

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA**

PLANNED PARENTHOOD SOUTH))	
ATLANTIC, <i>et al.</i> ,))	
)	
Plaintiff,))	
)	
v.))	Case No. 1:23-cv-480
)	
JOSHUA STEIN, <i>et al.</i> ,))	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 life-threatening 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 Leaf 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 do—even 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 life-threatening 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 rational-basis 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 ¶¶ 49, 50, 51, 52; 65-1 at ¶ 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 Intervenor’s 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 Asheville 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.

s/ W. Ellis Boyle

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Attorneys for Intervenor-Defendants

**** 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.

s/ W. Ellis Boyle
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.

s/ W. Ellis Boyle
W. Ellis Boyle

Exhibit 1

Post 12-week Complications Resulting in Hospital Transfer for 1/1/2020-6/30/2023

Complication	Weeks LMP	Health Center	Year	Hospital Status
Bleeding/Hemorrhage	14	Chapel Hill Health Center	2020	Treated & released in stable condition
Incomplete AB	13	Winston-Salem Health Center	2020	Treated & released in stable condition
Bleeding/Hemorrhage	21	Chapel Hill Health Center	2020	Admitted for treatment & released in stable condition
Incomplete AB	14	Chapel Hill Health Center	2020	Treated & released in stable condition
Incomplete AB	13	Winston-Salem Health Center	2020	Treated & released in stable condition
Bleeding/Hemorrhage	15	Chapel Hill Health Center	2021	Treated & released in stable condition
Incomplete AB	12	Asheville Health Center	2021	Treated & released in stable condition
Bleeding/Hemorrhage	15	Chapel Hill Health Center	2022	Admitted for treatment & released in stable condition
Bleeding/Hemorrhage	17	Chapel Hill Health Center	2022	Treated & released in stable condition
Bleeding/Hemorrhage	19	Chapel Hill Health Center	2022	Treated & released in stable condition
Incomplete AB	19	Chapel Hill Health Center	2022	Treated & released in stable condition
Bleeding/Hemorrhage	14	Asheville Health Center	2022	Treated & released in stable condition

Post 12-week Complications Resulting in Hospital Transfer for 1/1/2020-6/30/2023

Complication	Weeks LMP	Health Center	Year	Hospital Status
Bleeding/Hemorrhage	17	Chapel Hill Health Center	2023	Treated & released in stable condition
Bleeding/Hemorrhage	17	Chapel Hill Health Center	2023	Treated & released in stable condition
Bleeding/Hemorrhage	19	Chapel Hill Health Center	2023	Treated & released in stable condition
Bleeding/Hemorrhage	17	Chapel Hill Health Center	2023	Admitted for treatment & released in stable condition
Syncope	19	Chapel Hill Health Center	2023	Treated & released in stable condition

Exhibit 2

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
CIVIL ACTION FILE NO. 1:23-CV-480

Planned Parenthood South)
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)

VIDEOTAPED DEPOSITION
OF
KATHERINE A. FARRIS, MD

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09-01-2023
10:11 O'CLOCK A.M.

Laura Baker
Court Reporter
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1 2023, you would agree that PPSAT North Carolina was
2 performing surgical abortions on patients in their 13th
3 week and later gestational age and charging money to
4 perform those abortions, right?

5 A. Prior to July 1st, Planned Parenthood South
6 Atlantic was performing procedural abortions beyond the
7 12th week of pregnancy and charging for those
8 abortions, yes.

9 Q. And this law, this change in the law, has
10 caused PPSAT to lose the income that it made from
11 charging those patients for those abortions, right?

12 MS. SWANSON: Objection to form.

13 THE WITNESS: I am not aware of what our
14 income balance is since the change in the law.

15 Q. (Mr. Boyle) Well, you're aware that if you
16 were performing those abortions before and charging
17 money and getting paid for them, and now you're not,
18 you've lost that money, right?

19 MS. SWANSON: Objection to form.

20 THE WITNESS: I am not aware of what
21 money or what our income has been since the change in
22 the law.

23 Q. (Mr. Boyle) Yes, I'm not asking about your
24 general income or your general balance sheet. I'm
25 saying, the simple fact is, if you were doing those

1 abortions and charging money for them before, and now
2 you no longer are, you've lost that money that you made
3 before, correct?

4 MS. SWANSON: Objection to form.

5 THE WITNESS: I think that would require
6 me to speculate, because we've changed the services we
7 provide since the law went into effect, and I can't
8 speculate as to the exact impact that has had on our
9 income.

10 Q. (Mr. Boyle) I'm not asking you to compare
11 income. I'm just asking if you simply lose revenue
12 from that potential source if you're no longer doing
13 it.

14 MS. SWANSON: Objection to form.

15 THE WITNESS: I can state that we are
16 not charging for abortions that we are not performing,
17 and we are not performing abortions, routinely, beyond
18 the 12th week of pregnancy since the law went into
19 effect.

20 Q. (Mr. Boyle) You just said, "routinely." Are
21 you performing them at all?

22 A. Legally, we can perform them. And I'm not
23 personally aware of an abortion that has done -- that
24 has been done past the 12th week that meets one of the
25 exceptions.

1 Q. So as I understand your testimony, you're
2 saying that it's possible that an abortion after the
3 12th week that meets one of the exceptions under the
4 new law has been performed at a PPSAT clinic since July
5 1st leading up to today, September 1st, but you're just
6 not aware of that.

7 A. Correct.

8 Q. Okay. I just want to clarify. If you were
9 making money doing that type of abortion before July
10 1st when the law in effect, and now you're no longer
11 doing it, you would agree that you've lost at least
12 that money that you were able to make and charge for
13 those abortions that you're not able to make and charge
14 now, correct?

15 MS. SWANSON: Objection to form.

16 THE WITNESS: I would not characterize
17 that I -- that PPSAT has lost money. I would
18 characterize that PPSAT is not charging for procedures
19 that we are not performing.

20 Q. (Mr. Boyle) PPSAT is a nonprofit. Is that
21 correct?

22 A. Yes, that's correct.

23 Q. Does it provide any charity care to patients?

24 MS. SWANSON: Objection to form.

25 THE WITNESS: I am not deeply involved

1 is just anterior to the uterus in most patients,
2 although there can be a space, and often is a space,
3 between the uterus and the bladder; and the intestines
4 can be in the space generally surrounding the uterus.

5 Q. (Mr. Boyle) Any other organs that would be
6 immediately adjacent to the uterus, if there was a
7 uterine perforation?

8 A. Those are the organs that are closest to the
9 uterus.

10 Q. You would agree that uterine perforation is a
11 known complication of a surgical abortion, wouldn't
12 you?

13 A. Uterine perforation is an extremely rare but
14 known complication of procedural abortion.

15 Q. Have you ever had a patient who you performed
16 a surgical abortion on who suffered from a uterine
17 perforation?

18 A. I have had a patient that I performed a
19 procedural abortion on who had a uterine perforation.

20 Q. Did you have to transfer the patients, who
21 you performed a surgical abortion on who suffered a
22 uterine perforation from the Planned Parenthood clinic,
23 to the hospital?

24 A. No, I did not.

25 Q. You -- are you aware that sometimes, if a

1 patient has a uterine perforation during a surgical
2 abortion, it's required that they be transferred to a
3 hospital for higher level of care?

4 MS. SWANSON: Objection to form.

5 THE WITNESS: I am aware that there are
6 some cases of uterine perforation where the patient
7 does need to be transferred to a hospital for
8 additional care.

9 Q. (Mr. Boyle) Has that ever happened at PPSAT?

10 A. Yes, it has.

11 Q. Did you know before the surgical abortion was
12 performed that those patients who suffered a uterine
13 perforation would require transfer to the hospital
14 based on that known complication?

15 MS. SWANSON: Objection to form.

16 THE WITNESS: I just want to clarify.
17 Are you asking if I knew in advance that a patient
18 would experience a uterine perforation and require
19 transfer?

20 Q. (Mr. Boyle) That is what I'm asking.

21 A. No, it is not possible to know that in
22 advance.

23 Q. Because you can't always know what
24 complications will arise during a surgical procedure,
25 can you?

1 A. It is true that with any procedure, you
2 cannot always predict accurately what complications may
3 arise.

4 Q. What is a cervical laceration?

5 A. A cervical laceration is a tear of the
6 cervix.

7 Q. You agree that a cervical laceration is a
8 known complication of surgical abortion, don't you?

9 A. I would agree that a cervical laceration is
10 an extremely rare but known complication of procedural
11 abortion.

12 Q. Have you ever had a patient, who you
13 performed a surgical abortion on, who suffered from a
14 cervical laceration?

15 A. I would say that I have had a patient who
16 suffered from some bleeding associated with the
17 instruments we use on the cervix, but I've never had a
18 cervical laceration that required interventions such as
19 suturing.

20 Q. Do some patients who suffer the known
21 complication of surgical laceration during a surgical
22 abortion require transfer to a hospital for a higher
23 level of care?

24 MS. SWANSON: Objection to form.

25 THE WITNESS: I'm not aware of patients

1 needing to be transferred for cervical laceration.

2 Q. (Mr. Boyle) Are you aware of any patient
3 from PPSAT who suffered a cervical laceration during a
4 surgical abortion having to be transferred to a
5 hospital to care for that known complication?

