IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

ATLANTIC, et al.,)
Plaintiffs,)
v.)
JOSHUA STEIN, et al.,) Case No. 1:23-cv-00480-CCE-LPA
Defendants,)
and)
PHILIP E. BERGER, et al.,)
Intervenor-Defendants.)

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' AMENDED MOTION FOR PRELIMINARY INJUNCTION

INTRODUCTION

This spring, the North Carolina General Assembly radically rewrote and expanded the state's abortion restrictions, banning abortion after the twelfth week of pregnancy with few exceptions and passing a law riddled with inconsistencies, irrational requirements, and unconstitutional threats to North Carolinians' health and rights. *See* North Carolina Session Law 2023-14 ("S.B. 20," *see* DE 1-1) (codified as amended by Session Law 2023-65 ("H.B. 190," *see* DE 26-1) at N.C. Gen. Stat. art. 1I, ch. 90 (the "Act")).

With this amended motion, Planned Parenthood South Atlantic ("PPSAT") and Beverly Gray, M.D. (together, "Plaintiffs") seek a preliminary injunction against two

components of the Act which will significantly restrict abortion access for patients and impede medical professionals from providing quality care: (i) N.C. Gen. Stat. §§ 90-21.81B(3), -(4), 90-21.82A(c), 131E-153.1 (the "Hospitalization Requirement"); and (ii) *id.* § 90-21.83B(a)(7) (the "IUP Documentation Requirement").

Plaintiffs are likely to succeed on the merits of their claims that these provisions violate the Fourteenth Amendment because they impose vague and irrational requirements that subject Plaintiffs to a risk of professional and criminal penalties. In turn, Plaintiffs' patients will face unnecessary delays and additional burdens in accessing abortion—and, in some cases, may be denied abortion entirely—without any benefit to their health or safety. The challenged provisions will therefore cause irreparable harm to Plaintiffs and their patients. The balance of equities and public interest likewise weigh heavily in favor of injunctive relief. This Court should therefore enjoin the Hospitalization Requirement and the IUP Documentation Requirement before the former becomes effective on October 1, 2023.¹

STATEMENT OF FACTS

I. Abortion Is Common, Safe, and Essential Health Care

Abortion is a basic component of health care and is one of the safest medical treatments in the United States. All methods of abortion provided by Plaintiffs in licensed

¹ The Court's temporary restraining order enjoined enforcement of the IUP Documentation Requirement, DE 31 (TRO) at 6–9, and that order has been extended until the Court rules on this motion. DE 35 (Consent Order Extending TRO); DE 37 (Scheduling Order). The effective date of the Hospitalization Requirement is October 1, 2023. *See* DE 30 (Joint Stip.) at 2; DE 31 (TRO) at 9.

abortion clinics—medication abortion, aspiration abortion, and dilation and evacuation ("D&E")—are simple, straightforward treatments that typically take no more than fifteen minutes to perform, involve no incisions, have an extremely low complication rate, and, nationwide, are almost always provided in outpatient, office-based settings. Decl. of Katherine Farris, M.D., in Supp. of Pls.' Amended Mot. for a Prelim. Inj. ("Farris Decl.") ¶ 14, attached as Exhibit 1; Decl. of Christy M. Boraas Alsleben, M.D., M.P.H. in Supp. of Pls.' Amended Mot. for a Prelim. Inj. ("Boraas Decl.") ¶¶ 21–22, 32, attached as Exhibit 2; DE 42 (Am. Compl.) ¶ 47.

Abortion is far safer than continuing a pregnancy to term and childbirth, and complications related to pregnancy and childbirth are much more common than complications from abortion. Farris Decl. ¶ 33; Boraas Decl. ¶ 25. Indeed, the mortality rate for childbirth is approximately 12 to 14 times greater than that for abortion. Farris Decl. ¶ 34; Boraas Decl. ¶ 25.

There are two main methods of outpatient abortion: procedural abortion and medication abortion. Although procedural abortion is sometimes referred to as "surgical abortion," including in the Act, that is a misnomer, as procedural abortion methods do not involve the typical characteristics of surgery, such as incisions or use of general anesthesia. Farris Decl. ¶ 15; Boraas Decl. ¶ 22. These methods are therefore more appropriately characterized as procedures.²

² Definition of "Procedures" Related to Obstetrics and Gynecology, The Am. Coll. of Obstetricians & Gynecologists (reaffirmed Mar. 2023), https://www.acog.org

Plaintiffs provide procedural abortion using two common methods: aspiration abortion, which is available up to approximately 14 weeks of pregnancy, and dilation and evacuation abortion, or "D&E," which is available after approximately 14 weeks of pregnancy, depending on the provider's individual practice and the patient's individual medical characteristics. Farris Decl. ¶ 25; DE 42 (Am. Compl.) ¶ 66.

For aspiration abortion, the provider passes a small tube, called a cannula, through the patient's vagina and cervical opening. The cannula is attached to a syringe or electrical pump that creates gentle suction to empty the uterus. The entire procedure takes around three to five minutes. Aspiration abortion involves no incisions, cutting, or suturing. Farris Decl. ¶ 23; Boraas Decl. ¶ 22. The same procedure is used to manage incomplete miscarriages.³ Farris Decl. ¶ 24; Boraas Decl. ¶ 24.

For D&E, the provider uses a combination of gentle suction and additional instruments to evacuate the uterus. Before starting the evacuation procedure, the provider dilates the patient's cervix using medications, osmotic dilators, and/or mechanical dilators. Farris Decl. ¶ 26; Boraas Decl. ¶ 35. Mild to moderate sedation may be used. The entire evacuation procedure typically takes up to fifteen minutes. Like aspiration abortion, D&E does not involve any incisions, cutting, or suturing. Farris Decl. ¶ 28; Boraas Decl. ¶ 22.

[/]clinical information/policy-and-position-statements/position-statements/2018/definition-of-procedures-related-to-obstetrics-and-gynecology.

³ "Miscarriage" is when a pregnancy stops growing, as evident from the absence of embryonic or fetal cardiac activity. While sometimes a person's body naturally expels the pregnancy tissue, other times medical treatment, known as "miscarriage management," is needed to empty the uterus. The only thing distinguishing miscarriage management from abortion is the presence or absence of cardiac activity. Boraas Decl. ¶ 21 n.7.

D&E is also used to manage incomplete miscarriages. Farris Decl. ¶ 28; Boraas Decl. ¶ 24.

Procedural abortion is analogous to other procedures that take place in outpatient settings in terms of risks, invasiveness, and duration. Farris Decl. ¶¶ 36–44. In addition to being identical to the procedures used to manage miscarriage, procedural abortions are also substantially similar in technique and risk to certain outpatient procedures for removing tissue from the uterus or cervix for testing. Farris Decl. ¶¶ 24, 28, 40. Procedural abortion is safer than numerous other outpatient procedures and surgeries—for example, vasectomies or colonoscopies—and has been safely provided in clinics in North Carolina for years. §§ See Farris Decl. ¶¶ 15, 32.

The medication abortion regimen in the first trimester typically involves two medications: mifepristone and misoprostol. Farris Decl. ¶ 17; Boraas Decl. ¶ 21. Plaintiffs provide this regimen through eleven weeks of pregnancy. Farris Decl. ¶ 12; Am. Compl. ¶ 48. The patient first takes the mifepristone and then, usually 24 to 48 hours later, takes the misoprostol. Farris Decl. ¶ 17. Together, these medications stop the development of the pregnancy and cause uterine contractions that expel the contents of the uterus, as in a miscarriage. Farris Decl. ¶ 17; Boraas Decl. ¶ 21. Indeed, these same medications are used

⁴ See Elizabeth G. Raymond et al., Mortality of Induced Abortion, Other Outpatient Surgical Procedures and Common Activities in the United States, 90 Contraception 476 (2014); Farris Decl. ¶¶ 11–14.

⁵ Adverse events (including death, hospitalization, serious infection, and bleeding requiring transfusion) among mifepristone patients are "exceedingly rare, generally far below 0.1% for any individual adverse event." FDA, *Ctr. for Drug Evaluation & Rsch., Med. Rev., Application No. 020687Orig1s020*, at 47 (2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/ 2016/020687Orig1s020MedR.pdf; *see also* Farris Decl. ¶ 18.

to manage incomplete miscarriage. Farris Decl. ¶ 17; Boraas Decl. ¶ 21.

First-trimester medication abortion and procedural abortion through the second trimester can both be safely provided in a clinic, and there is no medical reason to require these abortions to occur in hospitals. Farris Decl. ¶¶ 14–15, 36, 44; Boraas Decl. ¶ 32. Only 3% of abortions nationwide are performed in hospitals, and abortions at outpatient clinics are often more affordable, easier to navigate, and less time-consuming for patients. Farris Decl. ¶ 36; Boraas Decl. ¶¶ 32, 38. In the rare event that a complication arises during a procedural abortion, the complication can nearly always be managed in the outpatient setting, and PPSAT has protocols in place to ensure safe transfer to a hospital-based provider in the exceedingly unlikely event that hospitalization is needed. Farris Decl. ¶ 43.

II. The Act Imposes Irrational and Unconstitutional Restrictions on Abortion Care

Prior to the Act, abortion was broadly lawful in North Carolina before 20 weeks of pregnancy and was provided safely and routinely at licensed outpatient abortion clinics like PPSAT's. E.g. Farris Decl. ¶¶ 12, 36–37. But in June 2023, after limited debate and over the Governor's veto, the Act radically overhauled North Carolina's abortion restrictions.

The Act provides: "It shall be unlawful after the twelfth week of a woman's pregnancy to procure or cause a miscarriage or abortion in the State of North Carolina." N.C. Gen. Stat. § 90-21.81A (the "Twelve-Week Ban"). After the twelfth week, there are limited exceptions, which include: a) when a qualified physician determines there is a medical emergency, *id.* § 90-21.81B(1); b) through the twentieth week of pregnancy, when

the pregnancy is a result of rape or incest, *id.* § 90-21.81B(3); and c) during the first twenty-four weeks of pregnancy if a qualified physician determines there exists a life-limiting anomaly, *id.* § 90-21.81B(4).

Although the Act creates exceptions to the Twelve-Week Ban in cases of rape, incest, or life-limiting anomalies, it also requires abortions provided after the twelfth week to occur in a hospital. *Id.* §§ 90-21.81B(3), 90-21.81B(4), 90-21.82A(c). This irrational limitation will further harm survivors of sexual assault and patients with grave fetal diagnoses, without increasing abortion safety.

The Act also requires that prior to medication (but not procedural) abortions, physicians must "[d]ocument in the woman's medical chart the . . . existence of an intrauterine pregnancy," *id.* § 90-21.83B(a)(7). Even as amended by H.B. 190, it is unclear whether physicians can provide early medication abortion when a patient has a positive pregnancy test but it is too soon to view the location of the pregnancy, even though research demonstrates the safety and efficacy of this practice.

A physician who violates the Act is subject to discipline by the North Carolina Medical Board, and any other licensed health care provider who violates the Act is subject to discipline by their respective licensing agency or board. *Id.* § 90-21.88A. Moreover, certain provisions of the Act carry criminal penalties. Relevant here, providing an abortion

that does not fit within the Act's exceptions to the Twelve-Week Ban is a felony. *Id.* §§ 90-21.81A, 90-21.81B; *see also id.* §§ 14-44, -45, -23.7(1).⁶

QUESTIONS PRESENTED

- 1. Are Plaintiffs likely to prevail on their claims that the Hospitalization and IUP Documentation Requirements violate due process and equal protection under the Fourteenth Amendment?
- 2. Will Plaintiffs and their patients suffer irreparable injury without preliminary injunctive relief?
- 3. Does the injury to Plaintiffs and their patients outweigh any injury to Defendants?
- 4. Is preliminary injunctive relief in the public interest?

ARGUMENT

A preliminary injunction is warranted upon a showing that: "(1) the party is likely to succeed on the merits of the claim; (2) the party is likely to suffer irreparable harm in the absence of an injunction; (3) the balance of hardships weighs in the party's favor; and (4) the injunction serves the public interest." *HIAS, Inc. v. Trump*, 985 F.3d 309, 318 (4th Cir. 2021). To satisfy the first prong, Plaintiffs "need not establish a certainty of success," but only "a clear showing that they are likely to succeed at trial." *Roe v. U.S. Dep't of Defense*, 947 F.3d 207, 219 (4th Cir. 2020) (cleaned up). Plaintiffs readily meet this test.

I. Plaintiffs Are Likely to Succeed on the Merits of Their Claims That the Act Violates Plaintiffs' and Their Patients' Constitutional Rights

The Hospitalization Requirement violates the Fourteenth Amendment's Equal Protection and Due Process Clauses because there is no rational basis for restricting access

⁶ See also DE 31 (TRO) at 6 ("Failing to comply with the intrauterine documentation requirement may carry the possibility of criminal penalties.").

to safe, compassionate, evidence-based abortion care in cases of rape, incest, or life-limiting anomaly by confining that care to the hospital setting. And the IUP Documentation Requirement is unconstitutionally vague in violation of the Due Process Clause because it is unclear whether physicians can provide medication abortion when an intrauterine pregnancy cannot yet be seen by ultrasound. To the extent the IUP Documentation Requirement prevents physicians from providing medication abortion in those circumstances, it too is irrational in violation of the Due Process Clause.

A. The Hospitalization Requirement Is Irrational in Violation of the Fourteenth Amendment

1. The Hospitalization Requirement irrationally distinguishes between abortion and other health care of equal or greater risk

The Act's requirement that abortions after the twelfth week of pregnancy in cases of rape, incest, or life-limiting anomaly be performed in a hospital violates the Equal Protection Clause of the Fourteenth Amendment. See N.C. Gen. Stat. §§ 90-21.81B(3), - (4). It irrationally singles out physicians who provide and patients who seek abortion, a politically stigmatized type of medical care, as compared to those providing and seeking medical procedures of equal or greater risk—including miscarriage management using identical methods. See Planned Parenthood of Wis., Inc. v. Van Hollen, 738 F.3d 786, 790 (7th Cir. 2013) ("An issue of equal protection of the laws is lurking in this case. For the state seems indifferent to complications from non-hospital procedures other than surgical abortion (especially other gynecological procedures), even when they are more likely to produce complications."); Planned Parenthood of Ind. & Ky., Inc. v. Comm'r, Ind. Dep't

of Health, 64 F. Supp. 3d 1235, 1257 (S.D. Ind. 2014) ("[Supreme Court precedent] does not . . . authorize the unequal treatment of those providing the exact same procedure, without a rational basis, and equal protection demands otherwise.").⁷

Procedural abortion is as safe as, and frequently safer than, a wide range of other medical procedures—including vasectomies, colonoscopies, wisdom tooth extraction, and tonsillectomies—that are routinely performed in North Carolina outside of hospital settings. Farris Decl. ¶ 32; Am. Compl. ¶ 74. North Carolina law permits outpatient clinics to provide gynecological procedures that are substantially similar to procedural abortion in technique and risk, such as endometrial biopsy and hysteroscopy. Farris Decl. ¶ 40. And although a woman is approximately 12 to 14 times more likely to die from childbirth than from having an abortion, Boraas Decl. ¶ 25, North Carolina law—including *the Act itself*—permits physicians and certified nurse-midwives to deliver babies outside of hospitals, at birthing centers and even in private homes. Farris Decl. ¶ 35; N.C. Gen. Stat. § 90-178.4 (as amended by S.B. 20, § 4.3(d), effective Oct. 1, 2023) (providing for "planned birth outside of a hospital setting").

Moreover, the *same* procedures that the Act requires to be performed in hospitals for abortions after twelve weeks—aspiration abortion and D&E—are also used to manage

⁷ The Hospitalization Requirement also violates substantive due process under the Fourteenth Amendment's Due Process Clause. Even where a fundamental substantive due process right is not implicated, laws restricting access to abortion remain subject to rational basis review. *See Doe v. Settle*, 24 F.4th 932, 943–44, 953 (4th Cir. 2022) ("A substantive due process challenge is considered under rational-basis review unless some fundamental right is implicated."). The Hospitalization Requirement fails rational basis review under the Due Process Clause and Equal Protection Clause alike.

miscarriage, and the Act permits these procedures to be performed at clinics for *that* purpose. Farris Decl. ¶¶ 24, 28, 40. That is, after fetal cardiac activity has ceased, procedures to empty a patient's uterus may be performed in an outpatient setting; if fetal cardiac activity is present, however, under the Act the patient must go to a hospital for the very same procedures. *See* Boraas Decl. ¶ 21 n.7. There is no rational basis to require different clinical settings for the same medical procedure based purely on the purpose for which the procedure is performed.

2. The Hospitalization Requirement is not rationally related to a legitimate government interest

Because the Hospitalization Requirement is not rationally related to a legitimate government interest, it fails rational basis review. The requirement plainly does not further any state interest in protecting potential life because the General Assembly has already deemed permissible (albeit in a different clinical setting) the abortions to which the requirement applies—abortions after the twelfth week of pregnancy in cases of rape or incest or upon diagnosis of a life-limiting anomaly. *See* N.C. Gen. Stat. §§ 90-21.81B(3), -(4) (providing that it "shall not be unlawful" to provide abortion in these circumstances). And the Hospitalization Requirement is not rationally related to any government interest in patient safety.

Indeed, in cases following *Roe v. Wade* and its progeny, the Supreme Court repeatedly recognized that hospitalization requirements for abortion serve no legitimate health and safety interest. *See e.g.*, *Whole Woman's Health v. Hellerstedt*, 136 S.Ct. 2292, 2315 (2016) (striking ambulatory surgical center requirement for abortion and recognizing

"well supported" district court finding that "requiring all abortion facilities to meet all surgical-center standards does not benefit patients and is not necessary"); *City of Akron v. Akron Ctr. for Reprod. Health, Inc.*, 462 U.S. 416, 435–37 & n.25 (1983) (in striking down second-trimester hospital requirement, finding these abortions were "rarely performed" in hospitals and relying on "present medical knowledge," including ACOG guidelines, to determine second-trimester abortions "may be performed safely on an outpatient basis"); *Planned Parenthood Ass'n of Kan. City, Mo., Inc. v. Ashcroft*, 462 U.S. 476, 481–82 (1983) (same); *Doe v. Bolton*, 410 U.S. 179, 195 (1973) (striking down second-trimester hospitalization requirement and finding no evidence "that only the full resources of a licensed hospital, rather than those of some other appropriately licensed institution, satisfy [the State's asserted] health interests").

