirelessly to advance the human right to life in culture, law, and policy. I appreciate the opportunity to submit legal testimony concerning HB 23-1150, a bill to ensure Colorado women are informed about the possibility of reversing chemical abortion.

I have thoroughly reviewed HB 23-1150 which is based, in substantial part, on AUL's model legislation and it is my opinion that HB 23-1150 protects Colorado women and children by ensuring that women know the full spectrum of the issues concerning chemical abortion and that there may be a chance to reverse the process if she changes her mind.

Informed Consent Laws, Including Those Concerning the Potential to Reverse Chemical Abortions, Are Good Policy

Abortion advocates frequently claim to be "pro-choice," but they only actually support the choice to have an abortion. Abortion providers sometimes fail to provide adequate and accurate information to women considering abortions. As a result,

¹ See, e.g., Revoking Your Rights: The Ongoing Crisis in Abortion Care Access Before the H. Comm. on the Judiciary, 117th Cong. (2022) (testimony of Catherine Glenn Foster, President & CEO, Americans United for Life); What's Next: The Threat to Individual Freedoms in a Post-Roe World Before the H. Comm. on the Judiciary, 117th Cong. (2022) (testimony of Catherine Glenn Foster, President & CEO, Americans United for Life).

many women are physically and psychologically harmed by the abortion process.² When a woman is not given comprehensive and medically accurate information, her "choice" to abort is, in reality, no choice at all.

In 1992, in the landmark case of *Planned Parenthood v. Casey*, the Supreme Court ruled that informed consent laws are constitutional.³ The Court found that such laws reduce "the risk that a woman may elect an abortion, only to discover later, with devastating psychological consequences, that her decision was not fully informed."⁴ The *Casey* Court further acknowledged that "[a]bortion is a unique act. It is an act fraught with consequences ... for the woman who must live with the implications of her decision."⁵

Later, in *Gonzales v. Carhart*, the Court again acknowledged that abortion can have devastating consequences, stating "[i]t seems unexceptional to conclude some women come to regret their choice to abort the infant life they once created and sustained."⁶ These consequences would seem especially pronounced in situations where a woman regrets her decision to use or ingest an abortion-inducing drug and later learns that she was not told that it might have been possible to reverse the effects of this drug, allowing her to continue her pregnancy and to deliver a healthy child.

Even in *Dobbs v. Jackson Women's Health Organization*, the United States Supreme Court recognized that states have an interest in the "respect for and preservation of prenatal life at all stages of development; *the protection of maternal health and safety*; the elimination of particularly gruesome or barbaric medical procedures; the preservation of the integrity of the medical profession; [and] the mitigation of fetal pain"⁷

Numerous states have affirmed their legitimate interest in protecting maternal health and safety by enacting informed consent safeguards. For example, currently, 32 states have enforceable general informed consent requirements.⁸ The

² See, e.g., Speckhard & Rue, Post-Abortion Syndrome: An Emerging Public Health Concern, J. SOC. ISSUES 48(3): 95-119 (1982) (reporting that 81 percent of women surveyed felt victimized by the abortion process).

³ 505 U.S. 833 (1992). The Supreme Court has also refused to review a lower court ruling which found Mississippi's informed consent law constitutional. *Barnes v. Moore*, 970 F.2d 12 (5th Cir. 1992), *cert. denied*, 506 U.S. 1013 (1992).

⁴ Planned Parenthood v. Casey, 505 U.S. at 882.

⁵ Planned Parenthood v. Casey, 505 U.S. at 852.

⁶ Gonzales v. Carhart, 550 U.S. 124, 159 (2007).

⁷ Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228, 2284 (2022) (internal citations omitted) (emphasis added).

⁸ Twenty-seven states require informed consent with at least a one-day reflection period (usually 24 hours): Alabama (48 hours), Arizona, Arkansas (48 hours), Florida, Georgia, Idaho, Indiana (18 hours), Kansas, Kentucky, Louisiana, Michigan, Mississippi, Missouri (72 hours), Nebraska, North Carolina (72 hours), North Dakota, Ohio, Oklahoma (72 hours), Pennsylvania, South Carolina, South Dakota

majority of these laws also include reflection periods for women to consider the information that they have been given in anticipation of making a final decision as to whether or not to have an abortion.

Importantly, states have also enhanced their general informed consent laws for abortion by requiring information on fetal pain, the availability of ultrasounds, perinatal hospice options for women faced with prenatal diagnoses of lethal fetal anomalies, coercion counseling, and, as in HB 23-1150, the potential ability to reverse the effects of chemical abortions before all of the drugs in the regimen have been ingested.