6 A. I do not recall any patient with a cervical
7 laceration having to be transferred for that
8 complication.

9 Q. Have you ever had a situation where you
10 performed a surgical abortion on a patient and the
11 patient suffered hemorrhaging such that you needed to
12 transfer that patient to a hospital for higher level of
13 care?

14 A. I have had a patient who hemorrhaged during a
15 procedural abortion who I transferred to the hospital
16 for care, yes.

17 Q. Is hemorrhage a known complication of
18 surgical abortion?

19 A. Hemorrhage is an extremely rare and known
20 complication of procedural abortion.

21 Q. Are you aware of other patients from PPSAT
22 who have suffered hemorrhage during a surgical abortion
23 that were transferred to a hospital for a higher level
24 of care?

25 A. I am aware of patients who have suffered

1 hemorrhage during a procedural abortion who have been
2 transferred to a hospital.

3 Q. Did you know, before the surgical abortion
4 was performed, that those patients who suffered
5 hemorrhage that required transfer to the hospital would
6 have that complication during that surgical abortion?

7 A. No. You cannot know in advance what
8 complication a patient may experience from any given
9 procedure.

10 Q. Do you disclose all possible complications
11 that can arise from an induced abortion to a woman who
12 has tested pregnant, who has tested positive for
13 pregnancy, who is your patient considering obtaining an
14 induced abortion?

15 A. We disclose the most common and most
16 concerning potential complications to patients as part
17 of their informed consent.

18 Q. And tell me, what -- how many days is the
19 waiting period now, under the new law, SB20 and HB190,
20 for informed consent for a patient seeking an induced
21 abortion before the induced abortion can actually
22 occur?

23 MS. SWANSON: Objection to form.

24 THE WITNESS: My understanding of the
25 current law is that it requires a 72-hour waiting

1 period from the time the State consent form is reviewed
2 by the patient and signed and when the abortion takes
3 place.

4 MR. BOYLE: I'm going to hand you a
5 document that has Bates numbers that was produced in
6 discovery.

7 MS. SWANSON: Thank you.

8 Q. (Mr. Boyle) It's Bates Numbers 31 through
9 50. If you don't mind, down at the bottom right-hand
10 corner, do you see Bates and then numbers there?

11 A. I do see those numbers, yes.

12 Q. And the first page says Bates 31. Do you see
13 that?

14 A. I do see that, yes.

15 Q. And then if you turn to the last page,
16 please, you see Bates 50?

17 A. Yes, I do see that.

18 Q. Okay. So do you recognize this document?

19 A. Yes, I do.

20 Q. What is it?

21 A. This is our education and consent packet for
22 procedural abortion.

23 Q. Can a patient die from complication of
24 bleeding if there is a cervical laceration or a uterine
25 perforation or hemorrhage?

1 correct?

2 A. This is a signature page. We don't actually
3 use paper forms for signature. We use an electronic
4 health record, so we use an electronic version of this
5 form, unless our electronic health system is down, and
6 then we use the paper form. But the patient does sign
7 an electronic version of this form, yes.

8 Q. Is the electronic version of this form
9 exactly the same format as this paper copy here, this
10 34, 35 and 36?

11 MS. SWANSON: Objection to form.

12 THE WITNESS: I would -- I can't speak
13 to the exact format, but it contains the same
14 information. We use this form to create the electronic
15 form.

16 Q. (Mr. Boyle) So you don't actually hand a
17 patient this piece of paper, this three-page document.
18 Is that what you're saying?

19 A. No, that is not what I'm saying. I do hand
20 the patient this three-page document. We at Planned
21 Parenthood hand the patient this document.

22 Q. Okay. So someone at -- at PPSAT hands the
23 patient a three-page document that looks like Bates
24 Number 34, 35 and 36, and that patient then has that
25 hard copy paper document to take with them? Is that

1 correct?

2 A. It is correct that the patient receives a
3 paper copy of this document before they leave the
4 clinic -- or actually, when they are arriving and going
5 through consent.

6 Q. Okay. Do the -- does the patient receive a
7 signed copy of this document?

8 A. The patient does not routinely receive a copy
9 of this form that they have signed, but they may
10 receive a copy, if they would like, that can be printed
11 from the EHR for them if they request it.

12 Q. So when the patient signs an electronic copy
13 of this document, is the patient looking at a computer
14 screen and having the opportunity to read all three
15 pages before they sign, or do they have a paper copy?
16 What's the method for that?

17 A. They have both. They have a paper copy in
18 front of them, and they can see the electronic form as
19 it is being filled out and they are signing it.

20 Q. And who goes over this document with the
21 patient?

22 A. A trained staff member.

23 Q. What level of training does that staff member
24 have?

25 MS. SWANSON: Objection to form.

1 THE WITNESS: They are -- they can have
2 a variety of backgrounds of training, but they are
3 specifically trained in the process of Planned
4 Parenthood South Atlantic's informed consent.

5 Q. (Mr. Boyle) Is that person who undertakes
6 informed consent with the patient, is that a nurse? Is
7 that a PA? Is that an MD doctor? What level of
8 training do they have?

9 A. It varies based on which aspect of informed
10 consent you're referring to.

11 Q. Okay. How about this aspect with this three-
12 page document? What level of PPSAT employee -- in
13 terms of training for that employee, what level of
14 employee is engaging with the patient to ensure
15 informed consent is obtained?

16 A. It can be multiple levels. I've had nurses
17 or physicians who participate in that. Routinely, it
18 is not a licensed person who is going over the form.
19 It is someone who is trained specifically in the
20 process of consent who had -- goes over the form with
21 the patient.

22 Q. Does the law speak to who has to interact
23 with a patient, what level of training that person has,
24 in order to ensure informed consent is indeed proper
25 and legal?

1 MS. SWANSON: Objection to form.

2 THE WITNESS: So the second category I
3 referred to, we call a probably intrauterine pregnancy.
4 And I don't know how to answer the question, "Is there
5 a different differential diagnosis?" I'm not really
6 clear what you're asking.

7 Q. (Mr. Boyle) Is your differential diagnosis
8 the same or different compared -- Category 1 to
9 Category 2?

10 MS. SWANSON: Objection to form.

11 THE WITNESS: I would say it was
12 different. One of the common ways we would see a
13 probably intrauterine pregnancy would be in someone who
14 had a large, empty uterine sac. And depending on the
15 size of that sac, would make us either suspicious for,
16 or clinically certain, that the patient was
17 experiencing a miscarriage.

18 Q. (Mr. Boyle) Okay. How about for Category 3,
19 which I believe you said was an ultrasound that
20 definitely showed an ectopic pregnancy? What's your
21 differential diagnosis for that patient?

22 MS. SWANSON: Objection to form.

23 THE WITNESS: I would consider that
24 patient to have an ectopic pregnancy or a pregnancy
25 outside the uterus.

1 Q. (Mr. Boyle) And what would you do as a
2 result of that?

3 A. If I see a patient with an ectopic pregnancy,
4 I refer them for treatment of that pregnancy.

5 Q. Refer them where?

6 A. Either to their primary gynecologist, if
7 that's their preference, and they're able to see them
8 quickly, or to a hospital for care.

9 Q. Because an ectopic pregnancy is a life-
10 threatening risk for a patient, isn't it?

11 MS. SWANSON: Objection to form.

12 THE WITNESS: An ectopic pregnancy can
13 be life threatening if not treated, yes.

14 Q. (Mr. Boyle) Because it's a pregnancy growing
15 outside of the uterus, where it's supposed to be, and
16 it can cause -- if it's in the fallopian tubes, it
17 cause those to rupture and bleed, right?

18 A. That is one form of ectopic pregnancy. There
19 are many locations that an ectopic pregnancy can exist,
20 including technically within the uterus.

21 Q. Okay. And if you have -- well, the fourth
22 category would be an ultrasound that showed a suspected
23 ectopic pregnancy. How would your differential
24 diagnosis for that fourth category differ, if any way,
25 from the third category, where you actually identified

1 ectopic pregnancy?

2 A. So a probable ectopic pregnancy would mean
3 that I am seeing something outside of the uterus that I
4 am suspicious is ectopic, but I don't see
5 characteristics that absolutely confirm that that is a
6 pregnancy that I'm seeing versus some other structure
7 such as an ovarian cyst that's complex.

8 Q. And what would your differential diagnosis
9 -- what would you do with that patient, that Category
10 4?

11 (Knock at door)

12 Q. You can continue. You can continue. I'm
13 listening.

14 MR. BOYLE: Thanks.

15 THE WITNESS: Differential diagnosis and
16 treatment are two very different things. Would you
17 like me to answer what the differential diagnosis was
18 or what I would do for it?

19 Q. (Mr. Boyle) Start with the differential,
20 yes.

21 A. So the differential diagnosis of a probable
22 ectopic pregnancy is would be that there is an ectopic
23 pregnancy that I can't definitely diagnosis or that
24 there is some other structure outside of the uterus
25 that I -- that could be a complex ovarian cyst, it

1 their gynecologist or an emergency room so that she can
2 get worked up further, and they can rule it out or rule
3 it in. Is that fair?