Although these cases' legal holdings—that second-trimester hospitalization requirements violate patients' Fourteenth Amendment fundamental due process right to abortion—have been overruled by *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022), the factual findings that hospital requirements do not serve any interest in patient health and safety were not. These cases therefore demonstrate that the Hospitalization Requirement is not based on "reasonable speculation," a "plausible reason," or a "conceivable basis." *Settle*, 24 F.4th at 943–44; *see also Abuelhawa v. United States*, 556 U.S. 816, 821 (2009) ("[W]e presume legislatures act with case law in mind.").

Medical evidence and professional consensus confirm this. Researchers have found that D&Es in a dedicated outpatient abortion facility can be both safer and less expensive

than hospital-based D&Es. Farris Decl. ¶ 38. As is true for nearly every medical procedure, fewer complications from abortion are seen in settings that perform higher volumes of those procedures, making abortion clinics like PPSAT safer for patients than most hospitals, many of which do not routinely provide abortions. *Id.* ¶¶ 38, 74.

On the rare occasions when complications do arise after a procedural abortion, they can nearly always be managed in an outpatient setting, with no need for hospital-based care. Id. ¶ 41. Serious complications—those that require hospital admission—are vanishingly rare, occurring in just 0.23% of all abortions performed in outpatient settings. Id. ¶ 31. The risk of death is even lower: the mortality rate for legal abortions—a vast majority of which are provided in outpatient facilities—is 0.43 per 100,000 procedures, making it at least twelve times safer than childbirth. Id. ¶ 34. When serious complications do arise, PPSAT follows established procedures to safely transfer the patient to a hospital. Id. ¶ 43.

Nationwide, 97% of abortions are provided in the outpatient setting, yielding an enormous volume of data establishing beyond any doubt the safety of outpatient abortions. *Id.* ¶ 36; Boraas Decl. ¶ 32. Reflecting this data, the National Academies of Sciences, Engineering, and Medicine, as well as major medical associations including the American College of Obstetricians and Gynecologists and the American Public Health Association, have made clear that hospitalization requirements for abortion lack any scientific or medical basis. Farris Decl. ¶ 37.

3. The Hospitalization Requirement is irrational specifically as to cases of rape, incest, or "life-limiting" anomaly

The irrationality of the Hospitalization Requirement is further underscored by its application *only* to survivors of rape or incest and patients with grave fetal diagnoses. By creating exceptions to the Twelve-Week Ban for patients in these circumstances, the Act appears to recognize the importance of maintaining their access to abortion. But requiring that these patients go to hospitals, where abortions are generally much more expensive than at clinics, reduces the number of providers available to them, especially if they have lower incomes or live in rural areas. *Id.* ¶ 20. The requirement therefore makes accessing abortion even more challenging for people already facing personal hardship due to the circumstances of their pregnancies. *Id.* The physical aspects of pregnancy can be especially traumatizing for survivors of sexual violence, and ongoing intimate partner violence may make it extremely difficult for people to obtain abortions without compromising their confidentiality. *Id.* ¶¶ 65–67. And patients who are diagnosed with a fetal anomaly usually receive this diagnosis after the twelfth week of pregnancy, since the screening and diagnostic procedures for anomalies are generally conducted in the second trimester. Farris Decl. ¶ 68; Boraas Decl. ¶ 20. Indeed, hospital providers in North Carolina refer patients with fetal diagnoses to PPSAT for abortion after twelve weeks. Farris Decl. ¶¶ 8, 46.

Specifically for survivors of rape or incest, abortion care in a licensed abortion clinic offers particular benefits related to the specialized setting. At PPSAT, for example, all staff are trained to recognize and counteract abortion stigma, and clinicians are trained annually on providing trauma-informed care for patients who have experienced intimate partner

violence—such as special considerations when performing a physical exam for those patients, and what words to use in their clinical interactions. *Id.* ¶ 75. One such traumainformed practice is offering the patient the opportunity to remain conscious during the procedure rather than receiving general anesthesia (which some hospitals administer as a matter of course for abortion patients, *see* Boraas Decl. ¶ 36): while some survivors may prefer general anesthesia, others wish to avoid the experience of being told after waking up from sedation what has happened to their body, with no firsthand memory of the procedure itself. Farris Decl. ¶ 75; Boraas Decl. ¶ 36.

When receiving care at a licensed abortion clinic, patients can trust that their care team—from the front desk staff to the physician performing their procedure—will not judge their reproductive decisionmaking, whether they decide to continue or end the pregnancy. Farris Decl. ¶ 76; Boraas Decl. ¶ 37. While there are of course excellent physicians and staff providing compassionate, patient-centered care in hospital settings too, patients are *more likely* to encounter stigma and judgment at a hospital than at a licensed abortion clinic in North Carolina. Farris Decl. ¶ 76; Boraas Decl. ¶ 37. Requiring people to go to a hospital for their abortion deprives them of the option to receive care in the specialized, supportive environment that a licensed abortion clinic offers.

* * *

Absent a health-related justification or an interest in protecting potential life, the only remaining justification for the Hospitalization Requirement is a "bare desire to harm" certain medical providers or patients, which is not a legitimate state interest. *City of*

Cleburne, Tex. v. Cleburne Living Ctr., 473 U.S. 432, 447, 450 (1985) (alteration omitted) (reasoning, after ruling out other purported justifications advanced by the government, that only impermissible animus towards persons with intellectual disabilities could have motivated the challenged regulation); see also U.S. Dep't of Agric. v. Moreno, 413 U.S. 528, 534 (1973) ("[A] bare [legislative] desire to harm a politically unpopular group cannot constitute a legitimate governmental interest."). As the Fourth Circuit has recognized, "[a]bortion may well be a special case" in some regards, "but it cannot be so special a case that all other professional rights and medical norms go out the window." Stuart v. Camnitz, 774 F.3d 238, 255–56 (4th Cir. 2014). Where, as here, the gulf between a legislature's action and "the realities of the subject addressed by the legislation" is vast, Heller v. Doe, 509 U.S. 312, 321 (1993), the challenged provision fails rational basis review.

B. The Act's IUP Documentation Requirement Is Unconstitutionally Vague and/or Irrational

1. The IUP Documentation Requirement is unconstitutionally vague

The Act is unconstitutionally vague because it fails to provide notice as to when medication abortion is lawful for pregnancies of unknown location.

"To survive a vagueness challenge, a statute must give a person of ordinary intelligence adequate notice of what conduct is prohibited and must include sufficient standards to prevent arbitrary and discriminatory enforcement." *Manning v. Caldwell for City of Roanoke*, 930 F.3d 264, 272 (4th Cir. 2019) (en banc); *see also Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972); *Sessions v. Dimaya*, 138 S. Ct. 1204, 1212 (2018). The Act may be unconstitutionally vague under either theory: lack of notice or lack of

standards. FCC v. Fox Television Stations, Inc., 567 U.S. 239, 253 (2012). Here, where the IUP Documentation Requirement "fails to provide any standard of conduct by which persons can determine whether they are violating the statute," the Act is "unconstitutionally vague." Manning, 930 F.3d at 274.

"The degree of vagueness that the Constitution tolerates—as well as the relative importance of fair notice and fair enforcement—depends in part on the nature of the enactment." *Vill. of Hoffman Ests. v. Flipside, Hoffman Ests., Inc.*, 455 U.S. 489, 498 (1982). Although "[l]ess clarity is required in purely civil statutes . . . laws that nominally impose only civil consequences warrant a 'relatively strict test' for vagueness if the law is 'quasi-criminal' and has a stigmatizing effect." *Manning*, 930 F.3d at 272–73. Because the IUP Documentation Requirement carries livelihood-threatening licensing penalties and possibly criminal penalties, *see* DE 31 (TRO) at 6, a stricter standard of review applies here.

The Act provides that medication abortion is lawful up to twelve weeks of pregnancy, but the IUP Documentation Requirement requires physicians to "[d]ocument in the woman's medical chart the . . . existence of an intrauterine pregnancy," N.C. Gen. Stat. § 90-21.83B(a)(7)—an impossibility for some in the early weeks of pregnancy, where an intrauterine embryo cannot yet be detected by ultrasound. *See* Farris Decl. ¶ 49; Boraas Decl. ¶ 41.

Plaintiffs are likely to succeed on their vagueness claim because the Act "is ambiguous as to whether a provider who cannot comply with the documentation

requirement because it is impossible is prohibited from proceeding." DE 31 (TRO) at 7. This is not a situation of "uncertainty about the normal meaning of the term at issue, but [is] rather about what specific conduct is covered by the statute and what is not," which is the core of a vagueness challenge. *Manning*, 930 F.3d at 274–75 (quoting *Lytle v. Doyle*, 326 F.3d 463, 469 (4th Cir. 2003)). The Act "specifies no standard of conduct," giving Plaintiffs no notice as to whether they can provide early medication abortion after screening for ectopic pregnancy (which appears to be the goal of the IUP Documentation Requirement) but before an intrauterine pregnancy can be visualized by ultrasound. *See id.* at 278. Further, the Act is vague because these inconsistencies "invite[] the very type of arbitrary enforcement that the Constitution's prohibition against vague statutes is designed to prevent." *Id.* Accordingly, Plaintiffs are likely to succeed on their claim that the IUP Documentation Requirement is vague in violation of their due process rights.

2. The IUP Documentation Requirement is irrational

If interpreted to ban early medication abortion, the IUP Documentation Requirement is also irrational. Providing early medication abortion when a patient has a positive pregnancy test but the pregnancy cannot be visualized on ultrasound is a safe, evidence-based practice that the State has no legitimate reason to bar. Boraas Decl. ¶ 50. This is especially so because the Act authorizes abortion only through twelve weeks, indicating a policy preference that if abortion is performed, it occurs very early in pregnancy.

Consistent with the General Assembly's policy preference, some patients present

for abortions at very early gestational ages. Indeed, access to early abortions is even more important in light of the time constraints imposed by the Twelve-Week Ban. Farris Decl. ¶ 60. At early stages of a pregnancy, when it is too soon to see an intrauterine gestational sac via ultrasound, abortion providers follow established protocols for safely administering medication abortion while simultaneously using additional testing to rule out ectopic pregnancy. Id. ¶ 51; Boraas Decl. ¶ 47. For these patients with "pregnancies of unknown location," Plaintiffs first screen for risk of ectopic pregnancy by asking questions about the patient's medical history and current symptoms. Farris Decl. ¶ 52; DE 42 (Am. Compl.) ¶ 54. If the patient is at high risk of ectopic pregnancy, Plaintiffs refer the patient to another provider, typically an emergency department. Farris Decl. ¶ 52; DE 42 (Am. Compl.) ¶ 54. If the patient is not at high risk of ectopic pregnancy, however, and the patient would like to proceed with a medication abortion, the provider *simultaneously* provides the medication abortion and conducts further testing using serial blood draws to rule out ectopic pregnancy. Farris Decl. ¶ 54; DE 42 (Am. Compl.) ¶ 56.

Administration of medication abortion according to this protocol has been shown to be safe and effective in terminating the pregnancy.⁸ And at least one study found that this

⁸ See, e.g., Alisa B. Goldberg et al., Mifepristone and Misoprostol for Undesired Pregnancy of Unknown Location, 139 Obstetrics & Gynecology 771 (2022); Karen Borchert et al., Medication Abortion and Uterine Aspiration for Undesired Pregnancy of Unknown Location: A Retrospective Cohort Study, 122 Contraception 109980 (2023); I. Bizjak et al., Efficacy and Safety of Very Early Medical Termination of Pregnancy: A Cohort Study, 124 BJOG: An Int'l J. of Obstetrics & Gynaecology 1993 (2017); Philip Goldstone et al., Effectiveness of Early Medical Abortion Using Low-Dose Mifepristone and Buccal Misoprostol in Women With No Defined Intrauterine Gestational Sac, 87 Contraception 855 (2012).

protocol leads to earlier exclusion of ectopic pregnancy than waiting to see if an intrauterine pregnancy can be detected later. Farris Decl. ¶ 58; Boraas Decl. ¶ 46; Am. Compl. ¶ 59.

Importantly, if a patient with a pregnancy of unknown location were referred to a hospital for ectopic evaluation instead of receiving a medication abortion, the hospital would generally perform the very same serial blood testing that, under the protocol, Plaintiffs perform *simultaneously* with the medication abortion. Farris Decl. ¶ 59; Boraas Decl. ¶ 48; *see* DE 42 (Am. Compl.) ¶¶ 54–59. Referring a patient for ectopic evaluation instead of providing a medication abortion to a patient with a pregnancy of unknown location therefore does not lead to earlier or more accurate diagnosis of ectopic pregnancy. Farris Decl. ¶ 59; Boraas Decl. ¶ 50. Instead, it only delays the patient's abortion.

Because there is no medical reason to deny medication abortion to patients with pregnancies that are too early to see via ultrasound, doing so does not serve any governmental interest in health or safety. In fact, it does the opposite, since forcing patients to wait until a later gestational age before getting a medication abortion unnecessarily exposes them to increased medical risk. Farris Decl. ¶ 73. And the IUP Documentation Requirement does not further any state interest in protecting potential life because any patient who is denied a medication abortion under it could still, under the Act, obtain a procedural abortion or (if they have the means) return later to get a medication abortion once the pregnancy is visible via ultrasound.

⁹ Goldberg, *supra* note 8.

II. Plaintiffs Will Suffer Irreparable Harm Absent Injunctive Relief

Absent injunctive relief, Plaintiffs and their patients will suffer irreparable harm. The Act will deprive them of their constitutional rights to due process and equal protection, DE 42 (Am. Compl.) ¶¶ 82–86, which "unquestionably constitutes irreparable injury." Leaders of a Beautiful Struggle v. Balt. Police Dep't, 2 F.4th 330, 346 (4th Cir. 2021) (en banc) (internal quotation marks omitted). This alone is sufficient to establish irreparable harm. The challenged provisions also impose additional harms that "impair[] a court's ability to grant an effective remedy, such as a harm that cannot be compensated by money damages at a later trial." Int'l Refugee Assistance Project v. Trump, 265 F. Supp. 3d 570, 629 (D. Md. 2017), aff'd, 883 F.3d 233 (4th Cir. 2018).

Moreover, the Act will harm Plaintiffs and their patients by delaying—and even, at times, denying—necessary health care, interfering with Plaintiffs' ability to practice evidence-based, patient-centered medicine. *See* Farris Decl. ¶ 81; DE 42 (Am. Compl.) ¶¶ 15–16.

The Hospitalization Requirement will have serious consequences for survivors of sexual violence and patients with life-limiting fetal diagnoses. It will limit the number of providers available to these patients and increase the cost of abortion, delaying access to urgently needed care that a licensed outpatient clinic could have provided but for the Act. Farris Decl. ¶¶ 67, 69–71. Thousands of North Carolinians suffer sexual abuse each year. *Id.* ¶ 65. For many survivors of rape or incest, pregnancy can trigger flashbacks, dissociative episodes, and other symptoms of trauma. *Id.* Those experiencing ongoing

intimate partner violence may find it difficult if not impossible to escape their partner's physical, emotional, and financial control long enough to access an abortion, id. ¶ 66, and delays resulting from the Act will worsen those challenges.

And because the vast majority of abortions are provided in clinics, not hospitals, physicians who primarily practice in hospital settings are likely less experienced in procedural abortion, particularly D&Es (given that most abortions occur before the point in pregnancy when D&Es are generally provided). *Id.* ¶ 74. Patients seeking abortion at hospitals may therefore be limited, either expressly or functionally, to the induction abortion method, which can be far more expensive, time-consuming, and physically arduous for the patient as compared to D&E. *Id.*

The IUP Documentation Requirement will harm patients by delaying their access to abortion, unnecessarily exposing them to increased medical risk, or compelling them to consider a procedural abortion even if medication abortion may offer important advantages over procedural abortion for them. Farris Decl. ¶ 19; Am. Compl. ¶¶ 50–52. For example, survivors of rape or other sexual abuse may choose medication abortion to feel more in control and to avoid further trauma from having instruments placed in their vaginas. Farris Decl. ¶ 19; Am. Compl. ¶ 50.

In particular, the Act is an attack on families with low incomes, North Carolinians of color, and rural North Carolinians, who already face inequities in access to medical care and who will bear the brunt of the Act's cruelties. Farris Decl. ¶ 10. While forced pregnancy carries health risks for everyone, it imposes greater risks on those already suffering from

health inequities. Black women, who in North Carolina are more than three times as likely as white women to die during pregnancy, *id.*, will acutely feel the Act's harms. Furthermore, North Carolinians face a critical shortage of reproductive health care providers, including obstetrician-gynecologists, especially in rural areas. *Id.* Some patients unable to access abortion due to the Act will therefore be forced to remain pregnant and give birth without adequate prenatal, obstetric, or postpartum medical support.

III. The Balance of Equities and Public Interest Weigh Strongly in Favor of an Injunction

Finally, the balance of equities and public interest weigh heavily in favor of injunctive relief. While Plaintiffs and their patients will suffer grave harm in the absence of an injunction, Defendants are "in no way harmed by issuance of a preliminary injunction which prevents [them] from enforcing" the provisions of the Act that are "likely to be found unconstitutional." Newsom ex rel. Newsom v. Albemarle Cnty. Sch. Bd., 354 F.3d 249, 261 (4th Cir. 2003); see also Legend Night Club v. Miller, 637 F.3d 291, 303 (4th Cir. 2011) (recognizing that "upholding constitutional rights is in the public interest"). Not only would an injunction preserve constitutional rights, it would preserve North Carolinians' health and safety by allowing pregnant people to access abortion without these restrictions which impede Plaintiffs' ability to continue to provide abortions consistent with evidence-based, patient-centered best practices. See Fruth, Inc. v. Pullin, No. 3:15-16266, 2015 WL 9451066, at *8 (S.D. W. Va. Dec. 23, 2015) (observing that "an injunction here will safeguard the public health and thereby serve the public interest").

IV. The Bond Should Be Waived.

Because Defendants will suffer no harm under a preliminary injunction against the challenged provisions, and because this case implicates fundamental constitutional rights, the Court should exercise its "discretion to . . . waive the security requirement" under Federal Rule of Civil Procedure 65(c). *Pashby v. Delia*, 709 F.3d 307, 322 (4th Cir. 2013).

CONCLUSION

For the foregoing reasons, this Court should grant Plaintiffs' amended motion for a preliminary injunction restraining Defendants, their employees, agents, delegates, and successors in office, and all those acting in concert with them, from enforcing or facilitating the Hospitalization Requirement and the IUP Documentation Requirement. Plaintiffs further request that the Court waive the requirement for bond or security.

