UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF NORTH CAROLINA

PLANNED PARENTHOOD SOUTH)
ATLANTIC, et al.,)
Plaintiff,))
v.) Case No. 1:23-cv-480
JOSHUA STEIN, et al.,) DEFENDANT-INTERVENORS') SUPPLEMENTAL BRIEF
Defendants,)))
and	/))
PHILIP E. BERGER and TIMOTHY K. MOORE,)))
Intervenor-Defendants.)
)

INTRODUCTION

Plaintiffs' lawsuit is an overt attempt to circumvent the Supreme Court's decision in *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022), by seeking to create new constitutional roadblocks to laws that protect women from unsafe abortion practices. But the Supreme Court instructed that "[a] law regulating abortion . . . is entitled to a 'strong presumption of validity" and "must be sustained if there is a rational basis on which the legislature *could have thought* that it would serve legitimate state interests," including "the protection of maternal health and safety." *Dobbs*, 142 S. Ct. at 2284 (emphasis added). North Carolina's abortion laws easily satisfy this test.

As the leading cause of maternal mortality in the first trimester, Wubbenhorst Decl. ¶ 246, ECF No. 65-1, ectopic pregnancies must be identified and treated before they rupture. Bane Decl. ¶ 60, ECF No. 65-3. The North Carolina General Assembly addressed this danger by requiring doctors to document an intrauterine pregnancy (IUP) *prior to* giving women drugs that can mask the symptoms of a life-threatening rupture. The U.S. Food and Drug Administration (FDA) has also addressed this risk by including a warning on mifepristone's label that a prescriber must "*exclude* [an ectopic pregnancy] *before* treatment." Mifeprex Label, ECF No. 65-2 (emphasis added). Codifying FDA's warning into law is rational.

The General Assembly also sought to provide safe conditions for women who seek abortions beyond the first trimester. As Plaintiffs have conceded, women who have post-12-week surgical abortions may experience lifethreatening complications that require hospitalization. *See* Def.-Intervenors' Opp'n to Am. Mot. for Prelim. Inj. 10, ECF No. 65. What's more, Planned Parenthood South Atlantic (PPSAT) admits that it has transferred women from its facilities to hospitals due to complications from post-12-week surgical abortions that it could not treat at its facilities. Ex. 1, Chart on Hospital Transfers.

Simply put, the North Carolina legislature had rational reasons to require IUP documentation prior to a chemical abortion and hospitalization for post-12-week surgical abortions. The Constitution affords the North Carolina General Assembly—not Plaintiffs—that choice.

ARGUMENT

The Court should deny Plaintiffs' Motion for Preliminary Injunction because it satisfies none of the requirements for this "extraordinary remedy." *See In re Search Warrant Issued June 13, 2019*, 942 F.3d 159, 170–71 (4th Cir. 2019).

I. Plaintiffs Are Not Likely to Succeed on the Merits.

Plaintiffs' constitutional challenges to the IUP documentation and post-12-week hospitalization requirements are unlikely to succeed.

A. The IUP documentation is constitutional.

The IUP documentation requirement satisfies the Due Process Clause because it is clear and rational.

1. The IUP documentation requirement is clear.

Plaintiffs argue that the IUP requirement is vague because the law contains both a provision that generally authorizes abortion during the first twelve weeks of pregnancy and a provision that may prevent a small number of women from obtaining a chemical abortion before five weeks—when it is not possible to exclude an ectopic pregnancy by ultrasound. Ordinary principles of statutory interpretation instruct otherwise. In particular, Section 90-21.81B of Article 1I contains a subordinating clause in its introduction of "When abortion is lawful": "Notwithstanding any provision of G.S. 14-44 and G.S. 14-45, and subject to the provisions of this Article." N.C. Gen. Stat. § 90-21.81B (emphasis added). The provision then states that abortion is lawful, *inter alia*, "during the first 12 weeks of a woman's pregnancy when a medical abortion is procured." N.C. Gen. Stat. § 90-21.81B(2).