4 MS. SWANSON: Objection to form.

5 THE WITNESS: If a patient has a
6 definite or probable ectopic pregnancy, that means that
7 I am concerned about a potentially life-threatening
8 condition, and I would refer them for further immediate
9 evaluation.

10 Q. (Mr. Boyle) A patient with the fifth
11 category, pregnancy of unknown location, could that be
12 an ectopic pregnancy?

13 A. It could be.

14 Q. Are you suspicious that it might be an
15 ectopic pregnancy?

16 MS. SWANSON: Objection to form.

17 THE WITNESS: No. If I'm suspicious
18 that it might be an ectopic pregnancy, then I would
19 consider it a probable or definite ectopic pregnancy.

20 Q. (Mr. Boyle) So if you have a pregnancy of
21 unknown location on an ultrasound, you're not seeing an
22 actual pregnancy or possible pregnancy either in the
23 uterus or outside the uterus, correct?

24 A. Correct.

25 Q. Doesn't that raise your suspicion that that

1 patient could have an ectopic pregnancy, because you
2 haven't ruled it out?

3 MS. SWANSON: Objection to form.

4 THE WITNESS: When I have a patient who
5 has a probable -- or, pardon me, who has a pregnancy of
6 unknown location, I consider three -- the most common
7 three possibilities in my differential diagnosis: that
8 they have an early intrauterine pregnancy that is not
9 yet visible; that they have an early intrauterine
10 pregnancy that is undergoing miscarriage; or that they
11 have an ectopic pregnancy that is not yet visible.

12 Q. (Mr. Boyle) So when you have a Category 5,
13 pregnancy of unknown location, on an ultrasound, part
14 of your differential diagnosis is Number 3, that they
15 may have an ectopic pregnancy that you just can't see
16 yet?

17 A. That is correct. That is part of the
18 differential diagnosis.

19 Q. Unless they are discovered and treated early,
20 you would agree that almost 40 percent of ectopic
21 pregnancies rupture suddenly, causing pain and bleeding
22 in the abdominal cavity, wouldn't you?

23 A. I do not have that data.

24 Q. You don't know that data?

25 A. I do not know that statistic off the top of

1 my head.

2 Q. You would agree, at least, that ruptured
3 ectopic pregnancies can be fatal, wouldn't you?

4 A. I would agree.

5 Q. At least 2 percent of pregnancies are ectopic
6 pregnancies. Isn't that right?

7 A. The categorization I have heard is that up to
8 2 percent of pregnancies are ectopic pregnancies.

9 Q. We were talking about ACOG before. Are you
10 familiar with ACOG Practice Bulletin 193?

11 A. I would have to look at it to know.

12 Q. You don't know it just off the top of your
13 head?

14 A. Not from a number.

15 Q. Okay.

16 MR. BOYLE: I'm going to hand you a
17 document.

18 MS. SWANSON: Thank you.

19 MR. BOYLE: You're welcome.

20 Q. (Mr. Boyle) Take your time, review that
21 please, and let me know when you're ready to identify
22 it.

23 A. I have not read it in detail, but I am -- I
24 do have it in front of me.

25 Q. Okay. Are you able to identify what this is,

1 Q. Okay. If you look over that Risk Factor
2 section on the first page, I'm going to read you a
3 sentence and ask you about that. First sentence says,
4 quote, "One-half of all women who receive a diagnosis
5 of an ectopic pregnancy do not have any known risk
6 factors," end quote. Do you see that?

7 A. I do see that.

8 Q. So you would agree that it's possible that a
9 woman who comes into a PPSAT clinic has an ectopic
10 pregnancy but doesn't have any known risk factors for
11 that ectopic pregnancy?

12 A. Yes, that is possible.

13 Q. And the gold standard to test and look for an
14 ectopic pregnancy is to conduct a transvaginal
15 ultrasound and see if there is an embryo or fetus seen
16 in the uterus. Isn't that right?

17 A. I don't know ---

18 MS. SWANSON: Object to form.

19 THE WITNESS: --- what you mean by,
20 "gold standard."

21 Q. (Mr. Boyle) You don't use the word -- the
22 term "gold standard" in your medical practice?

23 A. I would not use the term "gold standard" in
24 this context.

25 Q. Do you use it in any context in your medical

1 practice?

2 MS. SWANSON: Objection to form.

3 THE WITNESS: I don't know that I --
4 it's not a -- it's not a term that I routinely use, no.
5 I would say that ultrasound is a critical factor in
6 diagnosis of ectopic pregnancy.

7 Q. (Mr. Boyle) I will accept that. If you turn
8 to the second page of this Bulletin 193, under Clinical
9 Considerations and Recommendations, How is an Ectopic
10 Pregnancy Diagnosed; you see that section?

11 A. I do see that section.

12 Q. Okay. You see the sentence that says, quote,
13 "The minimum diagnostic evaluation of a suspected
14 ectopic pregnancy is transvaginal ultrasound evaluation
15 and confirmation of pregnancy," end quote. Do you see
16 that?

17 A. I do.

18 Q. So ACOG requires, according to this Bulletin,
19 that in order to rule in or rule out an ectopic
20 pregnancy, you have to have an ultrasound that shows
21 the pregnancy. Is that correct?

22 A. That ---

23 MS. SWANSON: Objection to form.

24 THE WITNESS: That's not actually what
25 it's saying. What it's saying is that the minimum

1 diagnostic evaluation, so the minimum you must do if
2 you suspect ectopic pregnancy, is a transvaginal
3 ultrasound evaluation.

4 And when they say, "and confirmation of
5 pregnancy," they mean that if you do a transvaginal
6 ultrasound but you haven't done another test to confirm
7 that the patient is pregnant, such as a urine or blood
8 pregnancy test, then it's not as useful.

9 For example, if a patient had a negative
10 pregnancy test, then the -- the transvaginal ultrasound
11 wouldn't be helpful. So if you do a transvaginal
12 ultrasound and don't see a pregnancy, you would next do
13 a pregnancy test to see if the patient was even
14 pregnant.

15 Q. (Mr. Boyle) So you think that sentence
16 there, that's talking clearly about ultrasound, means
17 that a doctor doesn't have to actually confirm the
18 pregnancy with the ultrasound? That's how you
19 interpret that sentence?

20 MS. SWANSON: Objection to form.

21 THE WITNESS: No. What I am saying is
22 that this sentence says that you must do an ultrasound,
23 and you must also confirm that the patient is pregnant.
24 Because often, for example, in pregnancy of unknown
25 location, you will do an ultrasound and not see a

1 over, Serum Human CH -- CG -- HCG, sorry. Serum HCG
2 Measurements, do you see that?

3 A. I see that.

4 Q. It says, quote, "Measurement of the Serum HCG
5 levels aids in the diagnosis of women at risk of
6 ectopic pregnancy. However, Serum HCG values alone
7 should not be used to diagnosis an ectopic pregnancy
8 and should be correlated with the patient's history,
9 symptoms, and the ultrasound findings," end quote.

10 Do you see that?

11 A. I see that.

12 Q. So doesn't that say that you have to see an
13 ectopic pregnancy by an ultrasound, either saying it's
14 intrauterine or it's not?

15 MS. SWANSON: Objection to form.

16 THE WITNESS: No, that's not at all what
17 it says.

18 Q. (Mr. Boyle) Okay. If you have a woman who
19 has tested pregnant -- tested positive for pregnancy,
20 and you take an ultrasound of her and you don't see a
21 fetus or an embryo anywhere on that ultrasound, doesn't
22 that actually raise your suspicion for her having an
23 ectopic pregnancy on that differential diagnosis you
24 were discussing earlier?

25 A. Yes, it does increase my suspicion for

1 ectopic pregnancy if I do not see a pregnancy either
2 inside or outside of the uterus, including a
3 gestational sac, not just a fetus or embryo.

4 Q. Okay. When you're treating a -- a woman
5 who's tested positive for pregnancy, but she has a
6 confirmed ectopic pregnancy, you don't provide her with
7 the two chemical abortion drugs, do you?

8 A. That is correct. We do not treat anyone with
9 a confirmed ectopic pregnancy with medication abortion
10 medications.

11 Q. Because mifeprax (sic) and misoprostol are
12 drugs that do not assist a woman in treating her for
13 her ectopic pregnancy, are they?

14 MS. SWANSON: Object to form.

15 THE WITNESS: Mifepristone and
16 misoprostol, as used in medication abortion, are not
17 effective in treating ectopic pregnancy.

18 Q. (Mr. Boyle) And the FDA label says that they
19 are contraindicated in patients with confirmed or
20 suspected ectopic pregnancies, doesn't it?

21 A. I don't know what the FDA label says without
22 looking at it.

23 Q. You've prescribed these medications several
24 times every week for the past 14 years, correct?

25 A. That is correct.

1 Q. And you are unaware that the FDA label says
2 that they are contraindicated for a woman who has an
3 actual diagnosed or suspected ectopic pregnancy?

4 MS. SWANSON: Object to form.

5 THE WITNESS: I cannot directly quote
6 the FDA label without looking at it. I am aware that
7 we do not use mifepristone and misoprostol, as designed
8 for medication abortion, in patients with known or
9 suspected ectopic pregnancy.