Dated: July 24, 2023

Respectfully submitted,

/s/ Hannah Swanson

Hannah Swanson*
Helene T. Krasnoff*
Planned Parenthood Fed. of America
1110 Vermont Avenue NW, Suite 300
Washington, DC 20005
Tel.: (202) 973-4800
hannah.swanson@ppfa.org
helene.krasnoff@ppfa.org

Anjali Salvador*
Planned Parenthood Fed. of America
123 William Street, 9th Floor
New York, NY 10038
Tel.: (212) 541-7800
anjali.salvador@ppfa.org

COUNSEL FOR PLANNED PARENTHOOD SOUTH ATLANTIC

Brigitte Amiri*
Lindsey Kaley*
Ryan Mendias*
American Civil Liberties Union
Foundation
125 Broad Street, 18th Fl.
New York, NY 10004
Tel: 212-549-2633
bamiri@aclu.org
lkaley@aclu.org
rmendias@aclu.org

COUNSEL FOR BEVERLY GRAY, M.D.

/s/ Kristi Graunke

Kristi Graunke
NC Bar # 51216
Jaclyn Maffetore
NC Bar # 50849
American Civil Liberties Union
of North Carolina Legal Foundation
P.O. Box 28004
Raleigh, NC 27611
Tel.: (919) 354-5066
kgraunke@acluofnc.org
jmaffetore@acluofnc.org

COUNSEL FOR ALL PLAINTIFFS

*Special appearance filed

CERTIFICATE OF WORD COUNT

Relying on the word count function of Microsoft Word, I hereby certify that this brief is 6,165 words in length and, therefore, complies with the word limitation of 6,250 words for briefs prescribed by Local Rule 7.3(d)(1).

/s/ Hannah Swanson

Hannah Swanson Planned Parenthood Federation of America 1110 Vermont Avenue NW, Suite 300 Washington, DC 20005

Tel.: (202) 494-8764 hannah.swanson@ppfa.org

CERTIFICATE OF SERVICE

I hereby certify that, on July 24, 2023, I electronically filed the foregoing with the clerk of the court by using the CM/ECF system, which served notice of this electronic filing to all counsel of record.

/s/ Hannah Swanson

Hannah Swanson Planned Parenthood Federation of America 1110 Vermont Avenue NW, Suite 300 Washington, DC 20005

Tel.: (202) 494-8764 hannah.swanson@ppfa.org

Exhibit 1

IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

PLANNED PARENTHOOD SOUTH ATLANTIC, et al.,))
Plaintiffs,) Case No. 1:23-cv-00480-CCE-LPA
v.) DECLARATION OF KATHERINE
JOSHUA STEIN, et al.,) FARRIS, M.D., IN SUPPORT OF PLAINTIFFS' AMENDED MOTION
Defendants,	FOR A PRELIMINARY
and) <u>INJUNCTION</u>)
PHILIP E. BERGER, et al.,))
Intervenor-Defendants.)

- I, Katherine Farris, M.D., declare as follows:
- 1. I am a physician licensed to practice medicine in North Carolina, South Carolina, West Virginia, and Virginia. I am board-certified by the American Board of Family Physicians in family medicine.
- 2. I have been employed by Planned Parenthood South Atlantic ("PPSAT") since 2009 in various capacities as a medical doctor. Since July 2013, I have been PPSAT's Interim Affiliate Medical Director, then Affiliate Medical Director, then Chief Medical Officer. (From 2013 to 2015, the Planned Parenthood affiliate in North Carolina was named "Planned Parenthood Health Systems, Inc.") As Chief Medical Officer, I am responsible for ensuring the high quality of the medical care that we provide to patients. In this position,

I provide oversight, supervision, and leadership on all medical services we provide, including abortion. As part of my role, I collaborate with other members of PPSAT senior management to develop policies and procedures to ensure that the medical services we provide follow evidence-based guidelines and comply with all relevant laws.

- 3. I also provide direct medical services for PPSAT. Specifically, I provide a range of family planning and reproductive health care to patients, including (among other things) both medication and procedural abortion, as well as miscarriage care, referrals for ectopic pregnancy care, contraception, and advanced gynecological care—such as complicated intrauterine device ("IUD") and Nexplanon removals (Nexplanon is a birth control implant placed under the skin in the upper arm)—at PPSAT's North Carolina health centers in Winston-Salem, Charlotte, and Asheville (and periodically in Fayetteville, Wilmington, and Chapel Hill), as well as in the other states in which I am licensed.
- 4. I earned my medical degree from the Northwestern University Medical School in 2000 and completed my residency at Valley Medical Center Family Practice, where I was Chief Resident in my last year. I am often called upon to present at educational institutions as an expert in abortion care and provider advocacy.
- 5. The facts I state here and the opinions I offer are based on my education, my years of medical practice, my expertise as a doctor and specifically as an abortion provider, my personal knowledge, my review of PPSAT business records, information obtained through the course of my duties at PPSAT, and my familiarity with relevant medical literature and statistical data recognized as reliable in the medical profession.

6. A copy of my *curriculum vitae* is attached as **Exhibit A**.

I. SUMMARY OF OPINIONS

- 7. I submit this Declaration in support of PPSAT's Amended Motion for a Preliminary Injunction against North Carolina Session Law 2023-14 ("S.B. 20"), as amended by 2023 House Bill 190 ("H.B. 190"), which is codified at Article 1I of Chapter 90 of the North Carolina General Statutes ("the Act").
- I understand that the Act's Hospitalization Requirement¹ for abortions after 8. the twelfth week of pregnancy could bar PPSAT from providing abortion care beyond twelve weeks to survivors of rape or incest or for pregnancies with a "life-limiting anomaly," despite the Act's exceptions for those circumstances. Requiring all abortions after the twelfth week of pregnancy to be performed in a hospital is contrary to the standard of care, under which abortions are routinely performed in outpatient clinic settings through twenty weeks. Indeed, PPSAT provides abortion after twelve weeks to patients with fetal diagnoses who have been referred to us by hospital providers. This Hospitalization Requirement is also illogical as a matter of patient health and safety because, even when the Act takes effect, licensed clinics like PPSAT's will still be allowed to perform identical procedures after twelve weeks to treat miscarriage. If interpreted to require all abortions after twelve weeks to be performed in hospitals, the Hospitalization Requirement will only serve to harm patients who have experienced sexual assault and those who are facing "lifelimiting" fetal diagnoses.

¹ N.C. Gen. Stat. §§ 90-21.81B(3)–(4), 90-21.82A(c), 131E-153.1.

- 9. I further understand that the Act's Intrauterine Pregnancy ("IUP") Documentation Requirement² could prevent us from providing early medication abortion to patients who have a very early pregnancy that is not yet visible by ultrasound (also known as a "pregnancy of unknown location"). Not only is it safe and evidence-based to provide medication abortion to patients whose pregnancies are too early to see by ultrasound and who are at low risk of ectopic pregnancy, but preserving patients' access to this very early abortion care is all the more important given North Carolina's twelve-week ban. Denying medication abortion to patients whose pregnancies cannot yet be seen on an ultrasound will force those patients either to delay wanted care, or to obtain a procedural abortion even if they have important reasons for preferring a medication-only method. Either of these alternatives subverts the patient autonomy that both patient-centered practices and medical evidence support.
- 10. In particular, the Act is an attack on families with low incomes, North Carolinians of color, and rural North Carolinians, who already face inequities in access to medical care and who will bear the brunt of the Act's cruelties. While forced pregnancy carries health risks for everyone, it imposes greater risks for those already suffering from health inequities. Black women,³ who in North Carolina are more than three times as likely

² N.C. Gen. Stat. § 90-21.83B(a)(7).

³ In this declaration, I use "woman" or "women" as a short-hand for people who are or may become pregnant, but people of many gender identities, including transgender men and gender-diverse individuals, may become pregnant and seek abortion and are also harmed by the Act.

as white women to die during pregnancy,⁴ will acutely feel the Act's harms. Furthermore, North Carolinians face a critical shortage of reproductive health care providers, including obstetrician-gynecologists, especially in rural areas.⁵

II. PPSAT AND ITS SERVICES

11. PPSAT is a non-profit corporation organized under the laws of North Carolina. PPSAT offers a wide range of affordable and reliable reproductive and sexual health care services in our 15 locations across North Carolina, South Carolina, Virginia, and West Virginia. PPSAT operates ten health centers throughout North Carolina, located in Asheville, Chapel Hill, Charlotte, Durham, Fayetteville, Greensboro, Raleigh,

⁴ See NC State Ctr. for Health Stats., Trends in Maternal Mortality Statistics, NC Dep't Health & Hum. Servs., tbl. 4 (2013), https://schs.dph.ncdhhs.gov/data/maternal/Table4_MMReport2013.pdf (available at https://schs.dph.ncdhhs.gov/data/maternal/); 2022 Health of Women and Children Report – Report Data (All States), Am.'s Health Rankings, (2022), https://www.americashealthrankings.org/learn/reports/2022-health-of-women-and-children-report (reporting a white maternal mortality rate of 17.3 and a Black maternal mortality rate of 52.8 per 100,000 live births); NC Health News, Childbirth Is Still Killing Black Moms at a Higher Rate. NC Advocates, Policymakers Discuss, Carolina Public Press, (April 19, 2023), https://carolinapublicpress.org/59894/childbirth- is-still-killing-black-moms-at-a-higher-rate-nc-advocates-policymakers-discuss-solutions/.

For the United States: A Case Study of the North Carolina Home Birth Freedom Act, 26 J. Trachtenburg Sch. Pub. Pol'y & Pub. Admin. at George Washington Univ. 1, 30 (2019), (reporting that about one-third of rural counties in North Carolina did not have an OB/GYN in 2017 (citing Cecil G. Sheps Ctr. for Health Servs. Rsch., North Carolina Hospital Health Professional Supply Data, Univ. N.C. Chapel Hill, (last modified February 10, 2019), https://nchealthworkforce.unc.edu/supply/); see generally NC Maternal Mortality Rev. Comm., North Carolina Maternal Mortality Review Report, NC Dep't of Health & Hum. Servs., (2021), https://wicws.dph.ncdhhs.gov/docs/2014-16-MMRCReport_web.pdf.

Wilmington, and Winston-Salem. Altogether, these health centers provide a full range of reproductive and sexual health services, including: cervical cancer screenings; breast and annual gynecological exams; family planning counseling; pregnancy testing and counseling; reproductive health education; testing and treatment for sexually transmitted infections; contraception; procedural and medication abortion services and related care; prenatal consultation; primary care; gender affirming hormone therapy; vasectomies; and health care related to miscarriage. PPSAT provides care to approximately 38,000 patients at its health centers in North Carolina each year.

- 12. PPSAT provides abortions at six health centers licensed under North Carolina law as abortion clinics located in Asheville, Chapel Hill, Charlotte, Fayetteville, Wilmington, and Winston-Salem. At these health centers, we provide both medication abortion through 77 days (or 11 weeks) gestation as measured from the first day of the patient's last menstrual period ("LMP") and, under S.B. 20, procedural abortion through the twelfth week. When one of S.B. 20's exceptions to the twelve-week ban applies, we may provide procedural abortion up to either 13.6 or 19.6 weeks LMP depending on location and staffing. PPSAT has been providing procedural abortions past the twelfth week of pregnancy for more than fifteen years in North Carolina.
- 13. But for the Hospitalization Requirement and the IUP Documentation Requirement taking effect later this fall, PPSAT would continue to provide abortion after twelve weeks to survivors of rape or incest and to patients with diagnoses of "life-limiting"

anomalies" and would continue to provide medication abortion to patients at low risk for ectopic pregnancy whose pregnancies are not yet visible by ultrasound.

III. ABORTION IS COMMON, SAFE, AND CRITICAL HEALTH CARE

A. Abortion Methods Performed in Outpatient Settings

- 14. All methods of abortion provided at PPSAT—medication abortion, procedural abortion using aspiration, and procedural abortion by dilation and evacuation ("D&E")—are simple, straightforward medical treatments that typically take no more than 10 to 15 minutes, have an extremely low complication rate, and, unlike some other office-based procedures such as vasectomies or contraceptive implant removals, involve no incisions. In North Carolina and nationwide, these methods are almost always provided in outpatient, office-based settings by clinicians adhering to widely-accepted medical standards of care.
- 15. Although aspiration abortion and D&E are both sometimes referred to as "surgical" abortion, they are not what is commonly understood to be surgery. Both aspiration abortion and D&E are done through the natural opening of the vagina and cervix and therefore involve no incisions. Both can be, and almost always are, performed in outpatient clinics like PPSAT's.

i. First-Trimester Medication Abortion

16. In a medication abortion, a patient takes medications to cause uterine contractions that empty the uterus. Medication abortion requires no anesthesia or sedation.

From the time a patient receives a positive pregnancy test through 11 weeks, or 77 days, LMP, PPSAT provides the most common form of medication abortion.

- 17. In a typical medication abortion, the patient takes a combination of two prescription drugs—mifepristone (also known as RU-486 or by its trade name, Mifeprex) and misoprostol (also known as a prostaglandin analogue or by its trade name, Cytotec)—a day or two apart. Mifepristone works by blocking the hormone progesterone, which is necessary to maintain pregnancy. Misoprostol causes the cervix to open and the uterus to contract and empty. These same medications are offered as a treatment option to patients who have a miscarriage with retained tissue. Indeed, the process of medication abortion very closely approximates the process of miscarriage.
- 18. Mifepristone and misoprostol are safe—substantially safer than Tylenol and Viagra, for example.⁶ The FDA approved mifepristone, by its brand name Mifeprex, in 2000. Decades of experience with medication abortion since then have resoundingly confirmed its safety and efficacy. According to the FDA, serious adverse events (including death, hospitalization, serious infection, and bleeding requiring transfusion) among mifepristone patients are "exceedingly rare, generally far below 0.1% for any individual adverse event." Indeed, earlier this year, the FDA modified its dispensing requirements

⁶ See Analysis of Medication Abortion Risk and the FDA report, "Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018", Advancing New Standards in Reprod. Health (2019), https://www.ansirh.org/sites/default/files/publications/files/mifepristone safety 4-23-2019.pdf.

⁷ FDA, Ctr. for Drug Evaluation & Rsch., Med. Rev., Application No. 020687Orig1s020, 47 (2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf.

for mifepristone to reflect the ever-growing body of evidence demonstrating the safety and effectiveness of medication abortion.⁸ While the FDA-approved labeling for mifepristone reflects its usage through 70 days LMP, there is significant evidence that supports its use through 77 days LMP, as is provided at PPSAT.⁹

19. For some patients, medication abortion offers important advantages over procedural abortion. Procedural abortion is contraindicated for patients with certain medical conditions, such as intolerance of available sedation or analgesic medications, or a history of seizure disorder. And medication abortion may be preferable for patients with some clinical conditions such as fibroids, or other uterine abnormalities such as bicornuate uterus, which can make it difficult to visualize the cervix and contents of the uterus during a procedural abortion. Some patients prefer medication abortion because it feels more natural to them to have their body expel the pregnancy rather than to have a provider use aspiration or instruments to empty the uterus. And some patients choose medication abortion because of fear or discomfort around a procedure involving aspiration or instruments. For example, survivors of rape and people who have experienced sexual abuse, molestation, or other trauma may choose medication abortion to feel more in control

⁸ See Information About Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation, FDA, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (last reviewed July 23, 2023).

⁹ See, e.g., Ilana G. Dzuba et al., A Repeat Dose of Misoprostol 800 mcg Following Mifepristone for Outpatient Medical Abortion at 64–70 and 71–77 Days of Gestation: A Retrospective Chart Review, 102 Contraception 104 (2020); Ilana G. Dzuba et al., A Non-Inferiority Study of Outpatient Mifepristone-Misoprostol Medical Abortion at 64–70 days and 71–77 Days of Gestation, 101 Contraception 302 (2020).

of the experience and to avoid further trauma from having instruments placed in their vaginas. In the rare event that a medication abortion is unsuccessful, the patient may require follow-up care with procedural abortion, but in the vast majority of cases a patient who prefers medication abortion will be able to use that method, saving them from an unwanted procedure or a hospital referral.

20. Additionally, the logistics of a procedural abortion may be prohibitive for some patients, especially those with lower incomes, those who have difficulty getting time off work and securing childcare, or those who live in rural areas far from facilities where procedural abortion care is provided. Some health care providers charge more for procedural abortions, meaning some patients must wait longer to get an abortion while they gather funds—if they can afford it at all. Survivors of intimate partner violence in particular may struggle to find such support, as telling their partner they are having an abortion could be dangerous. And unlike procedural abortion, medication abortion gives the patient a greater degree of control over when and where they will pass the pregnancy, including who is with them to offer support. For example, patients can time their medications so that they begin the process of passing the pregnancy—involving cramping and bleeding—when their partner is home with them or when a family member is available to care for their other children. This degree of control and predictability is a big factor for some patients.

ii. Aspiration Abortion

21. Aspiration abortion (also known as suction curettage or dilation & curettage) entails using suction to empty the uterus. It is a straightforward procedure performed in the

first and early second trimester. PPSAT provides aspiration abortion up to approximately 14 weeks LMP. For this method, a small plastic tube, called a cannula, is passed through the cervical canal. The cannula is attached to a syringe or electrical pump that creates gentle suction to empty the uterus.

- 22. Prior to starting the suction procedure, the provider dilates the cervix as needed to allow the cannula to enter the uterus. An analgesic such as ibuprofen, an anti-anxiety medication such as Ativan or Valium, a local anesthetic such as Lidocaine, and/or moderate sedation may be used during or prior to the procedure.
- 23. The entire procedure, including administration of local anesthesia, dilating the cervix, and aspirating the uterine contents usually takes 3 to 5 minutes. It involves no incision, cutting, or suturing.
- 24. This same aspiration method is used to treat a miscarriage after embryonic or fetal demise has occurred naturally, and for pregnancies of the same gestational age there is no difference in the risk of complications between a procedure to manage early miscarriage and aspiration abortion. PPSAT currently uses this aspiration procedure for miscarriage management up to approximately 14 weeks.

iii. D&E Abortion

25. Dilation and evacuation, or D&E, uses a combination of gentle suction and additional instruments, including specialized forceps, to evacuate the pregnancy contents from the uterus. While we generally refer to procedures starting at 14 weeks LMP as "D&Es," instruments are routinely used in addition to suction starting around 15 weeks

LMP, depending on the provider's individual practice and the patient's individual medical characteristics.