In summary, women need comprehensive information about abortion, its risks and consequences, and its alternatives. When a woman is considering a chemical abortion, this information includes an advisory that the effects of a chemical or druginduced abortion can be reversed, but time is of the essence. Strong informed consent requirements, such as HB 23-1150, manifest both a trust in women and a justified concern for their welfare.

The Growing Threat of Chemical Abortions

In a 2014 report, the pro-abortion Guttmacher Institute estimated that chemical (or drug-induced) abortions account for 23 percent of all abortions—an increase from 2008, when chemical abortions accounted for 17 percent of all abortions.⁹ This increase does not come as a surprise. AUL has long warned of a "chemical abortion revolution"—a marked increase in and emphasis on drug-induced abortions. The growing reliance on chemical abortions further underscores the need for informed consent specific to the efficacy, complications, and alternatives to chemical abortions. HB 23-1150 satisfies these needs.

What is the Chemical Abortion Process?

Mifeprex (also known as "mifepristone," RU-486," or simply the "abortion pill") is currently the only chemical abortion regimen approved for use in the United States. Yet, it is important to note that Mifeprex is undergoing litigation, which has the potential to reverse the U.S. Federal Drug Administration's ("FDA") allegedly

⁽⁷² hours), Tennessee (reflection period in litigation), Texas, Utah (72 hours), West Virginia, and Wisconsin.

Six states require informed consent with no reflection period: Alaska, California, Connecticut, Maine, Nevada, and Rhode Island.

Two states have enacted informed consent laws that are in litigation or enjoined: Massachusetts and Montana.

⁹ Guttmacher Institute, *Abortion Incidence and Service Availability in the United States*, 2011 (Mar. 2014), *available at* http://www.guttmacher.org/pubs/journals/psrh.46e0414.pdf (last visited July 10, 2015).

unlawful approval and deregulation of the drugs.¹⁰ Mifeprex is used, together with another medication called misoprostol, to end a pregnancy. The FDA first approved Mifeprex in 2000, and later amended approved guidelines for its use in March 2016.

The 2016 FDA-Approved Regimen has Endangered Women and Girls Seeking Chemical Abortions

Mifeprex is approved, in a regimen with misoprostol, to terminate a pregnancy through 70 days gestation (70 days or less since the first day of a woman's last menstrual period). The FDA-approved Mifeprex dosing regimen is:

- On Day One: 200 mg of Mifeprex taken by mouth.
- 24 to 48 hours after taking Mifeprex: 800 mcg of misoprostol taken buccally (in the cheek pouch), at a location appropriate for the patient.
- About seven to fourteen days after taking Mifeprex: follow-up with the healthcare provider.¹¹

From and after the FDA's approval of the chemical abortion drug RU-486 in September 2000, the abortion industry has blatantly ignored the sanctioned protocol for the use and distribution of this dangerous drug, often providing chemical abortion in a manner that directly conflicted with the standard of practice prescribed by the FDA. Then in December 2021, the FDA made permanent a total removal of the inperson dispensing requirement and permitted, for the first time, the abortion drug regimen (mifepristone and misoprostol) to be mailed to a woman's home for a DIY abortion, or dispensed through certified pharmacies rather than directly from certified providers.

The abortion industry used this loosening of the rules as pretext for "advance prescribing," or selling pills to a woman who is not pregnant so she can keep them for later use or give them to someone else. In October 2022, the FDA pushed back against this dangerous practice, calling it an "unauthorized use", and raising concerns about the lack of screening or oversight which places women at even higher risk of health complications.

In an August 2022 report, the U.S. Department of Health and Human Services ("HHS") laid out an action plan utilizing the full force and multiple agencies of the federal government to push abortion, especially abortion-inducing drugs, onto the states, threatening the loss of federal funds and other leverage. This plan includes

¹⁰ All. for Hippocratic Med. v. U.S. Food & Drug. Admin, No. 2:22-cv-223 (N.D. Tex. Filed Nov. 18, 2022).

¹¹ See "Mifeprex (mifepristone) Information ," available at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/uc m111323.htm (last visited February 3, 2017).

guidance to roughly 60,000 U.S. retail pharmacies, asserting the authority of the FDA, indefensible threats to emergency rooms, threatening to invoke civil rights laws against health care providers who oppose abortion based on moral, ethical, or religious grounds, and much more. However, most of the items in the HHS report are 'paper tigers' that states should push back against, as Texas and Idaho have already done in federal courts.¹²

Additionally, in July 2022, the Biden Administration's Department of Education published a proposed rule that would redefine "discrimination on the basis of sex" in Title IX to include "termination of pregnancy." This would mean that any school receiving federal funding could be forced to make chemical abortion drugs available to its students or else forfeit those federal funds. The Department of Education would thereby circumvent any life-protecting laws the states in which these schools operate may have. If this report and proposed rule are any indication of the passion that the Biden administration has for pushing abortion, states should take note and immediately pass the health and safety protections contained in this model bill.