10 Q. (Mr. Boyle) A patient who has a suspected
11 ectopic pregnancy needs to be worked up to see if she
12 needs surgical treatment for her ectopic pregnancy or
13 if she qualifies for a different drug treatment,
14 methotrexate, right?

15 A. There are different treatments for ectopic
16 pregnancy, and those treatments should be offered based
17 on the patient's exact circumstances, yes.

18 Q. Typically, the drug you give for ectopic
19 pregnancy is methotrexate, not the two chemical
20 abortion drugs, right?

21 A. I do not treat ectopic pregnancy, but it
22 is -- you do not use mifepristone and misoprostol to
23 treat ectopic pregnancy. Methotrexate is one of the
24 medications that can be used to treat ectopic
25 pregnancy.

1 Q. If you give a woman who tests positive for
2 pregnancy, who is actually suffering from an ectopic
3 pregnancy, the chemical abortion drugs, and it does not
4 stop her ectopic pregnancy from growing, that ectopic
5 pregnancy can rupture, possibly in her fallopian tubes
6 or some other internal structure, causing damage and
7 bleeding inside her abdomen. Isn't that right?

8 MS. SWANSON: Object to form.

9 THE WITNESS: Any woman who has an
10 ectopic pregnancy, that ectopic pregnancy can rupture
11 if it is not treated, regardless of whether the patient
12 receives mifepristone and misoprostol or not.

13 Q. (Mr. Boyle) That's fair. But the
14 prescription of those two drugs wouldn't have any
15 impact on whether that ectopic pregnancy will continue
16 to grow and possibly rupture, right?

17 A. I don't believe it's been extensively
18 studied, but we do not treat ectopic pregnancy with
19 mifepristone and misoprostol. There's a possibility
20 that they could stop the growth theoretically, but we
21 do not use it for that purpose.

22 Q. Okay. I appreciate that there may be further
23 research to be done, but there's none that you're aware
24 of that has been done to suggest that's an appropriate
25 treatment regimen for ectopic pregnancy. Is that

1 correct?

2 MS. SWANSON: Object to form.

3 THE WITNESS: I am unaware that anyone
4 would use mifepristone and misoprostol to treat a known
5 or suspected ectopic pregnancy.

6 Q. (Mr. Boyle) You agree that many of the
7 symptoms of a ruptured ectopic pregnancy mimic, or are
8 exactly the same as, the expected side effects of a
9 chemical abortion that you or one of your colleagues at
10 PPSAT have counseled your patient could occur if you
11 give that patient a chemical abortion, right?

12 MS. SWANSON: Object to form.

13 THE WITNESS: There are some overlapping
14 symptoms between the normal symptoms we expect with
15 medication abortion and the symptoms of an ectopic
16 pregnancy.

17 Q. (Mr. Boyle) It's possible that a patient who
18 took chemical abortion drugs and then suffered a
19 ruptured ectopic pregnancy, leading to internal
20 bleeding and vaginal bleeding, pain, dizziness,
21 headache, could misconstrue or confuse those symptoms
22 of the ectopic pregnancy with the normal expected side
23 effects of the chemical abortion, as it was described
24 to her by her doctor or other provider at PPSAT. Isn't
25 that true?

1 MS. SWANSON: Object to form.

2 THE WITNESS: It would be important to
3 educate any patient on whom we have not diagnosed an
4 intrauterine pregnancy, who takes mifepristone and
5 misoprostol, on the normal symptoms that they would
6 experience with a medication abortion and on the
7 abnormal symptoms that they might experience, including
8 detailed education on the symptoms of ectopic
9 pregnancy.

10 Q. (Mr. Boyle) But they might confuse a
11 ruptured ectopic pregnancy for the normal side effects
12 from the chemical abortion process, correct?

13 MS. SWANSON: Object to form.

14 THE WITNESS: I can't speculate on who
15 might get confused by what. It is important to give
16 clear education and closely follow up with patients.

17 Q. (Mr. Boyle) If you look at the document,
18 please, at, let's see, Bates 31, on the first page
19 there.

20 MS. SWANSON: And for the record, we're
21 now switching back to the patient education packet from
22 the ACOG bulletin.

23 Q. (Mr. Boyle) Right. Bates 31. Do you see
24 that?

25 A. I see that form, yes.

1 treated as a transient state. An effort should be made
2 to establish a definitive diagnosis when possible," end
3 quote.

4 Do you see that?

5 A. I see that statement.

6 Q. So does that inform your opinions about what
7 was going on back in 2018, as it relates to how to
8 diagnosis and treat a patient with -- or ultrasound of
9 pregnancy of unknown location?

10 MS. SWANSON: Object to form.

11 THE WITNESS: I would state that it is
12 true now that we should make efforts to establish a
13 definitive diagnosis when possible. We are just not
14 required to make those efforts in isolation.

15 Q. (Mr. Boyle) And I did not mean to interrupt
16 you in your review of -- I apologize, I did interrupt
17 you. I'm sorry.

18 You were looking at Bates Number 102, Bates
19 Number 103 and Bates Number 104 to tell us if there was
20 any recent research identified by PPSAT that would
21 support its position that it is acceptable medical
22 practice to provide chemical abortion drugs
23 simultaneous with a patient who has a diagnosis or a
24 transient state of pregnancy of unknown location on an
25 ultrasound.

1 MS. SWANSON: Object to form. I'm not
2 sure there's a question in there.

3 Q. (Mr. Boyle) The question is: show it to me,
4 please.

5 MS. SWANSON: Object to form.

6 THE WITNESS: So I do not see some of
7 the articles that I know are used to create those
8 protocols. I also don't think that the list of table
9 references are the sole source of the protocols.

10 Q. (Mr. Boyle) And that's fine. I was just
11 basing that off of what I understood you to say, that
12 they were. If you're saying they're not, then there
13 may be other things out there that go into the
14 protocols. Is that what you're saying?

15 Maybe other research out there -- I
16 apologize, maybe other research out there that goes
17 into making these protocols that's not included at the
18 end in that table?

19 A. There is much research and expert analysis
20 that goes into making these. I do not personally
21 create these protocols, so cannot speak to all of the
22 details.

23 Q. You would agree that induced abortions,
24 surgical abortions, become more complicated after the
25 gestational age is beyond 14 weeks, wouldn't you?

1 MS. SWANSON: Object to form.

2 THE WITNESS: The complexity of a
3 procedural abortion varies throughout gestational
4 duration. And over seven or eight weeks, I would say
5 that there is an incremental increase in complexity of
6 the procedure with increasing gestational duration.

7 Q. (Mr. Boyle) You cited the "Academies of
8 Medicine" article, and it says that "The risk of
9 serious complication increases with weeks gestation; as
10 the number of weeks increase, the invasiveness of
11 required procedure and the need for deeper levels of
12 sedation also increase."

13 Do you agree with that?

14 MS. SWANSON: Object to form.

15 THE WITNESS: I can't agree that that's
16 the exact quote without looking at the actual document.
17 I do agree that there is an incremental increase in
18 risk as gestational duration increases.

19 Q. (Mr. Boyle) I'm sorry, I'm working through
20 here.

21 You agree that some second trimester induced
22 abortions must take place in a hospital setting, don't
23 you?

24 MS. SWANSON: Object to form.

25 THE WITNESS: I would agree that some

1 abortions, regardless of gestational duration, must
2 take place in a hospital.

3 Q. (Mr. Boyle) You would agree that anything
4 beyond moderate sedation -- I think we've discussed it.
5 But anything beyond moderate sedation anesthesia level
6 for a surgical abortion must happen in a hospital, not
7 at a PPSAT clinic, right?

8 MS. SWANSON: Object to form.

9 THE WITNESS: No, I would not agree to
10 that. Deep sedation can be offered in an outpatient
11 setting if you have the right equipment and staff.
12 PPSAT does not have the staff to perform deep sedation
13 in our outpatient clinics, but that doesn't preclude
14 the safety of performing it in a clinic that has that
15 staff.

16 Q. (Mr. Boyle) If a patient comes to PPSAT and
17 has an ultrasound, and it's an ultrasound of unknown --
18 pregnancy of unknown location, do you charge for an
19 additional -- does PPSAT charge for an additional
20 ultrasound if that patient gets an additional
21 ultrasound?

22 MS. SWANSON: Object to form.

23 THE WITNESS: Do you mean that if the
24 patient had an ultrasound at an outside location that
25 showed a pregnancy of an unknown location, and then we

1 performed an ultrasound, would we charge the patient
2 for the ultrasound we performed?

3 Q. (Mr. Boyle) I didn't mean that, but do you?

4 A. If we perform an ultrasound, yes, we charge
5 them for ---

6 Q. And if ---

7 A. --- the ultrasound performed.

8 Q. I'm sorry. If you come up with an ultrasound
9 of pregnancy of unknown location and you take another
10 one at PPSAT, do you charge for the second one also?

11 A. We do not routinely charge for repeat
12 ultrasounds that we feel are clinically necessary, no.

13 Q. So if you charge for an ultrasound and the
14 patient gets a second or even a third, you don't charge
15 for the second or the third. Is that correct?

16 A. It is my understanding that we do not
17 routinely charge for repeat ultrasounds that we deem
18 clinically necessary.