- 26. Prior to the D&E procedure, the provider dilates the patient's cervix. This may be done through medications such as misoprostol, which softens the cervix, and/or through the placement of osmotic dilators in the cervix. Osmotic dilators are slender sticks made of a material that gradually swells as it absorbs moisture; as the dilators swell in the cervical opening, they cause the cervix to dilate. The provider may also use mechanical dilators or a combination of these techniques. The provider then empties the uterus using instruments or a combination of suction and instruments. When providing D&Es, PPSAT offers patients the option of local anesthesia or minimal or moderate sedation.
- 27. In the early part of the second trimester, physicians may perform the cervical preparation and evacuation procedure on the same day. Later in the second trimester, the physician may start the dilation process one day before the evacuation. In most cases, PPSAT begins the dilation process for patients from 16 to 20 weeks LMP through the placement of osmotic dilators the day before evacuation. If this first appointment for dilation also includes tests, examination, education and consent, it may take a few hours, though the actual procedure to place the dilators takes approximately five minutes. After this appointment, the patient then leaves the clinic and returns the next day for the evacuation procedure.
- 28. Once the patient's cervix is sufficiently dilated, the entire evacuation procedure typically takes 10 to 15 minutes. Like aspiration abortion, D&E does not involve

any incision, cutting, or suturing. And like aspiration, the D&E procedure is used both to provide abortion and to manage miscarriage.

B. Abortion Is One of the Safest Procedures in Medicine

- 29. To the extent the Act requires abortion after twelve weeks to be provided in a hospital, or prohibits medication abortion for low-ectopic-risk patients whose pregnancies are not yet visible by ultrasound, the Act does not improve patient health and safety.
- 30. Abortion is one of the safest forms of medical care in contemporary medical practice and is safely and routinely provided in outpatient settings in countries around the world. Leading medical authorities agree that abortion is one of the safest procedures in medical practice, 10 "stand[ing] in contrast to the extensive regulatory requirements that state laws impose on the provision of abortion services." 11
- 31. In fact, major complications, defined as those requiring hospital admission, surgery, or blood transfusion, occur in just 0.23 percent of abortions performed in outpatient, office-based settings.¹²

Nat'l Acads. Scis., Eng'g, & Med., *The Safety and Quality of Abortion Care in the United States* 1, 77 (2018), available at http://nap.edu/24950 ("The clinical evidence makes clear that legal abortions in the United States—whether by medication, aspiration, D&E, or induction—are safe and effective.").

¹¹ *Id*.

Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175, 181 (2015); see also Ushma D. Upadhyay et al., *Abortion-Related Emergency Room Visits in the United States: An Analysis of a National Emergency Room Sample*, 16 BMC Med. 1, 1 (2018).

- 32. Abortion compares favorably, with a markedly lower complication rate, to other procedures routinely performed outside of a hospital setting, including:
 - vasectomies, a form of male birth control that involves transecting and cauterizing the vas deferens, the tubes that carry sperm, resulting in hematoma formation two percent of the time while major complications requiring hospitalization occur in 0.2–0.8 percent of cases;¹³
 - colonoscopies, an exam used to look for changes in the large intestine (colon) and rectum, such as swollen, irritated tissues, polyps or cancer, with a complication rate of 1.6 percent;¹⁴
 - wisdom teeth extraction, a surgical procedure to remove one or more of the four permanent teeth located at the back corners of the mouth, with a complication rate of 6.9 percent; 15 and
 - tonsillectomies, surgical removal of the tonsils, with a complication rate of 7.9 percent. 16

¹³ Christopher E. Adams & Moshe Wald, *Risks and Complications of Vasectomy*, 36 Urologic Clinics N. Am. 331, 331 (2009).

¹⁴ Isuru Ranasinghe et al., Differences in Colonoscopy Quality Among Facilities: Development of a Post-Colonoscopy Risk-Standardized Rate of Unplanned Hospital Visits, 150 Gastroenterology 103, 109 (2016).

¹⁵ Francois Blondeau & Nach G. Daniel, Extraction of Impacted Mandibular Third Molars: Postoperative Complications and their Risk Factors, 73 J. Canadian Dental Ass'n 325, 325b (2007).

¹⁶ Jack L. Paradise et al., *Tonsillectomy and Adenotonsillectomy for Recurrent Throat Infection in Moderately Affected Children*, 110 Pediatrics 7, 12 (2002).

- 33. Abortion is significantly safer than the alternative of carrying a pregnancy to term and giving birth, and complications related to pregnancy and childbirth are much more common than abortion-related complications. ¹⁷ The United States has the highest maternal mortality rate among high-income countries (more than four times the rate of others in that group). Most concerningly, it is getting worse. ¹⁸ In 2021 alone, 1,205 pregnant women died of pregnancy-related causes in the United States. ¹⁹ The Centers for Disease Control and Prevention (CDC) measure maternal mortality rates as the number of maternal deaths per 100,000 live births. ²⁰ In 2021, the maternal mortality rate was 32.9 deaths per 100,000 live births. ²¹ And the maternal mortality rate in North Carolina is even higher than the national average. ²²
- 34. In contrast, the CDC reported 0.43 deaths per 100,000 legal abortions from 2013 to 2019.²³ While the U.S. maternal mortality rate has significantly increased, there is

¹⁷ See Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215 (2012); Nat'l Acads. Scis., Eng'g, & Med., *supra* note 10, at 11 tbl. S-1.

Donna L. Hoyert, , *Maternal Mortality Rates in the United States, 2021*, CDC, Nat'l Ctr. for Health Stats. 1, 1 (2023), https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates- 2021.pdf.

¹⁹ *Id*.

²⁰ *Id*.

²¹ *Id*.

²² Teddy Rosenbluth & Tyler Dukes, *Pregnancy Can Be Risky in the US. In North Carolina, the Threat of Death Is Even Higher.*, News & Observer, (July 19, 2023, 10:45 A.M.), https://www.newsobserver.com/news/state/north-carolina/article277397263 .html.

²³ Katherine Kortsmit et al., *Abortion Surveillance* — *United States*, 2020, 71 Morbidity & Mortality Weekly Rep. Surveillance Summaries 1, 6 (2022).

no evidence that has occurred for abortion care, making legal abortion approximately 12 to 14 times safer than live birth.²⁴

35. In North Carolina, physicians and certified nurse-midwives can deliver babies in locations other than a hospital, including at birthing centers and even in private homes.

C. Abortions Are Safely Performed in Outpatient, Office-Based Settings

- 36. There is no medical reason to require that all abortions after twelve weeks take place in hospitals and not abortion clinics. In North Carolina, as is done throughout the country, legal abortions are safely and routinely performed in doctors' offices and outpatient health center settings. Procedural abortions are almost always provided in an outpatient setting; nationwide, only 3% of abortions annually are performed in hospitals.²⁵ In addition, abortions at outpatient clinics are often more affordable, easier to navigate, and generally require considerably less time for patients than abortions in a hospital setting.
- 37. According to the National Academies of Sciences, Engineering, and Medicine, "most abortions can be provided safely in office-based settings," and a hospital setting is not clinically necessary. ²⁶ Similarly, major medical associations, including the American College of Obstetricians and Gynecologists ("ACOG") and the American Public

²⁴ Nat'l Acads. Scis., Eng'g, & Med., *supra* note 10, at 75; Raymond & Grimes, *supra* note 17, at 215.

²⁵ Rachel K. Jones et al., *Abortion Incidence and Service Availability in the United States*, 2020, 54 Persps. on Sexual & Reprod. Health 128, 134 (2022).

²⁶ Nat'l Acads. Scis. Eng'g, & Med., supra note 10, at 10.

Health Association, reject the notion that abortions should be required to be performed in hospitals.²⁷

38. The technique for a procedural abortion is clinically identical whether performed in a hospital or outpatient setting, and there is no scientific evidence indicating that abortions performed in a hospital are safer than those performed in an appropriate outpatient clinic or office-based setting.²⁸ To the contrary, as is true for nearly every medical procedure, fewer complications are seen in settings that perform higher volumes of the same procedure, making licensed abortion clinics like PPSAT's safer for most patients than most hospitals, many of which do not routinely provide abortion care.²⁹ In fact, at least one study demonstrated that second-trimester terminations of pregnancy by

No. 815: Increasing Access to Abortion, 136 Obstetrics & Gynecology e107, e109 (2020); Am. Pub. Health Ass'n, Policy Statement No. 20083—Need for State Legislation Protecting and Enhancing Women's Ability to Obtain Safe, Legal Abortion Services Without Delay or Government Interference (Oct. 2008), http://www.apha.org/policies-and-advocacy/public-healthpolicy-statements/policy-database/2014/07/23/09/30/needfor-state-legislation-protecting-and-enhancing-womensability-to-obtain-safe-legal-abortion; see also Barbara S. Levy et al., Consensus Guidelines for Facilities Performing Outpatient Procedures: Evidence Over Ideology, 133 Obstetrics & Gynecology 255 (2019) (concluding, based on an analysis of available evidence, that requiring facilities performing abortion to meet standards beyond those currently in effect for all general medical offices and clinics is unjustified).

²⁸ Sarah C. M. Roberts et al., Association of Facility Type with Procedural-Related Morbidities and Adverse Events Among Patients Undergoing Induced Abortions, 319 JAMA 2497, 2502 (2018).

²⁹ Steve Sternberg & Geoff Dougherty, *Risks are High at Low-Volume Hospitals*, U.S. News & World Rep. (May 18, 2015, 12:01 A.M.), https://www.usnews.com/news/articles/2015/05/18/risks-are-high-at-low-volume-hospitals#:~:text=These%20large%20numbers%20of%20low,similar%20patients%20rat her%20than%20by.

D&E in appropriate patients in a dedicated outpatient facility can be safer and less expensive than hospital-based D&E or induction of labor.³⁰

- 39. The features that differentiate hospitals from abortion clinics include system operations requirements, staffing requirements, and building construction requirements.³¹ Not only are these features irrelevant and unnecessary in the context of abortion care, they also provide no medical benefit.
- 40. Unlike invasive surgical procedures, aspiration abortion and D&E do not involve incisions of any kind. In North Carolina, procedures with risks similar to the risks associated with abortion—including inserting or removing an IUD; endometrial biopsy; colposcopy; hysteroscopy (scoping of the cervix and uterus); Loop Electrosurgical Excision Procedure (removing pre-cancerous cells from the cervix); and miscarriage management (which, from a clinical perspective, involves the exact same procedures as aspiration abortion and D&E, and is distinguished from those treatments only by the absence of embryonic or fetal cardiac activity)—are routinely performed in outpatient clinics and physicians' offices rather than in hospitals. And the procedures noted above with higher complication rates than abortion (like vasectomies and wisdom-tooth extractions) are routinely, and without controversy, performed outside of the hospital setting throughout North Carolina.

³⁰ David K. Turok et al, Second Trimester Termination of Pregnancy: A Review by Site and Procedure Type, 77 Contraception 155, 155 (2008).

³¹ Compare 10A N.C. Admin. Code 13B.3201 (hospital requirements) with 10A N.C. Admin. Code 14E .0100 et. seq. (abortion facility requirements).

- 41. Even in the rare event that complications arise during a procedural abortion, management can nearly always be safely and appropriately administered in the clinic where the abortion is being provided.³² For example, most cases of hemorrhage (the technical term for heavy bleeding) are managed in the clinic setting with uterotonic medications, like misoprostol, that cause uterine contractions and reduce bleeding, and with uterine massage.³³ Most cases of cervical laceration are managed in the clinic setting with suture.³⁴ Cases of incomplete abortion are generally managed through repeat aspiration or medication, and, at any rate, arise after completion of the procedure, such that even if the abortion took place in a hospital, this complication would occur only after the patient leaves the hospital setting. In fact, because the Hospitalization Requirement applies only to abortion and not to identical procedures for miscarriage management or removal of retained pregnancy tissue, patients who have retained tissue as a complication of a procedural abortion performed in a hospital could obtain treatment for that complication at an outpatient clinic using aspiration or D&E.
- 42. In the rare event that a patient experiences infection as a result of a procedural abortion, the infection would typically not develop until days after the procedure. At that time, the patient diagnosed with infection would receive treatment with oral antibiotics on an outpatient basis; i.e., they would take the antibiotics at home or a place of their choosing.

³⁴ *Id*.

Roberts et al., *supra* note 28; Nat'l Acads. of Scis., Eng'g, & Med., *supra* note 10.

³³ Jennifer Kerns & Jody Steinauer, *Management of Postabortion Hemorrhage*, 87 Contraception 331, 333 (2013).

Oral or intramuscular antibiotics almost always resolve infection without any long-term or permanent injury to the patient. The use of intravenous antibiotics to treat infection arising from procedural abortion is rare, and can often be provided in an outpatient setting.

- 43. As discussed above, major abortion complications occur in fewer than one-quarter of one percent (0.23 percent) of abortions.³⁵ In the exceedingly rare event that hospitalization is needed to manage complications, patients are safely stabilized and transferred to a hospital.
- 44. It is unreasonable, and a waste of hospital resources, to require an entire category of procedure to be performed in a hospital when there is no medical benefit for the vast majority of patients. As with any other medical procedure, whether an abortion should be provided in a hospital should be a patient-specific consideration, based on the patient's individual medical circumstances.
- 45. PPSAT physicians have low abortion complication rates and superb safety records. Because PPSAT specializes in providing patient-centered, holistic sexual and reproductive health care, PPSAT patients benefit from receiving care from highly experienced and specialized providers and staff. This is particularly important for the patient population we are talking about here—survivors of sexual assault or patients with a "life-limiting" fetal anomaly, who may be more comfortable with a specialized provider

Upadhyay et al., *Incidence of Emergency Department Visits*, *supra* note 12, at 175.

like Planned Parenthood than having to navigate a hospital, especially one for which they need to travel outside of their community.

- 46. Indeed, PPSAT receives referrals from North Carolina hospital-based physicians for patients seeking abortion after twelve weeks following a fetal anomaly diagnosis. Abortions in these circumstances are almost always clinically identical to abortions where no anomaly is present. For those patients, receiving an abortion at one of PPSAT's licensed abortion clinics is just as safe as getting that care in a hospital, and moreover, for most of them, it is more accessible from a logistical and financial standpoint, particularly where insurance would not cover the patient's abortion in a hospital setting.
- 47. There is no medical reason to require all abortions for "life-limiting" anomalies to be provided in a hospital, and PPSAT would continue to provide abortions to these patients after the twelfth week of pregnancy under the Act's "life-limiting anomaly" exception but for the Hospitalization Requirement.
 - D. Medication Abortion Is Safe to Provide to Patients at Low Risk of Ectopic Pregnancy Before an Intrauterine Pregnancy Can Be Documented
- 48. If the IUP Documentation Requirement requires express confirmation of an intrauterine pregnancy *before* administration of medication abortion, it will be impossible for PPSAT to comply in the early weeks of pregnancy, and accordingly impossible for us to provide medication abortion to patients at that gestational stage.
- 49. Specifically, some patients present for abortions very early in pregnancy. At these early gestational stages, though the patient has a positive pregnancy test, it may be

too soon to see an intrauterine gestational sac via ultrasound because the pregnancy is not yet sufficiently developed. Accordingly, if the IUP Documentation Requirement requires PPSAT to document that an intrauterine pregnancy is *visible by ultrasound* before providing a medication abortion, it would prohibit PPSAT from providing medication abortion to patients who are very early in their pregnancies.

- 50. The Act would therefore force patients with pregnancies of unknown location either to delay their abortion until an intrauterine pregnancy can be seen by ultrasound or to undergo a procedural abortion, even if they have been determined to be at low risk for ectopic pregnancy and have decided in consultation with their provider that a medication abortion is the best option for them.
- 51. Medical evidence supports the safety and efficacy of providing medication abortion to low-ectopic-risk patients before the pregnancy can be seen on an ultrasound, using a protocol that *simultaneously* (1) provides medication abortion to a patient who wants it and (2) conducts further testing to rule out ectopic pregnancy. Moreover, this protocol is more patient-centered than requiring the patient to wait for medication abortion at a later date or to obtain a procedural abortion despite their preference for medication abortion. PPSAT follows this evidence-based protocol at its clinics in North Carolina.
- 52. Under this protocol, when a patient is seeking abortion and their pregnancy is not visible by ultrasound, PPSAT first screens the patient for risk of ectopic pregnancy (i.e., a pregnancy that has implanted outside of the uterus) by asking questions about the

patient's medical history and symptoms.³⁶ If we determine that the patient is at high risk of ectopic pregnancy, we refer the patient to another provider, typically an emergency department, for diagnosis and treatment.

- 53. If the patient is not at high risk of ectopic pregnancy, the provider offers the patient three options for treatment: medication abortion, aspiration abortion, or a follow-up appointment at a later date to see if an intrauterine pregnancy can be seen on an ultrasound at that time. We explain the potential risks and benefits of each option, and the patient and the physician decide which option is best for the patient.
- 54. If a low-ectopic-risk patient with a pregnancy of unknown location chooses medication abortion, the provider *simultaneously* provides the medication abortion *and* conducts further testing to rule out ectopic pregnancy—specifically, by drawing a blood sample to test the level of the pregnancy hormone human chorionic gonadotropin ("hCG"). These test results usually come back no more than 24 hours later.
- 55. If the blood test results indicate that the patient's hCG levels are sufficiently high (indicating a more developed pregnancy), this may be evidence of ectopic pregnancy. At that point, even if the patient has already taken the medications for medication abortion,

³⁶ An ectopic pregnancy occurs when a fertilized egg implants and grows outside of the uterus. Ectopic pregnancies require treatment to terminate the non-viable pregnancy. Research has shown that it is safe and effective to screen for ectopic pregnancy by considering known risk factors—including symptoms such as pain and bleeding, history of ectopic pregnancies, past surgery on the fallopian tube, and presence of pelvic inflammatory disease. *See* Ushma D. Upadhyay et al., *Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study*, 182 JAMA Internal Med. 482 (2022).

the provider will offer the patient the option of returning for an aspiration procedure as a means of *both* testing for ectopic pregnancy and completing the abortion. If the patient with high hCG levels opts for aspiration, then following that procedure, the provider will examine the aspirated uterine contents to see if gestational tissue is identifiable—confirming that the pregnancy was intrauterine and that the abortion is complete. If the patient with high hCG levels does not opt for aspiration, or if a gestational sac is not identifiable following aspiration, the provider may refer the patient for further ectopic evaluation, usually in an emergency department.