Later in Article 1I, Section 90-21.83(B)(a)(7) states that "[a] physician prescribing, administering, or dispensing an abortion-inducing drug must examine the woman in person and, prior to providing an abortion-inducing drug, shall . . . [d]ocument in the woman's medical chart . . . the existence of an intrauterine pregnancy." N.C. Gen. Stat. § 90-21.83B(a)(7).

Applying the subordinating/superordinating canon of construction, Section 90-21.81(B) (which contains the subordinating clause "subject to the provisions of this Article") indicates that other provisions of Article 1I, including Section 90-21.83(B)(a)(7), would "prevail[] in the event of a clash" (but such language "does not necessarily denote a clash of provisions").¹ Read together, these Sections permit chemical abortions within the first 12 weeks of a woman's pregnancy *only if* a physician documents the existence of an intrauterine pregnancy. To read ambiguity into these straightforward provisions would be to disregard an established canon of statutory interpretation. *See Nat'l Labor Rel. Bd. v. SW Gen., Inc.*, 137 S. Ct. 929, 939 (2017) (applying the subordinating/superordinating canon to "show[] which provision prevails in the event of a clash") (citation omitted).

2. The IUP documentation requirement is rational.

Under the rational-basis test, the Supreme Court has repeatedly held that "it is up to legislatures, not courts, to decide on the wisdom and utility of legislation," and a court "err][s] in substituting its judgment for that of the legislature." *Minnesota v. Clover Leave Creamery Co.*, 101 S. Ct. 715, 726

¹ A. Scalia & B. Garner, *Reading Law: The Interpretation of Legal Texts*, 126–127 (2012).

(1981) (cleaned up). But that is what Plaintiffs are asking this Court to doeven though North Carolina's law is rational and well-supported.

In their own words, Plaintiffs' declarants reveal the rationality to require IUP documentation prior to giving women drugs that could mask a ruptured ectopic pregnancy. It is undisputed that "[a]n ectopic pregnancy can be life threatening if not treated[]." Ex. 2, Farris Dep. 107:12–13. It is also undisputed that a chemical abortion neither terminates a pregnancy nor treats an ectopic pregnancy. Ex. 3, Boraas Dep. 96:17-19, 99:3-12; Ex. 2, Farris Dep. 121:15-17. And a patient with a pregnancy of unknown location may have an ectopic pregnancy that the physician just can't see yet. Ex. 2, Farris Dep. 111:12–18; see also id. 147:19–24 (admitting to giving chemical abortion drugs to a woman with an ectopic pregnancy whose ultrasound showed a pregnancy of unknown location). In fact, "[h]alf of all women who receive a diagnosis of ectopic pregnancy do not have any known risk factors." Ex. 3, Boraas Dep. 124:16–20. "The only way to definitively diagnose an ectopic pregnancy is to see an embryo outside of the uterus with ultrasound." Ex. 3, Boraas Dep. 126:21-23; see also Ex. 2, Farris Dep. 115:5–6 (an "ultrasound is a critical factor in diagnosis of ectopic pregnancy"). Identifying an ectopic pregnancy is vital because "[t]here are some overlapping symptoms between the normal symptoms we expect with medication abortion and the symptoms of an ectopic pregnancy." Ex. 2, Farris Dep. 124:13-16.

Like Plaintiffs, FDA's approved label for mifepristone also recognizes this undisputed risk: "some of the expected symptoms experienced with a medical abortion (abdominal pain, uterine bleeding) may be similar to those of a ruptured ectopic pregnancy." ECF No. 65-2 at 6. FDA also identified a confirmed or *suspected* ectopic pregnancy as a contraindication for mifepristone, *id.*, and concluded the drug's risk "clearly outweighs any possible therapeutic benefit." *See* 21 C.F.R. § 201.57(c)(5).² FDA addressed this risk by including a warning on mifepristone's label that a prescriber must "*exclude* [an ectopic pregnancy] *before* treatment" with these drugs. ECF No. 65-2 at 1 (emphasis added).

Codifying FDA's warning into law is rational. Addressing a lifethreatening risk by requiring an ultrasound—which Plaintiffs' declarants acknowledge is the "only definitive way" to exclude the risk—is rational. The IUP documentation requirement is thus rational.