19 Q. Have you ever had a situation where you had a
20 patient with ultrasound finding of pregnancy of unknown
21 location, you gave that patient chemical abortion drugs
22 and then later, you determined that that patient had an
23 ectopic pregnancy?

24 A. Yes, that has occurred.

25 Q. Did you give that patient a refund for the

1 unnecessary procedure that you performed?

2 MS. SWANSON: Object to form.

3 THE WITNESS: The patient is charged for
4 the services they receive on the day they receive them,
5 so the patient paid for the services they received,
6 which included medications that they took.

7 Q. (Mr. Boyle) And you would agree that in that
8 circumstance, the medications that the patient paid for
9 were unnecessary, right?

10 MS. SWANSON: Object to form.

11 THE WITNESS: At the time that the
12 medications were given, we did not know that they were
13 unnecessary, so they were given in good faith.

14 Q. (Mr. Boyle) Absolutely. But had you waited,
15 eventually you were able to determine that that
16 particular patient had an ectopic pregnancy, right?

17 A. If it had been the patient's preference to
18 wait, we certainly could have waited and not done the
19 medication abortion yet.

20 Q. Well, you also could have just waited because
21 you don't know where the pregnancy is, regardless of
22 the patient's preference, right?

23 MS. SWANSON: Object to ---

24 Q. (Mr. Boyle) That's at least an option?

25 MS. SWANSON: Object to form.

Exhibit 3

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
CIVIL ACTION FILE NO. 1:23-CV-480

PLANNED PARENTHOOD SOUTH)
ATLANTIC, et al.,)
)
) Plaintiffs,)
)
) vs.)
)
) JOSHUA STEIN, et al.,)
)
) Defendants)
)
) and)
)
) PHILIP E. BERGER and TIMOTHY K.)
) MOORE,)
)
) Intervenor-)
) Defendants)

VIDEO CONFERENCE DEPOSITION
OF
CHRISTY MARIE BORAAS ALSLEBEN, MD

TAKEN VIA VIDEO CONFERENCE AT THE OFFICES OF:
CHAPLIN AND ASSOCIATES, INC.
NETWORKING WITH:
CAPE FEAR COURT REPORTING, INC.

08-29-2023
10:06 O'CLOCK A.M.

Gretchen Wells
Court Reporter

1 Parenthood North Central States and I also serve as
2 one of the associate medical directors. I am not the
3 chief medical officer of Planned Parenthood North
4 Central States.

5 Q. Do you know Dr. Farris personally?

6 A. I don't.

7 Q. Never met her at any Planned Parenthood
8 convention or seminar or anything like that?

9 A. I have never met her directly.

10 Q. Excluding the lawyers who represent the
11 Plaintiffs in this case, have you spoken to anyone
12 else, to include other doctors perhaps, about your
13 opinions in this case?

14 A. No. I mean, my husband knows I'm here, but
15 he -- he's not medical and he wouldn't know anything I
16 was speaking about if I tried to tell him.

17 Q. So you said you looked at Senate Bill 20 in
18 the process of developing your opinions. Did you see
19 where it defines possible complications that can arise
20 from an induced abortion at North Carolina General
21 Statue Section 90-21.81(2)a?

22 A. I mean, I'd have to see the text again to
23 say whether or not I reviewed that portion.

24 Q. Okay. What is a uterine perforation?

25 A. A uterine perforation is a known risk of

1 procedural abortion when an instrument goes into the
2 wall or through the wall of the uterus during the
3 procedure.

4 Q. When you say "instrument," what do you mean
5 by instrument?

6 A. A surgical instrument, either a suction
7 cannula or a forceps, typically.

8 Q. And how does that happen during a procedural
9 -- I'm sorry, surgical abortion?

10 A. How that happens, you know, really just
11 depends on the -- on the case. It is a very low risk.
12 It's a very -- it's a -- it's a known complication and
13 one that I counsel patients about, but it is not very
14 common.

15 Q. Do you agree that this is a possible
16 complication that can arise from an induced abortion,
17 surgical abortion, that should be disclosed to a
18 pregnant woman who is a patient considering that type
19 of abortion so that the patient can make an informed
20 decision with more complete knowledge of the risks of
21 the procedure?

22 MS. GRANDIN: Objection to form.

23 THE WITNESS: I believe all people
24 should -- that are pregnant and considering abortion
25 should be counseled on the risks and benefits of the

1 desired mode of abortion that they are considering.

2 Q. (Mr. Boyle) And who should inform the
3 patient of that potential risk?

4 A. I mean, our whole healthcare team takes onus
5 of that. But ultimately, it's my responsibility as
6 the treating physician to ensure that the patient has
7 good informed consent about the procedure that they
8 have selected.

9 Q. And how -- I'm sorry, when should that
10 patient be informed of this particular risk?

11 A. Prior to their procedural abortion.

12 Q. Are you aware that in -- under the North
13 Carolina law, there's a 72-hour informed consent
14 period where, after the initial counseling, the
15 patient has to wait 72 hours before the induced
16 abortion can occur?

17 A. I was not -- I'm -- I was not aware of that
18 mandatory counseling wait, but that is a common thing
19 that -- law that some patient -- some states have
20 enacted accepting and exceptionalizing the healthcare
21 that we provide during abortion care.

22 Q. What is a cervical laceration?

23 A. A cervical laceration is a tear that -- in
24 the cervix.

25 Q. And how -- well, do you agree that a

1 I think that's an intense word for what we're doing.

2 But I -- to, you know, get back to your
3 question, if that's what we're defining as curettage,
4 then I -- the last time I needed to use that in the
5 setting of a procedural abortion was -- I don't know.
6 It happens extremely rarely.

7 Q. (Mr. Boyle) Okay. With the D&E abortion,
8 after you have used the forceps to grasp and guide the
9 bigger portions of the fetus or baby out of the
10 uterus, what do you do after you -- you're done with
11 the forceps portion of the procedure?

12 A. Yeah, so once I'm confident that we have,
13 you know, nearly all the products of conception
14 evacuated safely from the uterus, then I would advance
15 a suction cannula to the fundus of the uterus, or the
16 top, and aspirate any remaining decidual tissue,
17 typically, that still remains within the uterus.

18 Q. When you say, "the fundus," or the top,
19 that's the part farthest away from the cervix, so sort
20 of up towards the rib cage and the lungs, that
21 direction of the body?

22 A. Yeah. I guess. It's the portion of the
23 uterus typically the furthest away both from me as the
24 operator, as the surgeon and, as you described, from
25 the cervix, yes.

1 Q. Is there anything else about the D&E
2 abortion procedure that you do that we didn't cover or
3 that we've missed?

4 MS. GRANDIN: Objection to form.

5 THE WITNESS: As far as the procedural
6 steps?

7 Q. (Mr. Boyle) Yes. The start to finish, how
8 it -- how it actually unfolds and your process.

9 A. Yeah, I mean, for every procedure, we would
10 start with a surgical timeout and make sure that the
11 healthcare team, you know, was all on the same page
12 and prepped and ready for the procedure that we
13 planned. We discuss, you know, the patient's wishes,
14 any allergies, planned anesthesia, type of specimen we
15 will have at the end. You know, we do many things.

16 But if you're talking about the procedure,
17 you know, the actual operating steps for me as
18 surgeon, then we've described those pretty much in
19 detail. The main last one is, you know, assessment of
20 hemostasis and ensuring that bleeding is appropriate.

21 Q. You mentioned anesthesia. What type of
22 anesthesia options are available for your patients who
23 you are performing a D&E abortion on?

24 MS. GRANDIN: Objection to form.

25 THE WITNESS: The patients that I see

1 have a -- a very wide range of anesthesia options.

2 Q. (Mr. Boyle) Such as?

3 A. Such as it is standard practice to ---

4 Q. Go ahead and drink water. I didn't mean to
5 interrupt you. I'm sorry.

6 A. Oh, that's okay.

7 Q. Take your time.

8 A. I got this one.

9 Q. Okay.

10 A. The standard practice, to use local
11 anesthesia by the cervix for all patients unless, for
12 example, a patient has a severe allergy. From there,
13 patients can opt for mild sedation with medicine or
14 moderate sedation with medicine, deep sedation with
15 medicine or a general anesthesia.

16 Q. So local anesthesia, what's the actual
17 anesthesia used there? Is it lidocaine or something
18 like that?

19 A. Yeah. Typically, in our current practice,
20 we use lidocaine plus or minus epinephrine.

21 Q. And that's standard for both aspiration and
22 D&E unless the patient has a known allergy. Is that
23 what I heard you say?

24 A. Yeah, generally, I think that's correct.

25 Q. Let's move on to the -- well, start at the

1 pregnancy and certainly with induced abortion as well.
2 It's typically -- it's typically referred to as
3 endometritis after a procedural abortion when we're
4 talking about a infection that's affecting the uterus.

5 Q. Okay. Would you agree that endometritis, an
6 infection of the uterus, is a possible complication
7 that can arise from an induced abortion?

8 A. Yes. A very rare one.

9 Q. Okay. Would you agree that a missed ectopic
10 pregnancy is a complication that can arise when you're
11 providing an induced abortion for a patient?

12 A. I mean, if -- ectopic pregnancy is a -- is a
13 reality of pregnancy in general. It's not more likely
14 to be associated with induced abortion versus a
15 population of people who aren't seeking an induced
16 abortion.