It is clear the States can no longer rely on the FDA to safely regulate chemical abortions. Thus, lawmakers must incorporate safeguards into state law to protect women from this dangerous overreach. The Supreme Court made it clear in *Dobbs* that states may regulate, or even prohibit, abortion throughout pregnancy, *regardless* of the method, for many legitimate reasons including respecting human life, ensuring women and girls receive appropriate medical care, and preventing the degradation of the medical profession.

It is imperative that states enact legislation protecting women from the abortion industry's systematic misuse of RU-486 and other abortion-inducing drugs. It is vital that states ensure that women are fully informed about the inherent health risks of drug-induced abortions, are given accurate information about their unborn child's development, are aware of alternatives to abortion, and are told of the potential to reverse drug-induced abortions. States must enact specific reporting requirements for drug-induced abortions and their complications to facilitate more extensive medical research into and study of these risky drugs.

The Possibility of Chemical Abortion Reversal is a Critical Informed Consent Disclosure

Because physicians know that mifepristone, the first drug in the Mifeprex or RU-486 regime, works by blocking progesterone, it is possible to reverse the effects of the drug by flooding the woman's body with progesterone. The process (which has

¹² See. United States of America v. State of Idaho (D. Idaho No. 1:22-cv-329); State of Texas v. Becerra (5th Cir. No. 22-11037)..

been detailed in a peer-reviewed study¹³) is based upon a well-established medical regimen that is used in other areas of healthcare: a methotrexate and "leucovorin rescue."

Methotrexate, a common chemotherapy drug, kills rapidly dividing cells (*e.g.*, cancer cells). Specifically, it blocks the action of folic acid. Typically, physicians allow the methotrexate to work for a day or two, and then give the patient a high dose of folic acid (leucovorin) to compensate for what has been lost. This high dosage of folic acid, in essence, "kicks" the methotrexate off of the cells. This flooding of the patient's body with folic acid is called a "leucovorin rescue" and is a well-established medical procedure.

Similarly, since physicians know that mifepristone works by blocking progesterone, they also know that treating a woman with progesterone can "kick off" the mifepristone. This allows the woman's body to respond naturally to the progesterone and to effectively fight the effects of the mifepristone. Progesterone itself has been used safely in pregnancies for decades. It is used in *in vitro* fertilization, infertility treatments, and high-risk pregnancies (such as those experiencing pre-term labor). Using progesterone to reverse the effects of mifepristone is a targeted response that is safe for women.

For a woman who regrets her decision to use the first drug in the RU-486 regime (mifepristone) and wishes to continue her pregnancy, knowledge of this potential reversal option could mean the difference between the life and death of her baby. *Abortion Pill Reversal*, an organization that assists women in locating physicians trained in the reversal process, reports a 55 to 60 percent success rate for women who attempt to reverse the effects of mifepristone. As of May 2016, 175 babies had been born and another 100 were on the way (*i.e.*, still *in utero*), following the reversal process.

Clearly, it is important that a woman contemplating a chemical abortion be informed that the process can be reversed. HB 23-1150, which is based on the *Abortion Inducing Risk Protocol*, mandates that women be informed of this possibility.

Chemical Abortion Drugs Pose Serious Threats to Patient Health and Safety

There is another reason why women should be informed that chemical abortions can be reversed: the two-drug, multi-day chemical abortion process has substantial – and sometimes deadly – consequences for women's health and safety.

¹³ George Delgado et al., "A case series detailing the successful reversal of the effects of mifepristone using progesterone," *Issues in Law & Medicine* 33 (Spring 2018), <u>https://pubmed.ncbi.nlm.nih.gov/30831017/</u>.