- 56. If, however, the patient's hCG levels are low (indicating a pregnancy at a very early gestational age), the patient's hCG levels are tested again 48–72 hours after taking the misoprostol.
- 57. Whether or not the patient's hCG levels have decreased more than 50% after the abortion is evidence of whether the pregnancy has been terminated by the medication abortion, the pregnancy is in the uterus and continuing to grow, or there is still a possibility of ectopic pregnancy. Patients whose hCG levels have not decreased sufficiently are further evaluated for ectopic pregnancy, including, where medically indicated, through referral to a hospital provider.
- 58. Administration of medication abortion according to this protocol has been shown to be safe and effective in terminating the pregnancy.³⁷ And at least one study found

³⁷ See, e.g., Alisa B. Goldberg et al., Mifepristone and Misoprostol for Undesired Pregnancy of Unknown Location, 139 Obstetrics & Gynecology 771 (2022); Karen Borchert et al., Medication Abortion and Uterine Aspiration for Undesired Pregnancy of

that this protocol leads to earlier exclusion of ectopic pregnancy than waiting to see if an intrauterine pregnancy can be detected later.³⁸

- 59. If a low-ectopic-risk patient with a pregnancy of unknown location were referred to a hospital for ectopic evaluation instead of receiving a medication abortion according to this protocol, in most cases the hospital would perform the very same serial hCG testing that, under the protocol, PPSAT performs simultaneously with the medication abortion. Referring a low-ectopic-risk patient with a pregnancy of unknown location for ectopic evaluation instead of providing a medication abortion per this protocol therefore does not lead to earlier or more accurate diagnosis of ectopic pregnancy. Instead, it only delays the patient's abortion.
- 60. Access to early abortion care is all the more important given the Act's twelve-week ban, which is already in effect in North Carolina. Delaying their abortion may not be possible for some patients, since scheduling constraints due to clinic capacity and personal matters such as work and childcare might force them past the twelve-week mark and prevent them from accessing abortion altogether. Further restrictions on access to abortion in North Carolina and surrounding states will put even more pressure on us to provide timely care to our patients.

Unknown Location: A Retrospective Cohort Study, 122 Contraception 109980 (2023); I. Bizjak et al., Efficacy and Safety of Very Early Medical Termination of Pregnancy: A Cohort Study, 124 BJOG: Int'l J. Obstetrics & Gynaecology 1993 (2017); Philip Goldstone et al., Effectiveness of Early Medical Abortion Using Low-Dose Mifepristone and Buccal Misoprostol in Women With No Defined Intrauterine Gestational Sac, 87 Contraception 855 (2013).

³⁸ Goldberg et al., *supra* note 37, at 771.

- 61. Furthermore, banning medication abortion, but not procedural abortion, for low-ectopic-risk patients with pregnancies of unknown location is arbitrary and unnecessary. It puts patients in a position of opting for a procedural abortion even though they feel that a medication abortion is best for them. Aspiration abortion is not the best option for every patient, and it is vital to make available to patients the full range of medically appropriate options.
- 62. Further, PPSAT sometimes has clinic days on which, for staffing reasons, it is able to offer medication abortion but not procedural abortion. Eliminating the option of medication abortion for some patients would reduce the availability of appointments at PPSAT health centers for them, thus hampering their access to abortion.

IV. IMPACT ON PPSAT PATIENTS

- A. Impact of the Hospitalization Requirement on Survivors of Rape or Incest and Patients with "Life-Limiting" Fetal Anomalies
- 63. If the Hospitalization Requirement means that PPSAT cannot provide abortion after the twelfth week of pregnancy even under the Act's exceptions for survivors of rape or incest and for people diagnosed with "life-limiting" fetal anomalies, it will limit the number of providers available to these patients, increasing the expense of abortion and delaying or denying their access to desperately needed care. These heightened barriers will force patients who are already facing personal hardship and even trauma due to the circumstances of their pregnancies to remain pregnant against their will even longer—all without any medical benefit.

- 64. It should go without saying that it is vitally important to preserve access to abortion after the twelfth week of pregnancy for survivors of rape or incest, and for patients who have received a diagnosis of a "life-limiting" fetal anomaly.
- 65. Thousands of North Carolinians suffer sexual abuse each year.³⁹ Because of the non-consensual nature of rape and incest, these survivors are at heightened risk of unwanted pregnancy. And the traumatic circumstances of the pregnancy may increase the urgency of access to abortion. The physical aspects of pregnancy, including the sense of losing control of one's body, can be particularly traumatic for patients who have experienced a forcible loss of control of their bodies or their lives. For these survivors, pregnancy can trigger flashbacks, dissociative episodes, and other symptoms of retraumatization.⁴⁰ Survivors experiencing mental health challenges may decide they are not healthy enough to parent a child (or an additional child, if they are within the roughly 62% of North Carolina abortion patients who already have children).⁴¹

³⁹ Sexual Violence in North Carolina, 2018-2019, NC Dep't of Health & Hum. Servs., (May 2021), https://injuryfreenc.dph.ncdhhs.gov/preventionResources/docs/BRFSS-SV-Factsheet-Final.pdf (reporting that over 940,000 North Carolina adults have ever experienced sexual violence); Council for Women & Youth Involvement, Sexual Assault in North Carolina July 2021–June 2022, NC Dep't of Admin., (2022), https://ncadmin.nc.gov/cfwyi/2021-2022-dvsa-statistical-briefpdf-0/download?attachment (reporting that the North Carolina Department of Administration's

^{0/}download?attachment (reporting that the North Carolina Department of Administration's Council for Women and Youth Involvement provided sexual-assault support services to 11,933 clients between July 2021 and June 2022).

⁴⁰ L. G. Ward, *Trauma-Informed Perinatal Healthcare for Survivors of Sexual Violence*, 34(3) J. Perinatal & Neonatal Nursing 199.

⁴¹ Katherine Kortsmit et al., *Abortion Surveillance* — *United States*, 2019, Morbidity & Mortality Weekly Rep. Surveillance Summaries 1, 22 tbl. 8 (2021) (reporting that in 2019, 37.4% of North Carolina abortion patients had zero previous live births;

- 66. It is already hard for those who have experienced intimate partner violence to access abortion care in many instances. In particular, it can be difficult if not impossible for people experiencing intimate partner violence to escape their partner's physical, emotional, and financial control long enough to access an abortion without compromising their confidentiality. In cases where they have been physically isolated from the community, they may not be able to leave their homes to seek routine medical care in the hours or days directly following the assault, let alone have access to transportation or the financial means to access abortion providers or follow-up services. At the same time, research has indicated that women who are denied a wanted abortion, when compared to those who are able to obtain abortions, face a greater likelihood of continued physical violence from the man involved in the pregnancy.⁴²
- 67. Even when survivors are able to access abortion, the process of finding a way to do so can delay them substantially, making them more likely to need abortion after twelve weeks of pregnancy. Survivors of repeated abuse may also be unsure of the gestational age of their pregnancies, so they may present to outpatient clinics for the statemandated informed consent visit but find they are already beyond their twelfth week of pregnancy. If the Hospitalization Requirement applies to patients seeking abortion due to rape or incest, those patients would have to be referred to a hospital provider, despite the

^{23.9%} had one previous live birth; 19.8% had two; 10.5% had three; and 8.5% had four or more).

⁴² Sarah C.M. Roberts et al., Risk of Violence From the Man Involved in the Pregnancy After Receiving or Being Denied an Abortion, 12 BMC Med. 1, 5 (2014).

clinic being able to safely provide the care, forcing the patient who has already experienced trauma to present to and share their story with an additional provider.

- 68. Meanwhile, patients who are diagnosed with a fetal anomaly usually receive this diagnosis after the twelfth week of pregnancy, since the screening and diagnostic procedures for anomalies are generally conducted in the second trimester, and structural anomalies may not be identified by ultrasound until the eighteenth or twentieth week of pregnancy.
- 69. Requiring abortion after twelve weeks to be provided in hospitals will reduce these patients' access to care. Most obviously, patients required to seek abortions in a hospital will have fewer options for care due to the fact that many hospitals do not provide abortion.⁴³
- 70. In addition, abortions at hospitals are generally much more expensive than they would be at PPSAT. Though hugely variable, abortions in hospitals can cost thousands of dollars. Given that only one in three Americans can comfortably cover a \$400 emergency expense, the financial burden of an abortion at a hospital will be insurmountable

⁴³ See Comm. on Health Care for Underserved Women, *supra* note 27, at e108 (recognizing that "many hospitals and health care systems limit the scope of reproductive health care for a range of reasons"); *see also* David L. Eisenberg & V. C. Leslie, *Threats to Reproductive Health Care: Time for Obstetrician-Gynecologists to Get Involved*, 216 Am. J. Obstetrics & Gynecology 256, 256 (observing that "health care institutions limit the scope of reproductive health care because of hospital policies, financial pressures, and a desire to limit negative press").

for many would-be patients.⁴⁴ At PPSAT, the cost of an abortion varies based on gestational age from \$625 to \$1795—a fraction of the cost charged by some hospitals.

- 71. Due to cost alone, if a patient could find a hospital willing to provide their abortion, hospital treatment would not be feasible for many of PPSAT's patients. Arranging for transportation, childcare, and taking time off work to come to PPSAT is challenging enough. A majority of patients seeking abortion are already parents. Many have multiple jobs or jobs with inflexible or unpredictable schedules with no paid sick leave. Some are compromised by physical and/or mental health conditions or struggle with a substance use disorder.
- 72. Patients who are able to get an appointment at a hospital may also face lengthy wait times, added stress, complicated paperwork and other logistical requirements, loss of confidentiality, and possibly increased medical risk from clinicians who provide abortion care infrequently. Particularly when deep sedation or general anesthesia is used—as is done at some hospitals, but not at PPSAT's clinics—the total appointment time, post-procedure recovery time, staffing and facility requirements, costs, and procedure risks increase, without any medical benefit to the patient.
- 73. Studies demonstrate that increased barriers to abortion access increase the likelihood a patient will not receive an abortion at all.⁴⁵ In addition, delay of any kind is

⁴⁴ Bd. Governors Fed. Reserve Sys., *Economic Well-Being of U.S. Households in 2021*, 1, 36 (2022), https://www.federalreserve.gov/publications/files/2021-report-economic-well-being-us-households-202205.pdf.

⁴⁵ See e.g., Benjamin P. Brown et al., Association of Highly Restrictive State Abortion Policies With Abortion Rates, 2000-2014, 3 JAMA Network Open 1, 1 (2020)

particularly concerning because, while abortion is safe, its risks increase with gestational age, as do the invasiveness of the procedure and the need for deeper levels of sedation.

- 74. Moreover, some hospitals may provide abortion using practices that are not patient-centered. Because only 3% of abortions nationwide are provided in hospitals, physicians who primarily practice in a hospital setting are likely less experienced in procedural abortion, particularly D&Es (given that most abortions occur before the point in pregnancy when D&Es are generally provided). Patients seeking abortion at a hospital may therefore be limited, either expressly or functionally, to the induction abortion method, even though induction can be far more expensive, time-consuming, and physically arduous for the patient as compared to D&E.
- 75. Specifically for survivors of rape or incest, abortion care in a licensed abortion clinic offers particular benefits related to the specialized setting. At PPSAT, for example, all staff are trained to recognize and counteract abortion stigma, and clinicians are trained annually on providing trauma-informed care for patients who have experienced intimate partner violence—such as special considerations when performing a physical exam for those patients, and what words to use in their clinical interactions. One such trauma-informed practice is offering the patient the opportunity to remain conscious during the procedure rather than receiving general anesthesia (which some hospitals administer as a matter of course for abortion patients): while some survivors may prefer general

("A highly restrictive legislative climate, when compared with a less restrictive one, was associated with . . . a 17% decrease [in] the median abortion rate....").

anesthesia, others wish to avoid the experience of being told after waking up from sedation what has happened to their body, with no firsthand memory of the procedure itself.

- 76. And when receiving care at a licensed abortion clinic, survivors and patients diagnosed with fetal anomalies can trust that their care team—from the administrative staff at the front desk to the physician performing their procedure—will not judge their reproductive decisionmaking, whether they decide to continue or end the pregnancy. While there are of course excellent physicians and staff providing compassionate, patient-centered care in hospital settings, too, patients are *more likely* to encounter stigma and judgment at a hospital than at a licensed abortion clinic in North Carolina. Requiring people to go to a hospital for their abortion deprives them of the option to receive care in the specialized, supportive environment that a licensed abortion clinic offers.
- 77. For all of these reasons, limiting access to abortion for survivors of rape or incest and for patients with "life-limiting" fetal anomalies would cause great harm even to those patients who are able to access abortion in a North Carolina hospital. For many others, the Hospitalization Requirement would put that care out of reach within North Carolina, such that the only remaining options will be to travel out of state to get an abortion or to attempt to manage their abortion outside of the medical system. Still others will be forced to remain pregnant and ultimately give birth against their will.

B. Impact of the IUP Documentation Requirement on Access to Early Abortion

78. If PPSAT is unable to offer medication abortion to patients with a pregnancy of unknown location, this too will be devastating for patients. This is especially so because

the Act already imposes a requirement that patients make two trips to a health center to access care (in addition to the follow-up appointment that must now be scheduled for medication abortion patients). If we cannot provide medication abortion to low-ectopic-risk patients while simultaneously doing further testing to exclude ectopic pregnancy, as supported by the best medical evidence and principles of patient-centered care, these patients may need to make another, wholly medically unnecessary trip, which will further delay their access to care. Early access to care is always preferable, but even more so because the Act bans almost all abortions after twelve weeks.

- 79. In my own practice, I see a patient with a pregnancy of unknown location at least once a week. Based on my experience providing abortion in states that have enacted early gestational age bans—for example, South Carolina, where a six-week ban was in effect for roughly 50 days in the summer of 2022—I expect that the number of patients who come to PPSAT in North Carolina for a medication abortion before their pregnancy is visible by ultrasound will increase now that the twelve-week ban is in effect. If the IUP Documentation Requirement prevents us from providing evidence-based abortion care to these patients, it will only delay their access to abortion without any effect on the speed or accuracy of ectopic pregnancy diagnosis.
- 80. It is important to note, however, that while patients who are able to recognize their pregnancies early on and *also* have resources and flexibility (in work schedules, caregiving obligations, and access to transportation) may be able to come to PPSAT earlier in pregnancy than they might have before the twelve-week ban took effect, patients who

do not recognize their pregnancies immediately and those lacking those resources and flexibility will not be able to come in any sooner, and in fact will be delayed in accessing abortion by the Act's many other medically unnecessary restrictions.

81. In these ways (and many others), the Act is not only harmful to our patients, but also impairs PPSAT's and its physicians' ability to practice our profession and to satisfy our personal and professional missions and obligations to provide high-quality, evidence-based comprehensive sexual and reproductive health care to people in North Carolina.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: July <u>24</u>, 2023

Katherine A. Farris, M.D.

EXHIBIT A

3000 Maplewood Avenue Winston-Salem, NC 27603 phone:

Employment

Planned Parenthood South Atlantic

Winston-Salem/Raleigh, NC

Chief Medical Officer: April 2020 - present

Duties of Affiliate Medical Director with increased focus on strategic planning, oversight of new service lines including Primary Care, and increased advocacy work in support of PPSAT mission.

Affiliate Medical Director: December 2014 - April 2020

Clinical, policy, and administrative oversight for 14 health centers located throughout NC, SC, VA, and WV.

Laboratory Director: December 2014 - present

Oversight of non-waived laboratories WS, NC; AVL, NC; WILM, NC; CLT, NC; waived laboratory VIE, WV

Infection Control Professional: 2014-present

Serves as consultant and expert on any infection prevention concerns as per medical training.

Interim Abortion Facility Administrator: December 2019 - March 2020

Acting Vice President of Patient Services: March - June 2016; May - August 2017

Interim Affiliate Medical Director: July 2013 - December 2014

Reproductive Health Care: September 2009-present

Provision of comprehensive family planning services to women of all ages as well as STI counseling, testing and treatment to men and women.

PPFA Succession Planning Task Force, Member: April 2017 – March 2021

Task force was charged with addressing some of the systemic challenges of abortion provider training and recruitment at Planned Parenthood affiliates.

Medical Directors Council (MeDC), Mentor: 2015 - present

Serve as mentor to new Medical Directors/Chief Medical Officers at other PPFA Affiliates.

BetterHealth IT Board of Directors.

Member: September 2020 – present

Chair, Compliance Committee: January 2023 - present

Board member for the organization responsible for providing revenue cycle services and supporting and rolling out Epic electronic medical records system across PPFA affiliates.

(Prior to merger and name change January 2015, organization was named Planned Parenthood Health Systems, Inc.)

Heywood Medical Group/Henry Heywood Hospital

Westminster/Gardner, MA

Family Practice/Obstetrics: August 2003 – May 2007

Meetinghouse Family Practice; 16 Wyman Rd.; Westminster, MA 01473

Provision of full-spectrum family medicine including comprehensive family planning and reproductive health care.

Planned Parenthood League of Massachusetts

Boston/Worcester, MA

Reproductive Health Care: August 2003 - May 2007

Provision of comprehensive family planning services to women of all ages.

Education

Valley Medical Center Family Practice Residency

Renton, WA

Chief Resident: 2002-2003 Residency: 2001-2003 Internship: 2000-2001

Northwestern University Medical School

Degree: MD, 1995-2000

Northwestern University College of Arts and Sciences

Evanston, IL

Chicago, IL

Degree: BA, 1991-1995

Major: Molecular and Cellular Biology Minor: Religion Studies

Certifications/Special Training

Physician for Reproductive Health, Leadership Training Academy Fellow 2018-2019

Basic Life Support/AED, Provider: renewed 10/2021 **Title X Family Planning Program Training**, Provider: 2015

CLIA Laboratory Director Training, Training for non-waived laboratory director: 2013 **Single-rod Hormonal Implant Insertion Training**, Provider: 2011, Certificate #30001820273

Professional Organizations / Positions

American Academy of Family Physicians (AAFP): 1995-present North Carolina Academy of Family Physicians: 2007-present National Abortion Federation (NAF): 2003-2005, 2018-present

Physicians for Reproductive Health: 2018-present

American College of Obstetricians and Gynecologists: 2020-present

Massachusetts Academy of Family Physicians: 2003-2007
Washington Academy of Family Physicians (WAFP): 2000-2003
American Medical Women's Association (AMWA): 1995-2000
Northwestern University Chapter President: 1997-1998

Vice-President: 1996-1997

Licenses

NC Physician License, active: 143375-2009 WV Physician License, active: 26126 VA Physician License, active: 0101265486 SC Physician License, active: MMD.84073 MD

American Board of Family Physicians, Board Diplomate

Honors/Awards

Sylvia Clark Award for Creativity in Clinical Services – Recipient 2023

Honors a clinical services provider team from a Planned Parenthood affiliate who, through their creativity in clinical services, have demonstrated special commitment and ingenuity in applying the PPFA mission to ensure access to reproductive and sexual health care for all.