17 Q. Okay. The general consensus, I believe, is
18 that 2 percent of pregnant -- positive pregnancies are
19 ectopic pregnancies. Is that correct?

20 A. I think, depending on the population, the
21 exact point estimate differs, but somewhere between a
22 -- probably a half point -- a half a percent up to
23 three, depending on the population.

24 Q. And would you agree that a missed ectopic
25 pregnancy, without regard to what the general sort of

1 prevalence of it is in any given population, that a
2 missed ectopic pregnancy is a potential complication
3 that can arise with providing an induced abortion to a
4 patient?

5 A. I guess I'm not sure "missed" is the
6 appropriate terminology here. People who come for
7 induced abortion care are assessed for their risk of
8 ectopic pregnancy regardless of what setting I'm
9 working in in order to, you know, try to ensure the
10 person is safe.

11 Q. If you have a patient who receives -- who
12 you provide a chemical abortion to, and it's actually
13 -- the patient actually has an ectopic pregnancy, do
14 those two drugs that you provide the patient for the
15 chemical abortion have any effect on the ectopic
16 pregnancy?

17 A. The medicines that we use for medication
18 abortion do not -- are not treatment for an ectopic
19 pregnancy.

20 Q. So if the patient has an ectopic pregnancy
21 and you are unaware of that and you provide a chemical
22 abortion, that chemical abortion, those drugs, those
23 two drugs that you provide that patient will not stop
24 or end the ectopic pregnancy, will they?

25 A. So for a person that comes and requests a

1 medication abortion, we do extensive counseling about
2 the expectations around what they might experience if
3 they take the medicines, but also assess their risk
4 for ectopic pregnancy.

5 So we certainly wouldn't provide medications
6 for abortion like mifepristone and misoprostol if we
7 thought a person had an ectopic pregnancy.

8 Q. Right. But sometimes you miss an ectopic
9 pregnancy even if you do screening, right?

10 A. Sometimes, we're not able to diagnose it
11 because we can't see it.

12 Q. On an ultrasound, right?

13 A. If a person has an ultrasound.

14 Q. So sometimes a patient who comes to you and
15 asks for -- tests positive for pregnancy and asks for
16 a chemical abortion has an ectopic pregnancy that you
17 don't diagnose, and you give that patient the chemical
18 abortion drugs, right?

19 A. So if someone screens low risk or -- and
20 doesn't have an ultrasound or if a person has an
21 ultrasound and we don't see an ectopic pregnancy, then
22 those people can safely access medication abortion
23 with mifepristone and misoprostol with close follow-up
24 to ensure that the abortion was successful.

25 Q. But sometimes those people actually have an

1 ectopic pregnancy even if you think they were low risk
2 or you took an ultrasound and did not locate the
3 pregnancy. Is that correct?

4 A. Again, for a low-risk population, it's
5 certainly something we discuss with people. But
6 again, because the risk of ectopic pregnancy is so
7 low, it's irrational to not provide the care that the
8 person needs based on that very, very low risk unless
9 that's a risk that's not acceptable to the patient.

10 Q. And I understand the question you're
11 answering, but it's not really the question I'm
12 asking.

13 A. Okay. Let me try again.

14 Q. Yeah. The -- and I appreciate your answer.
15 It's fine. The question I am asking is, sometimes
16 when those patients come to you, even if they are low
17 risk after you screen them and even if you take an
18 ultrasound and you cannot locate the pregnancy
19 anywhere on the ultrasound: intrauterine, adnexa,
20 wherever, sometimes those patients will have an
21 ectopic pregnancy. Sometimes, it's too early to be
22 seen on ultrasound and you just might not see it yet,
23 but sometimes they will have an ectopic pregnancy,
24 right?

25 A. Some -- a very small percentage of those may

1 go on to eventually be diagnosed with an ectopic
2 pregnancy, yes.

3 Q. Okay. And in that situation, if you had a
4 patient who you felt it was safe to give the chemical
5 abortion drugs to even though they slipped through the
6 screening process somehow and actually have an ectopic
7 pregnancy, that particular patient who has ectopic
8 pregnancy and chemical abortion drugs, those chemical
9 abortion drugs don't do anything to stop the ectopic
10 pregnancy, do they?

11 A. Not that is generally known within the
12 medical community.

13 Q. Okay. Beyond unstudied and unsubstantiated
14 possibilities, you use methotrexate to actually
15 medically treat an ectopic pregnancy. Is that
16 correct?

17 A. If a patient comes to me and has a known
18 ectopic pregnancy, then I would -- based on, you know,
19 various patient-level characteristics, I would discuss
20 with that person their options for treatment, which
21 would include expectant management with very close
22 follow-up.

23 That meaning, you know, watch -- what
24 colloquially people call "watch and wait" with good
25 symptom assessment and, you know, kind of close

1 follow-up, or medication management with methotrexate
2 typically, or a surgical procedure to treat the
3 ectopic pregnancy.

4 Q. But in any event, the two chemical abortion
5 drugs don't stop an ectopic pregnancy if they're given
6 to a patient who actually has an ectopic pregnancy.
7 Is that correct?

8 A. Not that we know.

9 Q. Okay. You agree that misoprostol has an FDA
10 approval through ten weeks or 70 days. Is that
11 correct?

12 A. Excuse me, can ---

13 MS. GRANDIN: Objection to form.

14 THE WITNESS: Can you say that again?

15 Q. (Mr. Boyle) Do you agree that the FDA has
16 approved misoprostol through ten weeks or 70 days?

17 MS. GRANDIN: Objection.

18 THE WITNESS: Are you saying
19 misoprostol, like m-i-s-o-p-r-o ---

20 Q. (Mr. Boyle) Mispronouncing that ---

21 A. Okay.

22 Q. --- because I have a terrible
23 pronunciation ---

24 A. Oh, that's okay. I just wanted to make sure
25 that I know what you're saying.

1 THE COURT REPORTER: Back on the record
2 at 1:52 p.m.

3 Q. (Mr. Boyle) Okay. So, Doctor, do you have
4 that ACOG Practice Bulletin 193 from March 2018
5 available?

6 A. I do. I have it pulled up here in PDF on my
7 computer.

8 Q. Okay. Do you agree with the -- that ACOG
9 bulletin 193 that, quote, "Despite improvements in
10 diagnosis and management, ruptured ectopic pregnancy
11 continues to be a significant cause of
12 pregnancy-related mortality and morbidity.

13 "In 2011 to 2013, ruptured ectopic pregnancy
14 accounted for 2.7 percent of all pregnancy-related
15 deaths and was the leading cause of hemorrhage-related
16 mortality," end quote?

17 A. Gosh, that's a long sentence. If you could
18 point me kind of specifically in the document where
19 you're discussing, then I can ---

20 Q. Yeah. In the first page, "Background
21 Epidemiology," about halfway through that paragraph.

22 A. Okay.

23 Q. "Despite improvements..." Do you agree that
24 that's what the ACOG says on this topic?

25 A. Yep. That -- what you read there is written

1 here in that -- in this practice bulletin, yes.

2 Q. Is that -- and you agree with the ACOG
3 bulletin, right?

4 MS. GRANDIN: Objection to form.

5 THE WITNESS: You know, I haven't seen
6 any specific mortality data related to ectopic
7 pregnancy in those specific years, but I know ACOG
8 takes, you know, the production of their practice
9 bulletins very seriously.

10 Q. (Mr. Boyle) And you rely on these practice
11 bulletins in your practice to provide you with
12 clinical management guidelines, right?

13 A. As a -- as a starting point, sure. Yeah.
14 Yes.

15 Q. If you look under -- sorry. If you look
16 under the "Risk Factors" section, do you agree with
17 ACOG that, quote, "Half of all women who receive a
18 diagnosis of ectopic pregnancy do not have any known
19 risk factors," end quote?

20 A. Yes.

21 Q. And so a lot of women who actually end up
22 having an ectopic pregnancy don't have flags for known
23 risks for an ectopic pregnancy. Is that correct?

24 A. Based in their history, not necessarily
25 what's happening in their body currently, yes.

1 Q. At what stage in pregnancy do you normally
2 screen a woman for an ectopic pregnancy?

3 A. Well, certainly if I'm taking care of a
4 patient doing their prenatal care visit at 30 weeks, I
5 usually don't discuss ectopic pregnancy at that time.
6 I don't know if you're asking for a specific
7 gestational age week.

8 I try to assess -- you know, once a pregnant
9 person has had a positive test, a positive pregnancy
10 test, we -- one of the first things we do is talk
11 about how they're feeling in their body and ask about
12 last menstrual period to try to assess an estimated
13 gestational age of the pregnancy.

14 Q. And so as I understand it, whenever you
15 become aware that your patients has -- patient has
16 tested positive for pregnancy, you consider an ectopic
17 pregnancy as a risk on that patient's differential
18 diagnosis, right?

19 A. Generally speaking, sure. Yes.

20 Q. And you screen that patient as soon as you
21 become aware that they're pregnant for ectopic
22 pregnancy immediately, right?