B. The hospitalization requirement is constitutional.

Plaintiffs are unlikely to succeed in their challenge to the hospitalization requirement for surgical abortions after 12 weeks' gestation. Under rationalbasis review, "it is for the legislature, not the courts, to balance the advantages and disadvantages of the new requirement." *Williamson v. Lee Optical of Okla. Inc.*, 348 U.S. 483, 487 (1955).

North Carolina rationally sought to help ensure the safety of women who may require hospitalization for complications from surgical abortions. In fact, PPSAT's Chief Medical Officer admitted that she is "aware that there are some

² "Suspected" is defined as "deserving to be regarded with suspicion."

Merriam Webster, Suspected, https://www.merriam-

webster.com/dictionary/suspected. And "suspicion" is defined as "a state of . . . uncertainty." Merriam Webster, *Suspicion*, https://www.merriam-webster.com/dictionary/suspicion.

cases of uterine perforation where the patient does need to be transferred to a hospital for additional care" and "aware of patients who have suffered hemorrhage during a procedural abortion who have been transferred to a hospital." Ex. 2, Farris Dep. 63:5–8, 65:21–66:2.

The legislature determined that requiring surgical abortions to be performed in a hospital after 12 weeks rationally addressed the increased risk associated with an increase in the baby's gestational age. ECF No. 65-3 at $\P\P$ 49, 50, 51, 52; 65-1 at \P 225. Plaintiffs and their expert witnesses agree that complications increase as the baby's gestational age increases. Ex. 3, Boraas Dep. 149:17–21 (conceding that "the risk, generally, for a procedural abortion increases as the gestation of the pregnancy increases" when comparing first-trimester and second-trimester surgical abortions); Ex. 2, Farris Dep. 144:23–145:18 (agreeing that "there is an incremental increase in risk as gestational duration increases"); Farris Decl. ¶ 41, ECF No. 49-1; Boraas Decl. ¶¶ 49–52, ECF No. 49-2.

Finally, Plaintiffs' assertion that "surgical abortion" is a "misnomer," Br. in Supp. of Am. Mot. for Prelim. Inj. at 3, ECF No. 49, is curious because it belies their expert witness's testimony, the commonly understood medical definition of "surgery," and their own counsel's prior usage of the term. During her deposition, Plaintiffs' expert described her "surgical" abortion work. Ex. 3, Boraas Dep. 33:6–7; 72:9–10 (explaining that she uses a "surgical instrument, either a suction cannula or a forceps" and stating that "for every procedure, we would start with a surgical timeout"). The American Medical Association's definition of "surgery," for example, would encompass

surgical abortions. *See* Ex. 4, Definition of Surgery H-475.983, American Medical Association ("Surgery is performed for the purpose of structurally altering the human body by the incision or destruction of tissues and is part of the practice of medicine."). And even Plaintiffs' counsel has repeatedly used the term "surgical abortion." *See, e.g.*, Ex. 5, ACLU Letter to FDA Commissioner Jane Henney on the Restrictions on Mifepristone. That letter also highlighted the increased risks associated with "surgical abortions" as the baby's gestational age increases: "[t]he risk of major medical complications increases approximately 20 percent with each week of gestation from 7 weeks onward." *Id*.³

North Carolina's elected representatives rationally addressed a known risk. That the legislature did not first require hospitalization for purportedly more dangerous surgical procedures does not violate the Equal Protection Clause. The Constitution does not require such prioritization. *Lee Optical*, 348 U.S. at 489.

C. Plaintiffs lack standing.

Plaintiffs are also not likely to succeed on the merits because they appear to lack standing. "At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice," but, as the litigation continues, "the plaintiff can longer rest on such 'mere allegations." *Lujan v*.

³ One recent study echoes the ACLU's concerns with surgical abortions, finding that 27 percent of women who underwent second-trimester surgical abortions experienced significant complications. T. Springler, et al., *Complication rate after termination of pregnancy for fetal defects*, 62 Ultrasound in Obstetrics & Gynecology 1, 92 (July 2023), https://obgyn.onlinelibrary.wiley.com/doi/epdf/10.1002/uog.26157.