Press Ganey Patient Experience Top Performing Provider 2020

Ranked in the top 10% of providers across the country for providing the highest level of patient experience.

2002 Roy Virak Memorial Family Practice Resident Scholarship Recipient

Awarded by the Washington Academy of Family Practice on the basis of academic achievement, excellence in patient care, and strong service to the community.

Exhibit 2

IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

PLANNED PARENTHOOD SOUTH ATLANTIC, et al.,)
Plaintiffs,))
v.)
JOSHUA STEIN, et al.,) Case No. 1:23-cv-00480-CCE-LPA
Defendants,)
and)
PHILIP E. BERGER, et al.,)
Intervenor-Defendants.)

DECLARATION OF CHRISTY M. BORAAS ALSLEBEN, M.D., M.P.H. IN SUPPORT OF PLAINTIFFS' AMENDED MOTION FOR A PRELIMINARY INJUNCTION

- I, Christy M. Boraas Alsleben, M.D., M.P.H., declare as follows:
- 1. I am a board-certified obstetrician-gynecologist who provides abortion for patients in a hospital as well as in an outpatient clinic setting. I am also an author on published, peer-reviewed research examining the safety and efficacy of providing medication abortion for patients with pregnancies of unknown location.
- 2. I submit this declaration in support of the Amended Motion for a Preliminary Injunction that Plaintiffs Planned Parenthood South Atlantic ("PPSAT") and Dr. Beverly Gray are filing to block two components of North Carolina Session Law 2023-14 ("S.B. 20") (codified as amended by Session Law 2023-65 ("H.B. 190") at N.C. Gen. Stat. art. 1I,

ch. 90 (the "Act")), which bans abortion after twelve weeks of pregnancy with narrow exceptions.

- 3. Specifically, I understand that the Act requires the following: (1) that an abortion provided after the twelfth week of pregnancy in cases of rape or incest or "life-limiting anomaly" be provided in a hospital, not an abortion clinic (the "Hospitalization Requirement"); and (2) that a physician providing an "abortion-inducing drug," among other things, "[d]ocument in the woman's medical chart the . . . existence of an intrauterine pregnancy" (the "IUP Documentation Requirement"). I have been asked whether there is any medical justification for these provisions of the Act and whether they would affect access to and the quality of reproductive health care.
- 4. Neither the Hospitalization Requirement nor the IUP Documentation Requirement will increase the safety of abortion care. In the United States, abortion is already one of the safest procedures a person could get.¹ Instead, these provisions will just delay and obstruct people's access to abortion.
- 5. I have reviewed the declaration of Dr. Katherine Farris, also submitted in support of Plaintiffs' Amended Motion for a Preliminary Injunction. I agree with Dr. Farris' statements and opinions regarding the safety and efficacy of performing abortions after the twelfth week of pregnancy in an outpatient facility and providing medication abortion for patients with pregnancies of unknown location.

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¹ See Nat'l Acads. of Scis., Eng'g, & Med., The Safety and Quality of Abortion Care in the United States, at 58, 60, 63, 77 (2018), https://nap.nationalacademies.org/cart/download.cgi?record id=24950 [hereinafter "Nat'l Acads."].

Professional Qualifications and Experience

- 6. I am a board-certified obstetrician-gynecologist ("OB/GYN") licensed to practice medicine in Minnesota. I provide abortions and other reproductive health care at the University of Minnesota Medical Center, a hospital in Minneapolis, Minnesota. I have worked as an OB/GYN at the University of Minnesota Medical Center since 2015. I provide second trimester abortions at the hospital one day per week.
- 7. I also provide first and second trimester abortions at outpatient health centers. I have worked at M Health Fairview Women's Clinic since 2015 and Whole Woman's Health Twin Cities since 2014, both in Minneapolis, Minnesota, and at Planned Parenthood North Central States in St. Paul, Minnesota since 2014. I provide abortions at the outpatient centers 1.5 days per week. I am also the Associate Medical Director and Director of Research at Planned Parenthood North Central States, which includes Minnesota, South Dakota, North Dakota, Iowa, and Nebraska.
- 8. Further, I am a faculty member at the University of Minnesota Medical School, and I provide education for trainees in the Department of Obstetrics, Gynecology and Women's Health. I also hold multiple consulting positions, including for the American College of Obstetricians and Gynecologists ("ACOG")—the leading U.S. professional association of OB/GYNs—and the Minnesota Department of Health. I am a member of several professional organizations, and have received honors and awards for my research, teaching, and public service. I have co-authored nearly twenty peer-reviewed research publications, including on the topics of medication abortion for pregnancies of unknown

location and history-based screening for ectopic pregnancies and eligibility for medication abortion.²

- 9. I earned a B.A. in Biology and English from St. Olaf College in 2001, a Masters in Public Health from the University of Minnesota School of Public Health in 2004, a doctorate from the University of Minnesota Medical School in 2008, and completed my residency in Obstetrics and Gynecology at The Ohio State University Medical Center in Columbus, Ohio in 2012. I also completed a fellowship in complex family planning at Magee-Womens Hospital at the University of Pittsburgh in 2014. In addition to my master's degree, I have a certificate in clinical research from the Institute for Clinical Research Education at the University of Pittsburgh, finished in 2014, and I completed a fellowship in reproductive health advocacy from the Leadership Training Academy, Physicians for Reproductive Health, also in 2014. I became board-eligible in obstetrics and gynecology in 2012 and board-certified in 2017.
- 10. The opinions I state here are based on my education, clinical training, experience as a practicing physician, regular review of medical research in my field, and regular attendance and presentation at professional conferences, including conferences for

² See, e.g., Karen Borchert, Christy Boraas et al., Medication Abortion and Uterine Aspiration for Undesired Pregnancy of Unknown Location: A Retrospective Cohort Study, 122 Contraception 109980 (2023); Ushma D. Upadhyay, Christy Boraas et al., Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study, 182 J. Am. Med. Ass'n Internal Med. 482 (2022); Holly A. Anger, Christy Boraas et al., Clinical and Service Delivery Implications of Omitting Ultrasound Before Medication Provided Abortion via Direct-To-Patient Telemedicine and Mail, 104 Contraception 659 (2021).

abortion providers. The literature considered in forming my opinions includes, but is not limited to, the sources cited in this declaration.

11. A copy of my *curriculum vitae* is attached as **Exhibit A**.

Summary of Opinions

- 12. If allowed to take effect, the Hospitalization Requirement and the IUP Documentation Requirement will have a detrimental impact on North Carolinians because pregnant people seeking abortions face many challenges getting the care they need, and these provisions will only make those challenges worse. People who are ultimately prevented from obtaining an abortion will be compelled to carry pregnancies to term against their wishes or seek ways to end their pregnancies without medical supervision. I am concerned about the effect these provisions of the Act will have on North Carolinians' emotional, physical, and financial wellbeing and the wellbeing of their families.
- 13. There is no medical reason to require that all abortions after twelve weeks of pregnancy—including abortions specifically in the cases of rape, incest, or life-limiting fetal anomaly—take place in hospitals because these abortions can be safely performed in outpatient clinic settings. In fact, there are many reasons that non-hospital settings may be preferable.
- 14. There is no medical reason to require the confirmation of an intrauterine pregnancy before administering medication abortion. With the proper protocol, counseling, surveillance, and follow up, medication abortion may be safely and effectively

administered to patients with pregnancies of unknown location who prefer that method of treatment.

The Challenged Laws

- 15. I understand the Act allows abortions in the case of rape or incest through 20 weeks of pregnancy, and abortions in the case of a "life-limiting anomaly" through 24 weeks of pregnancy, but the Hospitalization Requirement requires that such abortions take place in hospitals, not outpatient clinics. I understand that if these requirements are permitted to take effect, PPSAT and other outpatient abortion providers in North Carolina will be barred from providing abortion care after the twelfth week of pregnancy to survivors of rape or incest and to patients who have received a diagnosis of a "life-limiting" fetal anomaly.
- 16. I understand the IUP Documentation Requirement requires a physician to document in the patient's medical chart the existence of an intrauterine pregnancy. This provision seems like it could be understood to prohibit abortion providers in North Carolina from administering mifepristone and misoprostol to patients who have a very early pregnancy that is not yet visible by ultrasound (known as a "pregnancy of unknown location").
- 17. As I explain in more detail below, it is my opinion that the Hospitalization Requirement and the IUP Documentation Requirement do not serve patient health and are not medically necessary to ensure patient safety. In fact, they will most likely harm patient

health by making abortion more difficult to access and, in some cases, putting it entirely out of reach.

Abortion Reasons, Methods, Safety, and Harms of Delay

- 18. A patient's reasons for terminating a pregnancy depend on their own complex personal, medical, financial, and/or family circumstances. These are closely tied to each patient's values, culture and religion, health and reproductive history, family situation and support system, education or career goals, and resources and financial stability.
- 19. In my experience, many patients seeking abortion are already parenting and, after careful consideration of their lived reality, decide that expanding their family at that time is not in their or their family's best interest. Indeed, a majority of patients having abortions in the United States have already had at least one birth.³ The strain of trying to adequately provide for their existing children is all the more apparent if one considers that approximately 75% of abortion patients nationwide are poor or low-income.⁴

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³ See Jenna Jerman et al., Characteristics of U.S. Abortion Patients in 2014 and Changes Since Guttmacher Inst.. (May 2016), 2008. at 6-7https://www.guttmacher.org/sites/default/files/report pdf/characteristics-us-abortionpatients2014.pdf; see also Induced Abortion in the United States, Guttmacher Inst. (Sept. 2019), at 1, https://www.guttmacher.org/sites/default/files/factsheet/fb induced abortion .pdf; Katherine Kortsmit et al., Abortion Surveillance—United States, 2019, 70 Morbidity Mortality Weekly Report Surveillance **Summaries** 6 and https://www.cdc.gov/mmwr/volumes/70/ss/pdfs/ss7009a1-H.pdf ("Among the 45 areas that reported the number of previous live births for 2019, 40.2%, 24.5%, 20.0%, 9.2%, and 6.0% of women had zero, one, two, three, or four or more previous live births."). ⁴ Jerman et al., *supra* note 3, at 1.

- 20. Some people seeking abortion care are young and feel they are not ready to become a parent, and others are pursuing school or work opportunities. Some patients have health conditions that are complicated by pregnancy or have been diagnosed with health conditions that cannot be safely treated during pregnancy. These medical conditions can include hypertension, diabetes, lupus and other auto-immune diseases, kidney disease, and heart disease. I have cared for numerous patients who had abortions in order to protect their health or who have received a diagnosis of fetal anomaly (diagnoses that almost always occur after the twelfth week of pregnancy). Some patients lack the necessary financial resources, family support, or material stability to become a parent or to care for additional children. Others are in abusive relationships or are pregnant as a result of rape and are concerned that carrying to term will tether them to their abuser. Each patient's decision is valid in its own right.
- 21. There are two main methods of abortion: medication abortion and procedural abortion. First-trimester medication abortions most commonly involve the administration of two types of medications (mifepristone and misoprostol) to cause embryonic or fetal demise and passage of the pregnancy tissue in a manner similar to a miscarriage. First-trimester medication abortion requires no anesthesia or sedation; the patient simply takes

⁵ See, e.g., Sarah C. M. Roberts et al., Risk of Violence from the Man Involved in the Pregnancy After Receiving or Being Denied an Abortion, 12 BMC Med. 1, 5 (2014) (finding that "[a]mong women seeking abortion, having an abortion was associated with a reduction over time in physical violence from the [man involved in the pregnancy], while carrying the pregnancy to term was not").

the pills. First-trimester medication abortion is extremely safe.⁶ The process of medication abortion is very similar to the process of miscarriage, and incomplete miscarriage can be treated using the same medications.⁷

- 22. Procedural abortions, which are provided in both the first and second trimesters, are performed by dilating (opening) the cervix and then using gentle suction and/or instruments to empty the contents of the uterus. The two most common methods of procedural abortion are aspiration abortion and dilation and evacuation ("D&E"). Despite sometimes being referred to as "surgical abortions," these procedures are not surgical in the usual sense: they do not involve any incision into the patient's skin and in many cases can be performed with only local anesthesia or moderate sedation.
- 23. Another method of abortion using medications is abortion by induction of labor, which is most often performed in hospitals later in the second trimester as an alternative to D&E.
- 24. When a patient is choosing abortion because the fetus has been diagnosed with a fetal anomaly, the abortion procedures are generally the same as for those without such a diagnosis. And the procedures used for abortion and for miscarriage management are also both generally the same.

⁶ Nat'l Acads., *supra* note 1, at 79.

⁷ "Miscarriage" is when a pregnancy stops growing, as evident from the absence of embryonic or fetal cardiac activity. While sometimes a person's body naturally expels the pregnancy tissue, other times medical treatment, known as "miscarriage management," is needed to empty the uterus completely. The only thing distinguishing miscarriage management from abortion is the presence or absence of cardiac activity.

- 25. Regardless of the method of abortion used, abortion is safe and effective, and is approximately 12-14 times safer than continuing a pregnancy through to childbirth.⁸
- 26. Both medication and procedural abortion carry a low risk of complications and a very low risk that hospitalization is necessary to treat a complication. Numerous high-quality studies exist on the incidence of complications from abortion, and those studies converge on a single conclusion: risks of complications are very low. Indeed, abortion is considered one of the safest medical procedures in the United States, whether by medication, aspiration, D&E, or induction. As the National Academies has explained, It he risks of medication abortion are similar in magnitude to the risks of taking

⁸ Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215, 216–17, 217 fig. 1 (2012); Nat'l Acads., *supra* note 1, at 37, 75 tbls. 2–4, 77–78.

⁹ Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175, 180 tbl. 4 (2015); *see also* Ushma D. Upadhyay et al., *Abortion-Related Emergency Department Visits in the United States: An Analysis of a National Emergency Department Sample*, 16 BMC Med. 1, 2, 8 (2018).

¹⁰ Nat'l Acads., *supra* note 1, at 10–11, 55–56, 60–65; *id.* at 77–78 ("[s]erious complications are rare; in the vast majority of studies, they occur in fewer than 1 percent of abortions").

¹¹ Nat'l Acads., *supra* note 1, at 77; *see also Frequently Asked Questions: Abortion Care*, ACOG, (Last updated Aug. 2022) https://www.acog.org/womens-health/faqs/induced-abortion ("Abortion does not increase the risk of breast cancer, depression, or infertility."); *see also Preterm Birth*, Ctrs. for Disease Control & Prevention, (Last reviewed Nov. 1, 2022) https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pretermbirth.htm (listing risk factors for preterm birth, which do not include induced abortion). A D&E is a safe and common abortion procedure that "accounts for the majority of second-trimester abortions in the United States." Megan K. Donovan, *D&E Abortion Bans: The Implications of Banning the Most Common Second-Trimester Procedure*, Guttmacher Inst., (Feb. 21, 2017), https://www.guttmacher.org/gpr/2017/02/de-abortion-bans-implicationsbanning-most-common-second-trimester-procedure.

commonly prescribed and over-the-counter medications such as antibiotics and NSAIDs [nonsteroidal anti-inflammatory drugs]," such as ibuprofen.¹²

- 27. The risks associated with abortion increase with gestational age, but because they are very low to begin with, abortion remains a very safe procedure even later in the second trimester.¹³ In addition to being extremely safe, abortion is also extremely common: nearly one in four women in the United States will have an abortion by age 45.¹⁴
- 28. Abortion is a time-sensitive, essential health service. ACOG and other leading medical organizations stressed in a joint statement that "[a]bortion is an essential component of comprehensive health care" and "a time-sensitive service for which a delay of several weeks, or in some cases days, may increase the risks [to patients] or potentially make it completely inaccessible."¹⁵
- 29. Patients generally seek abortion as early in their pregnancy as they can. Nevertheless, in practice, there are many economic and logistical challenges that can cause delays. Some patients cannot afford to take multiple days off work in close proximity, as doing so will risk jeopardizing their jobs. Some patients cannot afford to arrange childcare for multiple days in close proximity without revealing to family or caregivers the reason

¹³ Suzanne Zane et al., *Abortion-Related Mortality in the United States*, 1998–2010, 126 Obstetrics & Gynecology 258, 262–63 (2015).

¹² Nat'l Acads., *supra* note 1, at 79.

¹⁴ See Rachel K. Jones & Jenna Jerman, Population Group Abortion Rates and Lifetime Incidence of Abortion: United States, 2008–2014, 107 Am. J. Pub. Health 1904, 1907 (2017).

¹⁵ Joint Statement on Abortion Access During the COVID-19 Outbreak, ACOG (Mar. 18, 2020), https://www.acog.org/news/news-releases/2020/03/joint-statement-on-abortion-access-during-the-covid-19-outbreak.

for their need, thus compromising the confidentiality of their decision to obtain an abortion. Patients who seek abortion care after surviving rape, incest, or other violent abuse may be delayed in seeking care while they deal with associated trauma.¹⁶

- 30. Delay causes harm to patients. Though abortion is extremely safe, the risk of complications associated with abortion increases as a patient's pregnancy advances.¹⁷ Moreover, pregnancy carries risk, and delaying abortion forces a pregnant person to remain pregnant longer, experiencing the symptoms, risks, and potential complications of pregnancy. Even an uncomplicated pregnancy stresses a pregnant person's body, affects every organ system, and increasingly compresses abdominal organs as pregnancy progresses. Delay is also problematic for people for whom pregnancy worsens underlying health conditions, such as hypertension, heart failure, lung disease, or sickle cell disease.
- 31. For some patients, being forced to remain pregnant against their will causes psychological harm. Some patients may need to conceal the pregnancy from an abusive or controlling partner or others who would disapprove or shame them. Additionally, delay can be very upsetting to patients terminating wanted pregnancies due to fetal anomalies.

¹⁶ See, e.g., Ushma D. Upadhyay et al., Denial of Abortion Because of Provider Gestational Age Limits in the United States, 104 Am. J. Pub. Health 1687, 1689, 1691 fig. 1 (2014); Diana Greene Foster et al., Timing of Pregnancy Discovery Among Women Seeking Abortion, 104 Contraception 642 (2021); Jenna Jerman et al., Barriers to Abortion Care and Their Consequences for Patients Traveling for Services: Qualitative Findings from Two States, 49 Persps. on Sexual & Reprod. Health 95 (2017).