23 A. I mean, we have -- in all the locations
24 where I work, we have -- we have, you know, kind of
25 general protocols about how to assess somebody's risk

1 for an ectopic pregnancy. One of which is, you know,
2 just talking about past history, as we've described.
3 The other is to talk about any current signs or
4 symptoms that might be concerning for an ectopic
5 pregnancy.

6 Q. And the gold standard to test and look for
7 an ectopic pregnancy is to conduct a transvaginal
8 ultrasound and see if there is an embryo or fetus
9 inside the uterus. Isn't that right?

10 MS. GRANDIN: Objection to form.

11 THE WITNESS: There are, you know, kind
12 of five main categories of early pregnancy. Much of
13 which can rely on ultrasonography.

14 Q. (Mr. Boyle) Yeah. My question was, the
15 gold standard to test and look for an ectopic
16 pregnancy is to conduct a transvaginal ultrasound and
17 see if there is an embryo or fetus seen in the uterus.
18 Isn't that right?

19 A. The only ---

20 MS. GRANDIN: Objection to form.

21 THE WITNESS: The only way to
22 definitively diagnose an ectopic pregnancy is to see
23 an embryo outside of the uterus with ultrasound. It
24 doesn't necessarily have to be a transvaginal one.

25 Q. (Mr. Boyle) Okay. So you can do a

1 ultrasound outside the woman's body ---

2 A. Again, it really -- it really just depends
3 on the patient characteristics. But yes, we, at
4 times, certainly can use transabdominal
5 ultrasonography also.

6 Q. You said the only time you can definitively
7 diagnose it is when you do the ultrasound and see the
8 ectopic pregnancy. Did I hear you correctly?

9 A. So what -- if we're using ultrasound in
10 early pregnancy, there are kind of five main diagnoses
11 we could come up with, right? The first is a definite
12 intrauterine pregnancy. The second is a probable
13 intrauterine pregnancy. The third is a pregnancy of
14 unknown location. The fourth is a probable ectopic
15 pregnancy. And the fourth is -- or the fifth, excuse
16 me, the fifth is a definite ectopic pregnancy.

17 Q. But under those categories, number one, if
18 you do the ultrasound and you see the pregnancy inside
19 the uterus, you've ruled out ectopic pregnancy there,
20 right?

21 A. In the -- in the vast majority of cases,
22 yes.

23 Q. You agree that you should always perform an
24 ultrasound on a patient you provide care to when they
25 test positive for pregnancy so that you can confirm if

1 just the word I chose.

2 Q. Okay. You're not trying to couch it in
3 terms of the law or the lawsuit when you say
4 irrational?

5 A. I'm not an attorney, so I don't -- I don't
6 know.

7 Q. Okay. Were you able to confirm that that
8 patient who you saw at gestational age three weeks was
9 pregnant?

10 A. (No audible answer)

11 Q. You mentioned earlier the earliest that you
12 had treated a patient -- a pregnant patient was three
13 weeks gestational age, right?

14 A. Yes.

15 Q. How were you able to confirm that patient
16 was three weeks gestational age pregnancy?

17 A. The patient reported a sure last menstrual
18 period, a history of regular, predictable menstrual
19 cycles that lasted -- that were consistent with, you
20 know, the -- her history of menstrual cycles, so we
21 were able to date the pregnancy that way.

22 And this particular patient that I'm
23 thinking about also had a urine pregnancy test in our
24 health center.

25 Q. Did you perform an ultrasound on that

1 patient?

2 A. I mean, again, I -- it's my -- it's our
3 standard practice to go through a protocol of
4 history-based screening to determine whether or not we
5 need to recommend an ultrasound for a person.

6 Q. You agree that induced abortion of any type
7 is more complicated after the unborn child reaches the
8 second trimester, don't you?

9 A. I'm -- I guess I'm not clear what you're
10 asking.

11 Q. Complications for induced abortions
12 increase, the risks increase the older the gestational
13 age, so when you get to the second trimester it is
14 more risky to perform an induced abortion in the
15 second trimester than the first trimester. Is that
16 correct?

17 A. Comparing a procedural abortion in the
18 second trimester to a procedural abortion in the first
19 trimester, yes, the risks are -- the risk, generally,
20 for a procedural abortion increases as the gestation
21 of the pregnancy increases. That would also be true
22 for a person who decided to continue their pregnancy.

23 Q. Do you agree with the Academy of Medicine's
24 article you cited from extensively when it says that,
25 "The risk of serious complication increases with weeks

1 gestation. As the number of weeks increase, the
2 invasiveness of the required procedures and the need
3 for deeper levels of sedation also increase"?

4 A. Again, I'd have to review the specific
5 portion of that document that you're, you know,
6 alluding to to determine whether or not I agree with
7 that. I think, generally speaking, you know, the
8 academy didn't -- yeah, I'll just stop there.

9 Q. Do you agree with this statement: "The risk
10 of serious complication increases with weeks
11 gestation. As the number of weeks increase, the
12 invasiveness of the required surgical procedure for an
13 abortion and the need for deeper levels of sedation
14 also increase"?

15 A. That was kind of a lot of things there. So
16 generally, you know, as a person who doesn't -- you
17 know, who recognizes the invasive nature of just
18 having a pelvic exam, I don't -- I don't know exactly
19 what the invasive portion means in that, that you're
20 referring to. But generally, the -- again, for a
21 procedural abortion, as the pregnancy advances, the
22 risk -- the risk can increase.

23 Q. After 11 weeks gestational age, you don't
24 perform a chemical abortion, right?

25 A. Not after 77 days.

Exhibit 4

Surgery

Definition of Surgery H-475.983

Topic: Surgery	Policy Subtopic: NA
Meeting Type: Annual	Year Last Modified: 2023
Action: Reaffirmed	Type: Health Policies
Council & Committees: Council on Constitution and Bylaws, Council on Long Range Planning and Development	undefined

Our AMA adopts the following definition of 'surgery' from American College of Surgeons Statement ST-11:

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. **Surgery** also is the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reductions for major dislocations or fractures, or otherwise altered by mechanical, thermal, light-based, electromagnetic, or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system also is considered to be **surgery** (this does not include the administration by nursing personnel of some injections, subcutaneous, intramuscular, and intravenous, when ordered by a physician). All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical procedure are not eliminated by using a light knife or laser in place of a metal knife, or scalpel.

Patient safety and quality of care are paramount and, therefore, patients should be assured that individuals who perform these types of **surgery** are licensed physicians (defined as doctors of medicine or osteopathy) who meet appropriate professional standards.

Policy Timeline

Res. 212 A-07 Reaffirmed: BOT Rep. 16, A-13 Reaffirmed: CCB/CLRPD Rep. 01, A-23

Exhibit 5



LETTER

Letter to FDA Commissioner Jane Henney on the Restrictions on Mifepristone

Document Date: September 22, 2000

Jane Henney, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Henney:

We understand that the Food and Drug Administration (“FDA”) is considering a variety of restrictions on the distribution and administration of the drug mifepristone. As an organization committed to women’s health and reproductive freedom, we write to urge you to consider the serious health consequences of any restrictions that would curtail access to this drug.

A primary promise of mifepristone is its ability to provide access to earlier abortion options for women who live far from a surgical abortion provider. Restrictions on the drug – particularly any limitation on who can administer it – would rob women of mifepristone’s promise of access to earlier, and therefore in many cases safer, abortions. Moreover, such restrictions are not necessary, where the FDA has already found mifepristone to be safe and efficacious.¹ Considered in the broader context of the provision of reproductive health care in this country, restrictions that limit who can provide the drug and that thereby reduce access will disserve, not further, women’s health. Because the FDA’s mandate is to further public health, it should approve mifepristone without the considered restrictions.

Restrictions on mifepristone that unjustifiably limit the number of licensed providers will serve to delay abortions to the detriment of women’s health. Mifepristone is available for procedures used between the earliest point at which a pregnancy can be confirmed and 49 days (or 7 weeks) of pregnancy, whereas many facilities do not perform surgical abortions until 6 to 8 weeks. In addition, many women experience further delay in their attempts to obtain a surgical abortion. A primary cause of this delay is lack of access to an abortion provider.

The problem of access is pervasive. In 86% of counties in the country, there is no abortion provider.² South Dakota, for example, has only one abortion provider, leaving women to travel hundreds of miles for care.³ Women who live far from a provider often have difficulty arranging the procedure: They face difficulties scheduling an absence from home or work for the



Any delay in obtaining an abortion is significant because gestational age is an important determinant of medical risk. While surgical abortions are extremely safe, the risk of death from abortion increases approximately 30 percent with each week of gestation from 8 weeks of pregnancy measured from the woman's last menstrual period (lmp) to 20 weeks lmp.⁵ The risk of major medical complications increases approximately 20 percent with each week of gestation from 7 weeks onward.⁶

Thus, for example, without mifepristone, a woman located several hundred miles away from the nearest surgical abortion provider might be unable to obtain an abortion until the 10th week of pregnancy. If mifepristone were available in her community, she could obtain an earlier non-surgical abortion that would possibly be safer.