Defenders of Wildlife, 504 U.S. 555, 561 (1992) (citation omitted). Plaintiffs must establish standing for each claim because "standing is not dispensed in gross; rather, plaintiffs must demonstrate standing for each claim that they press and for each form of relief that they seek." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2208 (2021). Thus far, Plaintiffs have not tried to set forth Article III standing for themselves or their patients. But discovery conducted to date undermines any support for standing on their claims.

For the IUP documentation requirement, Plaintiffs appear to allege two injuries: (1) their potential exposure to disciplinary actions and criminal penalties; and (2) an irrational delay for a woman to receive chemical abortion drugs. First Am. Compl. at 4, ECF No. 42. If the Court agrees the law is not vague, then Plaintiffs must rely on third-party standing to pursue their challenge. But PPSAT's Chief Medical Officer admitted that its abortion *doctors* do not spend *any* time with women before they receive the drugs. Ex. 2, Farris Dep. 78:12–22. This revelation and the *de minimis* time that PPSAT abortion providers spend with women when handing them drugs fail to establish the requisite "close relation[ship]" between abortion doctors and their patients. *See Powers v. Ohio*, 499 U.S. 400, 411 (1991).

For the hospitalization requirement, Plaintiffs appear to allege two injuries: (1) purported interference with the doctor-patient relationship; and (2) burdens on women for having surgical abortions in a hospital. But Intervenors are unaware of any case that found Article III standing based solely on a law's purported interference with the doctor-patient relationship, nor have Plaintiffs cited such a case. And PPSAT provided no evidence of any

woman seeking a post-12-week surgical abortion under one of the legal exceptions in any of their facilities since the new law went into effect. *See* Ex. 6, Chart of Surgical Abortions by Week and Facility; Ex. 2, Farris Dep. 23:22–25 ("I'm not personally aware of an abortion . . . that has been done past the 12th week that meets one of the exceptions."). Abortion doctors cannot invoke third-party standing on behalf of hypothetical women who are not their patients and do not seek their services.

II. Plaintiffs Will Not Suffer Irreparable Harm.

Plaintiffs are not entitled to extraordinary relief based on a mere possibility of irreparable harm. *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (per curiam). At the outset, Plaintiffs will not suffer irreparable harm because they lack standing for themselves and their patients. Further, "the required irreparable harm must be neither remote nor speculative, but actual and imminent." *Direx Israel, Ltd. v. Breakthrough Med. Corp.*, 952 F.2d 802, 812 (4th Cir. 1991) (cleaned up). At most, Plaintiffs allege that a small number of women may be required to wait a few more days to ensure that chemical abortion drugs can be safely administered to them in compliance with FDA guidance. Ex. 7, Chart of Chemical Abortions by Week and Facility (identifying only six women whose babies were under five weeks' gestation in 2023). This is not an irreparable injury.

Finally, discovery revealed that PPSAT performs post-14-week surgical abortions only in its Ashville and Chapel Hill facilities—cities that contain many hospitals (*i.e.*, not the rural areas that Plaintiffs assert lack a hospital). Ex. 6, Chart of Surgical Abortions by Week and Facility.

CONCLUSION

The North Carolina General Assembly enacted straightforward, rational protections for women who seek certain types of abortions. And for Plaintiffs to ask the Court to grant their Motion for Preliminary Injunction is to ask the Court to impermissibly "substitute [its] social and economic beliefs for the judgment of" these representatives. *See Dobbs* 142 S. Ct. at 2283–84. Intervenors respectfully request that the Court deny Plaintiffs' Motion.

RESPECTFULLY SUBMITTED THIS 12th day of September 2023.

<u>s/ W. Ellis Boyle</u>

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*** Notice of Special Appearance Filed

CERTIFICATE OF SERVICE

I hereby certify that on September 12, 2023, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system which will send a notice of electronic filing to all counsel of record.

<u>s/ W. Ellis Boyle</u> W. Ellis Boyle

CERTIFICATE OF WORD COUNT

I hereby certify that the foregoing brief complies with LR 7.3(d) and the word count set forth by the Court in its July 6, 2023 Scheduling Order (ECF No. 37). The foregoing brief contains 2,483 words.

<u>s/ W. Ellis Boyle</u> W. Ellis Boyle