¹⁷ Nat'l Acads., *supra* note 1, at 10–11, 65.

The Hospitalization Requirement Impedes Access to Abortion Without Adding to Patient Health and Safety

- 32. I understand that the Hospitalization Requirement mandates that an abortion provided after the twelfth week of pregnancy in cases of rape, incest, or "life-limiting anomaly" be provided in a hospital, not an outpatient abortion clinic. There is no medical reason to require that all abortions after the twelfth week of pregnancy take place in hospitals and not abortion clinics. ¹⁸ Throughout the country, legal abortions are safely and routinely performed in doctors' offices and outpatient health center settings—in fact, only 3% of abortions are performed in hospitals in the U.S annually. ¹⁹
- 33. As a highly experienced OB/GYN who has worked providing abortions at both outpatient facilities and in a hospital for 16 years, I have performed and observed abortion care in both settings. At the University of Minnesota Medical Center hospital, I perform second-trimester abortions—including aspiration, D&E, and induction—through 23.6 weeks of pregnancy.
- 34. When I am providing a second trimester procedural abortion in the hospital, the hospital staff first perform an intake over the phone and then schedule the patient for the next available convenient appointment, which is often two to three weeks out due to capacity constraints. There are two main physicians who provide second trimester abortions at my hospital, including myself. I provide second trimester abortions at the

¹⁸ See Nat'l Acads., supra note 1, at 10, 77 ("most abortions can be provided safely in office-based settings").

¹⁹ Rachel K. Jones et al., *Abortion Incidence and Service Availability in the United States*, *2020*, 54 Perspect. Sex Reprod. Health 128, 134 tbl. 3 (2022).

hospital one day per week. I have time in the operating room in the hospital one half day per week to see patients that need hospital-based abortion care, up to four patients in a typical week.

- 35. For most patients that obtain second trimester abortions at my hospital, they must go to the hospital's associated clinic the day prior to have osmotic dilators placed in their cervix. On the day of their procedure, they must check in two hours before their scheduled procedure time. Their time in the operating room is about an hour (including resident education, as I work at a teaching hospital), and their recovery time, depending on the type of sedation used, can be between 1-4 hours, making the total time in the hospital between 4-7 hours. D&E patients in a hospital must sit in the waiting room or pre-operative area potentially for hours, and alongside patients awaiting other hospital procedures or surgeries, despite the fact the abortion procedure itself typically takes no more than 15-30 minutes in most cases. At the outpatient clinics where I provide second trimester abortions, the total appointment time is much less, usually approximately 2-4 hours.
- 36. General anesthesia or deep sedation are not necessary for most second trimester abortion patients, and moderate or minimal sedation with local anesthesia are sufficient. At the outpatient clinics where I work, most patients choose moderate sedation. While I always endeavor to consult with patients and honor their preferred level of sedation for a procedural abortion—particularly patients who have survived sexual violence and do not feel comfortable being fully asleep during the procedure—at the hospital, it is most often the anesthesiologist that recommends the level of sedation, and some

anesthesiologists prefer general anesthesia. When general anesthesia is used, the recovery time and costs of the procedure usually increase.

- 37. Further, while staff at the outpatient clinics where I work receive training on how to provide judgment-free abortion care and how to interact compassionately with those who have survived sexual assaults, the same is not true for every staff member that a patient might interact with in a hospital setting. Therefore, patients who worry about the stigma and confidentiality surrounding their abortion may prefer to go to an outpatient facility where abortion care is more frequently provided.
- 38. Patients may have other valid and compelling reasons to seek abortion care at an outpatient clinic versus a hospital, including cost, facility proximity, total appointment time, confidentiality, staff familiarity with the procedure, sedation options, and more.
- 39. Regardless of whether the patient receiving an aspiration abortion or D&E is a survivor of rape or incest, or if they have received a diagnosis of a life-limiting fetal anomaly, there is no reason to categorically require either procedure to be performed in a hospital. In my experience, the only patients that are better taken care of in a hospital than an outpatient setting are those who have certain life-threatening maternal health conditions; those for whom the physician may need immediate access to blood products due to an individual patient's pre-existing medical condition in case transfusions may be needed; those who require a deeper level of sedation than would be available at an outpatient clinic; or those for whom the expertise of physicians with other subspecialty experience is critical in providing optimal care.

40. Based on all the above, it is my opinion that there is no medical reason to require that all abortions after the twelfth week of pregnancy for rape or incest survivors or those who have received a diagnosis of life-limiting fetal anomaly take place in hospitals because these abortions can be safely performed in outpatient settings. There are many reasons that patients justifiably prefer abortions in outpatient centers like PPSAT's, including shorter appointments, lower costs, and treatment from staff and medical professionals with more experience providing abortions.

Medication Abortion is Safe and Effective in Terminating Pregnancies of Unknown Location

- 41. The IUP Documentation Requirement mandates that a physician providing an "abortion-inducing drug," among other things, "[d]ocument in the woman's medical chart the . . . existence of an intrauterine pregnancy." I understand this provision could be interpreted to prohibit abortion providers in North Carolina from administering mifepristone and misoprostol to patients whose pregnancies are not visible by ultrasound. There is no medical reason to require ultrasound confirmation of an intrauterine pregnancy before administration of medication abortion. Therefore, there is no medical reason to deny patients with pregnancy of unknown location this care, or to mandate that they delay their medication abortion until an intrauterine pregnancy can be diagnosed, which would expose them to increased and unnecessary medical risks.
 - 42. General categories of pregnancy location include the following:

- a patient has a "definite intrauterine pregnancy" if the gestational sac and yolk sac and/or an embryo with or without cardiac activity are visible in the uterus;
- a patient has a "probable intrauterine pregnancy" if there is a likely gestational sac (intrauterine echogenic sac-like structure), but no yolk sac, visible in the uterus;
- a patient has a "pregnancy of unknown location" if there is no intrauterine or extrauterine pregnancy visible on transvaginal ultrasonography, but the patient has a positive pregnancy test;
- a patient has a "probable ectopic pregnancy" if there is an inhomogeneous adnexal mass or extrauterine sac-like structure;
- a patient has an "ectopic pregnancy" if an extrauterine gestational sac with yolk sac and/or embryo with or without cardiac activity is visualized.²⁰

When we speak about "pregnancies of unknown location," we are talking about the category where neither an intrauterine nor an extrauterine pregnancy is visible and the patient has a positive pregnancy test.

43. The ability to immediately provide abortion for patients with a pregnancy of unknown location offers important benefits to those patients, including those who prefer medication abortion. In my experience, and as is also documented in research studies, most

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²⁰ See generally Kurt Barnhart et al., Pregnancy of Unknown Location: A Consensus Statement of Nomenclature, Definitions, and Outcome, 95 Fertility and Sterility 3 (2011).

people who choose a medication abortion have a strong preference for this method.²¹ Medication abortion, in contrast to aspiration abortion, allows the patient to complete the abortion at home or in another safe and private location. It is also less invasive than procedural abortion, and therefore may be preferable for many patients, including those who are sexual assault survivors.

- 44. Administration of medication abortion for patients with pregnancies of unknown location, combined with simultaneous screening for ectopic pregnancies, has been shown to be both safe and effective. I recently co-authored a study of pregnancy outcomes for patients presenting for abortion at Planned Parenthood in St. Paul, Minnesota, between July 1, 2016 and December 31, 2019, who were diagnosed with a pregnancy of unknown location (the "St. Paul Study"). The St. Paul Study examined the outcomes from a protocol for providing medication abortion for patients with a pregnancy of unknown location who were at low risk for ectopic pregnancy and who had chosen that method of abortion. Our study found that this protocol—immediate medication abortion treatment with simultaneous serial testing of the pregnancy hormone human chorionic gonadotropin ("hCG") to further exclude ectopic pregnancy—was safe and effective.²²
- 45. Based on our research, we concluded that the option of proceeding with a medication abortion before the pregnancy location had been clinically diagnosed has the

²¹ Daniel Grossman et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine*, 118 Obstetrics & Gynecology 296, 300 (2011).

²² Borchert et al., *supra* note 2 at 6; *see also* Alisa B. Goldberg et al., *Mifepristone and Misoprostol for Undesired Pregnancy of Unknown Location*, 139 Obstetrics & Gynecology 771, 780 (2022).

potential to help improve access to care and patient satisfaction and does not delay the diagnosis of ectopic pregnancy.

- 46. In addition to the St. Paul Study, another peer-reviewed study, which also demonstrated the safety and efficacy of medication abortion for patients with a pregnancy of unknown location, showed that this protocol leads to earlier exclusion of ectopic pregnancy than waiting to see whether an intrauterine pregnancy can be diagnosed.²³
- 47. From Dr. Farris's declaration, I understand that PPSAT uses the same evidence-based protocol for administering medication abortion for patients with pregnancies of unknown location as the one used in the St. Paul Study. At a high level, this protocol involves screening for ectopic pregnancy and referring high-ectopic risk patients for appropriate treatment; counseling low-ectopic-risk patients on their options (medication abortion, aspiration abortion, or returning at a later date to see if an intrauterine pregnancy can be seen on an ultrasound at that time); performing serial blood testing to test whether the hCG level rises or falls over time; and conducting appropriate surveillance and follow-up to ensure the pregnancy was terminated and any complications are identified and treated (the "Protocol"). This Protocol is substantially identical to the protocol I use both in outpatient clinics and the hospital.
- 48. If an outpatient clinic were to refer a patient with a pregnancy of unknown location to a hospital for ectopic evaluation instead of administering a medication abortion according to this Protocol, based on my experience the hospital would likely perform the

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²³ Goldberg et al., *supra* note 22 at 778.

same serial hCG testing that the outpatient clinic could have performed while simultaneously administering the medication abortion (assuming the hospital does not itself offer the patient the option of medication abortion plus serial hCG testing according to the Protocol). Therefore, such a referral would not increase patient safety and would only serve to delay abortion care.

49. It is important to note that the Protocol (both in my research and as employed by PPSAT) would only be used to treat patients who have already been determined to be at a low risk for ectopic pregnancy. Ectopic pregnancies continue to be a significant cause of pregnancy-related morbidity and mortality because, if left untreated, they can rupture and cause serious internal bleeding. For this reason, clinicians at both hospitals and outpatient health centers routinely provide detailed counseling and conduct a symptom assessment to identify patients at risk for ectopic pregnancies, including by considering known risk factors, symptoms, and prior and current health history—all of which can be assessed by a conversation with the patient.²⁴ For example, when I conduct this type of ectopic screening, I ask patients about their last menstrual cycle (date, timing, regularity, amount of bleeding and cramping); whether they have had a prior ectopic pregnancy or treatment and/or hospitalization for pelvic inflammatory disease or prior tubal sterilization;

²⁴ See, e.g., Abigail R. Aiken et al., Effectiveness, Safety and Acceptability of No-Test Medical Abortion (Termination of Pregnancy) Provided via Telemedicine: A National Cohort Study, 128 British J. of Obstetrics and Gynaecology 1464, 1466 (2021) (explaining that patients "were offered a consultation via phone or video call, during which an assessment of eligibility for treatment via telemedicine was made," which included assessing whether "they had a low risk of ectopic pregnancy"); see also Upadhyay et al. (2022), supra note 2.

whether they were using hormonal birth control, an intrauterine device or oral emergency contraception when they became pregnant; whether they have had a pregnancy recently and the outcome of that pregnancy; and whether they are experiencing any symptoms such as abdominal or pelvic pain and bleeding that was not typical for a menstrual cycle.

- 50. In fact, use of an ultrasound to rule out an ectopic pregnancy is not medically indicated for most patients. I co-authored a research study which showed that screening for medication abortion eligibility based on a patient's medical history is as safe as screening protocols that utilize an ultrasound or pelvic exam.²⁵ Another recent study examining patients screened for ectopic pregnancy via phone or video call, who went on to have medication abortions without prior ultrasound, found no statistically significant difference in the rate of ectopic pregnancy between the group of patients that had ultrasound and the group that did not, further demonstrating the safety and efficacy of using ectopic screening methods other than ultrasound for patients planning medication abortion.²⁶
- 51. Based on all the above, it is my opinion that there is no medical reason to require the confirmation of an intrauterine pregnancy before administering medication abortion. With the proper protocol, counseling, surveillance, and follow-up, medication abortion may be safely and effectively administered to low-ectopic-risk patients with pregnancies of unknown location who prefer that method of treatment. Sending a patient

²⁵ Upadhyay et al. (2022), *supra* note 2 at 488; Anger et al., *supra* note 2 at 663–64.

²⁶Aiken et al., *supra* note 24, at 1469 (finding that "[t]he overall incidence of ectopic pregnancy was equivalent in both cohorts — 39 (0.2%) in the traditional cohort and 49 (0.2%) in the telemedicine-hybrid cohort").

away solely because they have a pregnancy of unknown location does not serve the patient

and only serves to unnecessarily delay care and impede abortion access.

52. In sum, the Hospitalization Requirement and IUP Documentation

Requirement do not improve patient safety. They single out abortion—an extremely safe

and common procedure—for burdensome treatment and, rather than helping patients,

impede their access to care. My opinion is supported by the research cited above, by my

education and clinical training, and by my own experience providing sexual and

reproductive health care, including abortion.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: July 24th, 2023

Christy M. Boraas Alsleben, M.D., M.P.H.

EXHIBIT A

CURRICULUM VITAE FOR PROMOTION AND TENURE

CHRISTY M. BORAAS, M.D., M.P.H United States

PROFESSIONAL ADDRESS

Address M Health Fairview Women's Clinic

606 24th Avenue South, Suite 300

Minneapolis, MN 55454

Telephone FAX

Email

Address Planned Parenthood North Central States

671 Vandalia Street St. Paul, MN 55114

Telephone FAX

Email



IDENTIFYING INFORMATION

Education

Degree	Institution	Date Degree Granted
B.A.	St. Olaf College, Northfield, MN Biology and English, magna cum laude	2001
	University of Pittsburgh, Pittsburgh, PA Semester at Sea Study Abroad Program	Fall 2000
M.P.H.	University of Minnesota School of Public Health, Minneapolis, MN <i>Epidemiology</i>	2004
M.D.	University of Minnesota Medical School, Minneapolis, MN <i>With Honors</i>	2008
Residency in Obstetrics and Gynecology	The Ohio State University Medical Center, Columbus, OH	07/2008-06/2012
Fellowship in Family Planning	Magee-Womens Hospital, University of Pittsburgh, Pittsburgh, PA	07/2012-07/2014
Certificate in Clinical Research	Institute for Clinical Research Education, University of Pittsburgh, Pittsburgh, PA	07/2012-07/2014

Fellowship in Reproductive Leadership Training Academy, Physicians for 07/2013-06/2014 Health Advocacy Reproductive Health, New York, NY Certifications Fellow, American Board of Obstetrics and Gynecology (#9028922) 2017-present Licenses Medical Physician and Surgeon, Minnesota (#58304) 2014-present Medical Physician and Surgeon, Pennsylvania (#MD445822) 2012-2014 **Academic Appointments** University of Minnesota Minnesota Population Center **Faculty Member** 2019-present University of Minnesota Medical School, Twin Cities (2016-2022) Center for Global Health and Social Responsibility Associate Global Health Faculty 2016-present University of Minnesota Medical School, Twin Cities (2015-2022) Department of Obstetrics, Gynecology and Women's Health **Assistant Professor** 2015-present Department of Obstetrics, Gynecology and Reproductive Sciences University of Pittsburgh School of Medicine, Pittsburgh, PA Clinical Instructor 2012-2014 University of Pittsburgh School of Medicine, Pittsburgh, PA Center for Family Planning Research Investigator 2012-2014 Academic Administrative Appointments University of Minnesota Medical School, Twin Cities Ryan Residency Training Program in Abortion and Family Planning Director 2015-present University of Minnesota Medical School, Twin Cities Fellowship in Family Planning (ACGME approval pending) Director 2015-present Planned Parenthood Minnesota, South Dakota, North Dakota, St. Paul, MN Director of Obstetrics and Gynecology Resident Education 2014-present The Ohio State University, Columbus, OH Department of Obstetrics and Gynecology Chief Administrative Resident 2011-2012

Clinical/Hospital Appointments	
M Health Fairview Women's Clinic, Minneapolis, MN Staff Physician	2015-present
University of Minnesota Medical Center, Minneapolis, MN Staff Physician	2014-present
Planned Parenthood Minnesota, South Dakota, North Dakota, St. Paul, MN Associate Medical Director Director of Research	2014-present 2014-present
Whole Woman's Health Twin Cities, Minneapolis, MN Staff Physician	2014-present
Planned Parenthood of Western Pennsylvania, Pittsburgh, PA Staff Physician	2012-2014
Consulting Positions	
ViiV Healthcare	2022-present
American College of Obstetricians and Gynecologists, Optimizing Care for Pregnancy Loss (OCPL) Program Trainer	2021-present
American College of Obstetricians and Gynecologists, Implementing Progress in Abortion Care and Training (IMPACT) Trainer	2021-present
University of Global Health Equity, Rwanda	2020-present
American College of Obstetricians and Gynecologists, Immediate Postpartum Long-Acting Reversible Contraception Trainer	2018-present
Minnesota Department of Health	2017-present
Basic Health International	2014-present
American Refugee Committee International	2013-present
Current Membership and Offices in Professional Organizations	
Member, Consortium of Abortion Providers Abortion Equity Cohort	2021-present
Member, Education Committee, Fellowship in Complex Family Planning	2020-present
Minnesota Public Health Association (MPHA)	
Member Member, MPHA Global Health Committee	2018-present 2018-present
Society of Family Planning (SFP) (2015-2022) Member, Finance Committee	2021-present