Importantly, the manufacturer of Mifeprex admits that "[n]early all of the women who receive Mifeprex [RU-486] and misoprostol will report adverse reactions, and many can be expected to report more than one such reaction."¹⁴ These adverse reactions include, but are not limited to, abdominal pain, cramping, vomiting, headache, fatigue, uterine hemorrhage, viral infections, and pelvic inflammatory disease.¹⁵

Since 2016, the FDA has only required adverse events reporting for deaths resulting from chemical abortion drugs; reporting is otherwise voluntary. As one study concludes, "FAERS [the FDA Adverse Event Reporting System] is inadequate to evaluate the safety of mifepristone" due to reporting discrepancies, and the fact that the FDA no longer mandates reporting of non-lethal adverse events.¹⁶ Even so, the FDA has received FAERS Mifeprex reports through June 30, 2022, documenting 28 deaths, 4,213 adverse events, 1,048 hospitalizations (excluding deaths), 604 blood loss incidents requiring transfusions, 414 infections, and 71 severe infections.¹⁷

Further, the Mifeprex or RU-486 regimen is particularly dangerous because its side effects are confusingly similar to the symptoms of an ectopic pregnancy. Failing to properly diagnose an ectopic pregnancy can lead to a rupture of the fallopian tube, causing bleeding, severe pain, and even death.

Chemical Abortions Result in More Complications than Surgical Abortions

Medical evidence demonstrates that chemical abortions can pose more significant risks to women than surgical abortions. Importantly, peer-reviewed studies have also found that the overall incidence of immediate adverse events is fourfold higher for chemical abortions than for surgical abortions.¹⁸

In particular, hemorrhage and incomplete abortions are more common after chemical abortions. A 2009 study found the incidence of hemorrhage is 15.6 percent following chemical abortions, compared to 5.6 percent for surgical abortions.¹⁹ It also found 6.7 percent of chemical abortions result in incomplete abortions, as compared

¹⁴ See Mifeprex FPL, supra (emphasis added).

 $^{^{15}}$ Id. at 12 (Table 3).

¹⁶ Christina A. Circucci et al., *Mifepristone Adverse Events Identified by Planned Parenthood in 2009* and 2010 Compared to Those in the FDA Adverse Event Reporting System and Those Obtained Through the Freedom of Information Act, Health Servs. Rsch. & Managerial Epidemiology, Dec. 21, 2021, at 1, 4.

¹⁷ Mifepristone U.S. Post-Marketing Adverse Events Summary Through 06/30/2022, U.S. Food & Drug Admin. 1, 1–2 (June 30, 2022), https://www.fda.gov/media/164331/download.

 ¹⁸ M. Niinimaki et al., Immediate Complications after Medical compared with Surgical Termination of Pregnancy, Obstet. Gynecol. 114:795 (Oct. 2009).
¹⁹ Id.

to 1.6 percent of surgical abortions. $^{20}\,$ Further, 5.9 percent of women required surgery after failed chemical abortions. $^{21}\,$

An earlier 1999 study found that chemical abortions failed in 18.3 percent of patients and that surgical abortion failed in only 4.7 percent of patients.²² It also found that patients who undergo chemical abortions also report significantly longer bleeding and higher levels of pain, nausea, vomiting, and diarrhea than women who undergo surgical abortions.²³

Significantly, chemical abortions pose a greater risk of bacterial infection than surgical abortions. The CDC has found a risk of death from C. sordelli (bacterial infection) in a chemical abortion is ten times the death rate from all causes following a surgical abortion at a comparable gestational age.²⁴

Moreover, the American College of Obstetricians and Gynecologists ("ACOG") admits that chemical abortions fail more often than surgical abortions.²⁵ ACOG takes special note that chemical abortions require multiple visits to a healthcare provider, while surgical abortions usually require only one visit,²⁶ and that chemical abortions can take days or weeks to complete, while surgical abortions take shorter, more predictable periods of time.²⁷ Finally, chemical abortions require patient participation throughout a multistep process, while surgical abortions require patient participation in a single-step process.

Informing women that chemical abortions can be reversed potentially allows women to reduce the health and safety risks associated with using or ingesting the two-drug regimen.

Sincerely,

Catherine Glenn Foster President and CEO Americans United for Life

 $^{^{20}}$ Id.

 $^{^{21}}$ Id.

²² J.T. Jenson et al., Outcomes of Suction Curettage and Mifepristone Abortion in the United States: A Prospective Comparison Study, Contraception 59:153-59 (1999).

 $^{^{23}}$ Id.

²⁴ M. Fisher et al., *Fatal Toxic Shock Syndrome Associated with Clostridium sordelli after Medical Abortion*, N.E. J.M. 353:2352-60 (2005).

²⁵ ACOG, ACOG Practice Bulletin 67 Medical Management of Abortion, at Table 2. See also J.T. Jenson et al., supra.

 $^{^{26}}$ Id.

 $^{^{27}}$ Id.