Mifepristone can serve women's health by increasing the number of abortion providers and making the procedure available outside the traditional surgical abortion setting. In a recent survey, 31% of gynecologists who have never performed surgical abortions or have not performed them in the past five years stated that they were "very likely" or "somewhat likely" to prescribe mifepristone if it were available.⁷ The promise is even greater when other physicians are considered. Thirty-one percent of family practice physicians, 98% of whom do not perform surgical abortions, similarly indicated that they were "very" or "somewhat" likely to prescribe mifepristone.⁸

Moreover, some women may prefer a non-surgical abortion and may be motivated to seek care earlier if such an option were available. The fact that mifepristone is available only in the first few weeks of pregnancy is part of the publicity surrounding the drug. In contrast, many women are unaware of the fact that surgical abortions are safer if performed earlier in pregnancy. Thus, wide access to mifepristone may steer women away from later, and potentially riskier surgical abortion procedures.

In approving mifepristone, the FDA should not focus narrowly on what may, in a perfect world, be the ideal conditions for a single administration of the drug. Rather, as an agency dedicated to protecting public health, the FDA should also consider the health advantages of increased access to earlier and safer abortion options. Any restrictions by the FDA limiting those who may prescribe mifepristone would dramatically decrease its availability and would thus rob women of one of the drug's major health benefits. We urge you to consider the broad health implications of any such restrictions.

Sincerely,

Laura Murphy
Director, Washington National Office

Catherine Weiss
Director, Reproductive Freedom Project

Endnotes:

¹). See Letter from FDA to Population Council (Sept. 18, 1996).

²). Stanley K. Henshaw, Abortion Incidence and Services in the United States, 1995-1996, 30 Fam. Plan. Persp. 263, 266



effort to impose such a requirement, or to otherwise limit the physicians who can provide abortions, is dubious at best. See *Pro-Choice Mississippi v. Thompson*, No. 3:96CV596BN, slip op. at 18 (S.D. Miss. Sept. 28, 1996) (preliminarily enjoining regulations requiring physicians providing abortions to have completed an American Medical Association-approved residency in obstetrical/gynecology). The United States Supreme Court has held that a physician licensed by the state possesses sufficient qualifications to perform an abortion. See *Doe v. Bolton*, 410 U.S. 179, 199-200 (1973); *Word v. Poelker*, 495 F.2d 1349, 1352 (8th Cir. 1974) (“We are referred to no other single surgical procedure where doctors are required to ‘prove up’ their overall fitness as they are here.”); *Mahoning Women’s Ctr. v. Hunter*, 610 F.2d 456, 460 (6th Cir. 1979) (holding that the city may not define the term “physician” to mean more than “a physician currently licensed by the State”) (quoting *Roe v. Wade*, 410 U.S. 113, 165 (1973)), vacated and remanded on other grounds, 447 U.S. 918 (1980).

4). See Ada Torres & Jaqueline Darroch Forrest, *Why Do Women Have Abortions*, 20 *Fam. Plan. Persp.* 169, 174 (1988).

5). See Herschel W. Lawson et al., *Abortion Mortality, United States, 1972 through 1987*, 171 *Am. J. Obstet. & Gynecol.* 1365, 1367 (Table II) (1994).

6). Christopher Tietze & Stanley K. Henshaw, *Induced Abortion: A World Review 1986*, at 103 (The Alan Guttmacher Institute, 6th ed. 1986).

7). The Henry J. Kaiser Family Foundation, *A National Survey, Views of Women’s Health Care Providers on Abortion: An Update on Mifepristone 2 (2000)* <

8). *Id.* at 2-3.

Related Issues

Reproductive Freedom

Abortion

Exhibit 6

Procedural Abortion Volume by Gestational Age								
		Asheville	Chapel Hill	Charlotte	Fayetteville	Wilmington	Winston-Salem	
01/20-12/20	Under 5 weeks	1	0	0	3	1	0	
	5 weeks	14	33	9	22	3	17	
	6 weeks	51	112	68	91	29	64	
	7 weeks	55	155	73	97	37	51	
	8 weeks	53	114	69	84	45	54	
	9 weeks	32	93	45	72	30	48	
	10 weeks	34	80	35	80	36	38	
	11 weeks	38	98	51	93	35	52	
	12 weeks	29	70	42	67	25	43	
	13 weeks	30	62	30	54	21	40	
	14 weeks	1	82	18	42	0	14	
	15 weeks	0	46	0	0	0	0	
	16 weeks	0	51	0	0	0	0	
	17 weeks	0	64	0	0	0	0	
	18 weeks	0	51	0	0	0	0	
	19 weeks	0	36	0	0	0	0	
	20 weeks	0	38	0	0	0	0	
	21 weeks	0	17	0	0	0	0	
		Under 5 weeks	0	0	0	2	0	0
		5 weeks	15	40	7	14	2	19
		6 weeks	50	136	64	78	18	66
7 weeks		46	115	77	57	29	71	
8 weeks		61	85	53	92	49	79	
9 weeks		44	70	49	70	32	61	
10 weeks		27	55	36	45	37	45	
11 weeks		43	107	59	91	52	71	
12 weeks		36	97	57	75	33	68	
13 weeks		24	65	34	41	31	41	
14 weeks		0	92	13	38	0	16	
15 weeks		0	75	0	0	0	1	

Procedural Abortion Volume by Gestational Age									
		Asheville	Chapel Hill	Charlotte	Fayetteville	Wilmington	Winston-Salem		
01/21-12/21	16 weeks	0	72	0	0	0	0	0	
	17 weeks	0	96	0	0	0	0	0	
	18 weeks	0	57	0	0	0	0	0	
	19 weeks	0	56	0	0	0	0	0	
	20 weeks	0	37	0	0	0	0	0	
	21 weeks	0	28	0	0	0	0	0	
01/22-12/22	Under 5 weeks	1	2	0	3	0	0	0	
	5 weeks	10	59	7	38	4	28		
	6 weeks	42	179	57	104	35	85		
	7 weeks	58	144	88	112	61	89		
	8 weeks	93	122	86	100	51	102		
	9 weeks	82	128	86	88	49	78		
	10 weeks	52	88	68	47	35	43		
	11 weeks	111	143	89	128	65	102		
	12 weeks	87	97	108	105	51	68		
	13 weeks	66	110	68	58	35	43		
	14 weeks	25	135	25	39	1	23		
	15 weeks	4	108	0	0	0	0		
	16 weeks	2	117	0	0	0	0		
	17 weeks	1	116	0	0	0	0		
	18 weeks	0	94	0	0	0	0		
	19 weeks	0	86	0	0	0	0		
	20 weeks	0	26	0	0	0	0		
	21 weeks	0	21	0	0	0	0		
		Under 5 weeks	0	0	0	0	0	0	0
		5 weeks	5	12	5	11	2	6	
		6 weeks	19	54	17	45	11	21	
7 weeks		37	58	34	67	28	38		
8 weeks		59	63	51	51	29	51		

Procedural Abortion Volume by Gestational Age							
		Asheville	Chapel Hill	Charlotte	Fayetteville	Wilmington	Winston-Salem
	9 weeks	58	82	58	65	34	41
	10 weeks	49	59	41	43	23	37
	11 weeks	95	78	57	96	43	69
	12 weeks	73	60	63	85	40	52
	13 weeks	77	65	50	45	22	37
	14 weeks	32	114	14	39	3	12
	15 weeks	17	74	0	0	0	0
	16 weeks	6	79	0	0	0	0
	17 weeks	7	92	0	0	0	0
	18 weeks	2	99	0	0	0	0
01/23-06/23	19 weeks	0	69	0	0	0	0

Exhibit 7

Medication Abortion Volume by Gestational Age							
		Asheville	Chapel Hill	Charlotte	Fayetteville	Wilmington	Winston-Salem
01/2020-12/202	Under 5 weeks	1	0	0	3	1	6
	5 weeks	43	98	57	109	20	126
	6 weeks	117	298	213	362	72	308
	7 weeks	140	270	219	332	110	232
	8 weeks	98	235	171	252	122	179
	9 weeks	54	143	75	161	68	107
	10 weeks	31	70	43	69	36	52
	11 weeks	2	7	2	14	4	7
01/21-12/21	Under 5 weeks	3	0	1	1	0	3
	5 weeks	39	163	48	71	15	69
	6 weeks	120	428	270	334	75	256
	7 weeks	133	345	279	334	129	233
	8 weeks	130	263	215	311	133	208
	9 weeks	87	167	132	199	102	156
	10 weeks	50	106	72	146	64	80
	11 weeks	3	14	2	23	3	15
01/22-12/22	Under 5 weeks	2	0	2	10	2	0
	5 weeks	61	181	66	180	37	70
	6 weeks	208	465	290	441	162	244
	7 weeks	237	384	355	407	156	240
	8 weeks	242	329	293	398	136	242
	9 weeks	187	243	230	221	101	166
	10 weeks	112	155	130	157	77	88
	11 weeks	14	25	12	22	1	7
	Under 5 weeks	3	0	0	3	0	0
	5 weeks	97	29	27	52	11	25
	6 weeks	210	139	121	189	74	106
	7 weeks	227	176	179	260	93	119
	8 weeks	257	173	216	218	125	125
	9 weeks	204	151	179	172	80	101

Medication Abortion Volume by Gestational Age							
		Asheville	Chapel Hill	Charlotte	Fayetteville	Wilmington	Winston-Salem
01/23-06/23	10 weeks	112	67	90	86	63	52
	11 weeks	11	8	11	13	1	6