Member, Research Implementation Special Interest Group Junior Fellow Member, Program Committee Member, Annual Meeting Session Working Group Member, Audit Committee	2021-present 2012-present 2019-2020 2019 2015-2018
Minnesota Medical Association (MMA) (2014-2022) Chair, Abortion Policy Work Group Member, Policy Council Member Member, Medical Practice and Quality Committee	2021-present 2017-present 2014-present 2014-2018
Minnesota section of ACOG (MN ACOG) (2014-2022) Member, Annual Meeting Planning Committee Member, Advisory Council Member Member, Legislative Committee	2021-present 2019-present 2015-present 2014-present
Member, Association of Professionals of Gynecology and Obstetrics (APGO)	2014-present
Member, Physicians for Reproductive Health	2010-present
American Congress of Obstetricians and Gynecologists (ACOG) (2008-2022) Fellow Junior Fellow	2017-present 2008-2017
Member, Academy of Breastfeeding Medicine	2013-2016
Member, Association of Reproductive Health Professionals	2009-2016
Visiting Professorships or Visiting Scholar Positions American Refugee Committee International Ban Don Yan Refugee Camp, Sangkhlaburi, Thailand	2012
Family Planning Specialist Kilimanjaro Christian Medical Center, Moshi, Tanzania	2013
Clinical Instructor in Obstetrics and Gynecology	2011
Pro-Link Organization, Accra, Ghana Reproductive Health Epidemiologist	2003
NORS AND AWARDS FOR RESEARCH, TEACHING, PUBLIC ENGAGEMENT AND SERVI	CE

HONORS AND AWARDS FOR RESEARCH, TEACHING, PUBLIC ENGAGEMENT AND SERVICE

University of Minnesota

Gold Humanism Honor Society	2007-2008
Medical School Basic Science Overall Top Honors (Top 20%)	2006
Student Research Grant, Minnesota Medical Foundation	2005

Walter H. Judd Fellowshi	o in Global Health	2003, 2007

External Sources

UMP Clinical Excellence Award	2022
Top Doctor, Minnesota Monthly Magazine	2018, 2021, 2022, 2023
Rising Star, Mpls St. Paul Magazine	2021
David E. Rogers Fellowship	2005
Phi Beta Kappa	2001
St. Olaf College Biological Honor Society	2001
Semester at Sea Dean's List	2000

RESEARCH AND SCHOLARSHIP

Grants and Contracts

External Sources

Current

Role: Co-Investigator
 PI: Sharon Allen, MD, PhD
 Grant Number: 5R01DA047287

External Agency: National Institutes of Health

Grant Title: Bupropion for the Prevention of Postpartum Smoking Relapse

Project Dates: 09/01/18-08/30/23

Total costs: \$2,372,039 Direct costs/year: \$440,350 % Effort/salary support: 5%

2. Role: Co-Investigator

Principal Investigator: Alison Ojanen-Goldsmith External Agency: Male Contraceptive Initiative

Grant Title: Acceptability, preferences, and values related to contraception for people who

produce sperm

Project Dates: 12/01/20-11/30/22

Total costs: \$150,000

Direct costs/year: \$71,442.50 Funded salary support: 1%

3. Role: Site Principal Investigator External Agency: Mayo Clinic

Grant Title: Validation study of self-collected rectal and pharyngeal swabs for Chlamydia and

Gonorrhea testing

Project Dates: 10/01/21 - 10/01/22 Direct costs/year: \$34,793.94 Funded salary support: 1%

4. Role: Site Principal Investigator

External Agency: Gynuity Health Projects

Grant Title: Medication Abortion with Autonomous Self-Assessment

Submitted: November 2021

Project Dates: 03/01/2022-02/28/2023

Total costs: \$34,345.84 Direct costs/year: \$25,759.38 Funded salary support: 1%

Pending

1. Role: Site Principal Investigator

External Agency: Gynuity Health Projects

Grant Title: Extending outpatient medical abortion in the late first trimester of pregnancy

Submitted: September 2020 Project Dates: 10/01/22-TBD

Total costs: TBD
Direct costs/year: TBD
Funded salary support: 1%

Completed

1. Role: Site Principal Investigator

External Agency: University of Pennsylvania

Grant Title: Development of an implementation strategy to integrate HIV pre-exposure

prophylaxis into family planning care Project Dates: 11/01/21 - 11/01/22

Total costs: not applicable
Direct costs/year: not applicable
Funded salary support: 1%

2. Role: Site Principal Investigator

Principal Investigator: Elizabeth Raymond, MD External Agency: Gynuity Health Projects

Grant Title: Feasibility of Medical Abortion by Direct-to-Consumer Telemedicine.

Project Dates: 09/01/19-11/01/21

Total costs: \$85,000 Direct costs/year: \$63,750 Funded salary support: 1%

Role: Co-Investigator
 PI: Rebecca Shlafer, PhD

Grant Number: 5R03HD093961

External Agency: National Institutes of Health

Grant Title: Efficacy and Cost-Effectiveness of Doula Care for Incarcerated Pregnant Women

Project Dates: 07/01/17 - 06/30/20

Total cost: \$154,000 Direct costs/year: \$50,000 Funded salary support: 10%

4. Role: Co-investigator

Principal Investigator: Vivian Bardwell, PhD

Grant Number: 5R01HD084459

External Agency: National Institutes of Health

Grant Title: Control of Trophoblast Differentiation in Placental Development

Project Dates: 03/01/16-01/01/18

Total costs: \$1,424,260 Direct costs/year: \$215,463 Funded salary support: 0%

5. Role: Site Principal Investigator

Principal Investigator: Ilana Dzuba, MHSc. External Agency: Gynuity Health Projects

Grant Title: Non-surgical alternatives to treatment of failed medical abortion: A randomized

controlled double-blind trial. Project Dates: 03/01/17-01/31/18

Total costs: \$24,000 Direct costs/year: \$18,000 Funded salary support: 1%

6. Role: Principal Investigator

External Agency: William and Flora Hewlett Foundation

Grant Title: Quantifying contraceptive failure with unprotected intercourse 6-14 days prior to

contraceptive initiation.

Project Dates: 11/01/16-08/30/18

Total costs: \$63,000 Direct costs/year: \$50,400 Funded salary support: 10%

7. Role: Site Principal Investigator

External Agency: Gynuity Health Projects

Grant Title: Simplified Medical Abortion Screening: A Pilot Demonstration Project

Project Dates: 08/01/16-01/31/17

Total: \$24,000

Direct costs/year: \$19,200 Funded salary support: 1%

8. Role: Principal Investigator

External Agency: Society of Family Planning Research Fund

Grant Title: Quick start levonorgestrel intrauterine contraceptive initiation in the setting of

unprotected intercourse: a pilot study. Project Dates: 02/01/14-12/31/15

Total costs: \$30,000 Direct costs/year: \$24,000 Funded salary support: 5%

9. Role: Principal Investigator

External Agency: Society of Family Planning Research Fund

Grant Title: Dilapan-S with Adjunctive Misoprostol for Same-day Second Trimester

Dilation and Evacuation: A Randomized, Double-Blind, Placebo-Controlled Trial

Project Dates: 06/01/13-07/31/14

Total costs: \$70,000 Direct costs/year: \$56,000 Funded salary support: 10%

Business and Industry (Clinical) Trials

Current

1. Role: Site Principal Investigator External Agency: Sebela, Inc.

Title: A Phase 3, Prospective, Multi-Center, Single-Arm, Open-Label Study to Evaluate VeraCept®, a Long-Acting Reversible Intrauterine Contraceptive for Contraceptive Efficacy, Safety, and

Tolerability.

Submitted: March 2017

Project Dates: 10/01/18-06/01/24

Total cost: \$1,165,751

Direct costs/year: \$124,901.89 Funded salary support: 10%

2. Role: Site Principal Investigator External Agency: Merck, Inc.

Title: A Phase 3, Open-Label, Multi-Center, Single Arm Study to Assess Contraceptive Efficacy and Safety of the Etonogestrel (MK-8415) Implant during Extended Use Beyond 36 months from

Insertion in Premenopausal Females up to 35 years of age.

Submitted: June 2020

Project Dates: 12/01/20-11/30/22

Total costs: \$761,364

Direct costs/year: \$266,477.40 Funded salary support: 1%

Pending

1. Role: Site Principal Investigator

External Agency: PRA Health Sciences, Inc.

Title: A Phase 3, Prospective, Multi-Center, Single-Arm, Open-Label Study to Evaluate

LevoCept[™], a Long-Acting Reversible Intrauterine System (IUS) for Contraceptive Efficacy, Safety,

and Tolerability.
Submitted: May 2020

Project Dates: 01/01/22-12/31/29

Total Costs: TBD
Direct costs/year: TBD
Funded salary support: TBD

2. Role: Site Principal Investigator External Agency: Cepheid

Title: 248C3: Clinical Evaluation of the Xpert Xpress CT/NG Test in Female Extragenital Specimens

Submitted: July 2022

Project Dates: 10/01/22-04/30/2023

Total costs: \$149,349.50

Direct costs/year: \$104,544.65 Funded salary support: 1%

Completed

1. Role: Site Principal Investigator

External Agency: Beckman Coulter, Inc.

Title: Access HBV Serological Markers Subject Enrollment US Protocol, Access HCV AB Assay Subject Enrollment US Protocol, Access HIV AG/AB Combo Assay US Enrollment Protocol

Submitted: October 2021

Project Dates: 11/01/21-11/01/22

Total Costs: \$828,281.25 Direct costs/year: \$621,210.94 Funded salary support: 1%

2. Role: Site Principal Investigator

External Agency: EvoFem Biosciences

Title: Phase 3 double-blind placebo-controlled efficacy trial of EVO100 vaginal gel for the prevention of urogenital Chlamydia trachomatis and Neisseria gonorrhea infection

Submitted: July 2020

Project Dates: 10/21/20-10/21/22

Total costs: \$279,977.50 Direct costs/year: \$193,692.50 Funded salary support: 1%

3. Role: Site Principal Investigator

External Agency: Abbott Molecular, Inc.

Title: Alinity m HR HPV Specimen Collection Study from Women Referred to Colposcopy

Submitted: May 2021

Project Dates: 05/01/21-05/01/22

Total costs: \$240,000 Direct costs/year: \$168,000 Funded salary support: 1%

4. Role: Site Principal Investigator External Agency: Cepheid

Title: Clinical Evaluation of the Xpert Xpress CT/NG Test in Female Urogenital Specimens

Submitted: April 2020

Project Dates: 04/28/20-4/28/21 Direct costs/year: \$50,000 Funded salary support: 1%

5. Role: Site Principal Investigator External Agency: Cepheid

Title: Pre-Clinical Evaluation of the Xpert Xpress CT/NG Test

Submitted: April 2019

Project Dates: 07/08/19-10/30/19

Direct costs/year: \$28,475 Funded salary support: 1% 6. Role: Site Principal Investigator

External Agency: Visby Medical (Click Dx)

Title: Clinical Evaluation of the Click Sexual Health Test for the Detection of Neisseria

gonorrhoeae, Trichomonas vaginalis, and Chlamydia trachomatis in Women.

Submitted: July 2019

Project Dates: 09/19/19-12/30/19

Direct costs/year: \$28,650 Funded salary support: 1%

7. Role: Site Principal Investigator

External Agency: Abbott (Alere) San Diego Title: Alere hCG Test Method Comparison Study.

Submitted: February 2019

Project Dates: 03/15/19-07/30/19

Direct costs/year: \$55,050 Funded salary support: 5%

8. Role: Site Principal Investigator External Agency: HRA Pharma

Title: Multi-Center Study to Test the Comprehension of the Ovrette® OTC Drug Facts Label

Project Dates: 10/01/16-01/31/17

Direct costs/year: \$8,450 Funded salary support: 1%

9. Role: Site Principal Investigator External Agency: Hologic, Inc.

Title: Prospective Collection and Testing of Lesion Specimens for the Development of a Herpes

Simplex Virus Assay.

Project Dates: 10/01/14-07/31/16

Direct costs/year: \$30,300 Funded salary support: 1%

University of Minnesota Sources

Current

1. Role: Co-Principal Investigator

Principal Investigator: Karen Borchert, MD

Internal Agency: University of Minnesota Medical School, Department of Family Medicine Title: Pregnancy of Unknown Location in Abortion Care: Management and Outcomes.

Project Dates: 01/01/17-12/31/22 Direct costs/year: non-applicable

Completed

1. Role: Principal Investigator

Internal Agency: University of Minnesota Medical School, Department of Obstetrics, Gynecology

and Women's Health Progressive Grant, Phase II

Title: Identifying predictors of post-abortion contraceptive uptake using a comprehensive,

multisite database

Project Dates: 07/01/20-06/30/22

Direct Costs/Year: \$20,000 Funded salary support: 0%

2. Role: Principal Investigator

Internal Agency: University of Minnesota Medical School, Department of Obstetrics, Gynecology

and Women's Health Research Support Grant

Title: Quantifying contraceptive failure with unprotected intercourse 6-14 days prior to

contraceptive initiation

Project Dates:01/01/17-6/30/21

Total Cost: \$3,500

Funded salary support: 0%

3. Role: Principal Investigator

Internal Agency: University of Minnesota Medical School, Department of Obstetrics, Gynecology

and Women's Health Research Support Grant

Title: Contrasperm: the Future of Male Birth Control

Project Dates: 08/01/19-07/31/20

Total Cost: \$4,500

Funded salary support: 0%

4. Role: Principal Investigator

Internal Agency: University of Minnesota Medical School, Department of Obstetrics, Gynecology

and Women's Health Progressive Grant, Phase I

Title: Identifying predictors of post-abortion contraceptive uptake using a comprehensive,

multisite database

Project Dates: 08/01/19-07/31/20

Total cost: \$10,000

Funded salary support: 0%

Publications

Impact Analytics

<i>h</i> -Index	<i>h(fl)</i> -Index	Total Publications	First/Last Author Publications	Total Citations	First/Last Author Citations
6	1	15	4	142	11

Publication #1 not yet in Manifold

Peer-Reviewed Publications

 Borchert K, Thibodeau C, Varin P, Wipf H, Traxler S, Boraas CM. Medication Abortion and Uterine Aspiration for Undesired Pregnancy of Unknown Location: A Retrospective Cohort Study. <u>Contraception</u>. 2023 Feb 16:109980. doi:10.1016/j.contraception.2023.109980. *Impact Factor: 2.335; Times Cited: 0; Role: Developed study concept and design, defined intellectual content, conducted literature search, data acquisition, manuscript preparation, editing and review.*

- Koenig LR, Raymond EG, Gold M, Boraas CM, Kaneshiro B, Winikoff B, Coplon L, Upadhyay UD. Mailing abortion Pills does not delay care: a cohort study comparing mailed to in-person dispensing of abortion medications in the United States. <u>Contraception</u>. 2023 Feb 1:109962. doi: 10.1016/j.contraception.2023.109962.
 Impact Factor: 2.335; Times Cited: 0; Role: Protocol editing, site administration of multicenter trial, data acquisition, manuscript preparation, editing and review.
- 3. Groene EA*, **Boraas CM**, Smith MK, Lofgren SM, Rothenberger MK, Enns EA. Evaluation of Strategies to Improve Uptake of Expedited Partner Therapy for *Chlamydia trachomatis*Treatment in Minnesota: A Decision Analytic Model. MDM Policy Pract. 2023 Jan 22;8(1):23814683221150446. doi: 10.1177/23814683221150446. eCollection 2023 Jan-Jun. Impact Factor: 1.54; Times Cited: 0; Role: Developed study concept and design, defined intellectual content, conducted data acquisition, manuscript preparation, editing and review.
- Groene EA*, Boraas CM, Smith MK, Lofgren SM, Rothenberger MK, Enns EA. A statewide mixed-methods study of provider knowledge and behavior administering Expedited Partner Therapy for chlamydia and gonorrhea. Sex Transm Dis. 2022 Jul 3. doi: 10.1097/OLQ.000000000001668.
 Impact factor: 3.686; Times Cited: 0; Role: Protocol creation, manuscript preparation, editing and review.
- 5. Ralph JA, Westberg SM, **Boraas CM**, Terrell CA, Fischer JR. PrEP-aring the General Gynecologist to Offer HIV Pre-exposure Prophylaxis. <u>Clin Obstet Gynecol</u>. 2022 Jun 16. doi: 10.1097/GRF.000000000000013. Online ahead of print.

 Impact factor: 1.619; Times Cited: 0; Role: manuscript preparation, editing and review.
- 6. Henke L*, Martins S*, **Boraas CM**. Associations Between Income Status and Perceived Barriers to Using Long-Acting Reversible Contraception: An Exploratory Study. <u>Front Reprod Health</u>, 12 April 2022. https://doi.org/10.3389/frph.2022.856866 *Impact factor: NA; Times Cited: 0: Role: Protocol creation, data acquisition, manuscript preparation, editing and review.*
- 7. Upadhyay UD, Raymond EG, Koenig LR, Coplon L, Gold M, Kaneshiro B, **Boraas CM**, Winikoff B. Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study. <u>JAMA Intern Med.</u> 2022 Mar 21. Online ahead of print. *impact factor: 44.41; Times Cited: 6; Role: Protocol editing, site administration of multicenter trial, data acquisition, manuscript preparation, editing and review.*
- Anger HA, Raymond EG, Grant M, Haskell S, Boraas C, Tocee K, Banks J, Coplon L, Shochet T, Platais I, Winikoff B. Clinical and service delivery implications of omitting ultrasound before medication provided abortion via direct-to-patient telemedicine and mail. <u>Contraception</u>. 2021 Dec;104(6):659-665. doi: 10.1016/j.contraception.2021.07.108. Epub 2021 Jul 28. *Journal Impact Factor: 2.335; Times Cited: 2; Role: Protocol editing, site administration of multicenter trial, data acquisition, manuscript preparation, editing and review.*
- 9. Chong E, Shochet T, Raymond E, Platais I, Anger HA, Raidoo S, Soon R, Grant MS, Haskell S, Tocce K, Baldwin MK, **Boraas CM**, Bednarek PH, Banks J, Coplon L, Thompson F, Priegue E, Winikoff B. Expansion of a direct-to-patient telemedicine abortion service in the United

States and experience during the COVID-19 pandemic. <u>Contraception</u>. 2021 Jul;104(1):43-48. doi: 10.1016/j.contraception.2021.03.019. Epub 2021 Mar 27. Journal Impact Factor: 2.335; Times Cited: 21; Role: Protocol review and editing, site administration of multicenter trial, data acquisition, manuscript preparation, editing and review.

- 10. **Boraas CM**, Sanders JN, Schwarz EB, Thompson I, Turok DK. Risk of Pregnancy With Levonorgestrel-Releasing Intrauterine System Placement 6-14 Days After Unprotected Sexual Intercourse. <u>Obstet Gynecol</u>. 2021 Apr 1;137(4):623-625. Journal Impact Factor: 4.982; Times Cited: 0; Role: Protocol review and editing, grant writing and submission, site administration of multicenter trial, data acquisition, manuscript preparation, editing and review.
- 11. Raymond EG, Anger HA, Chong E, Haskell S, Grant M, **Boraas C**, Tocce K, Banks J, Kaneshiro B, Baldwin MK, Coplon L, Bednarek P, Shochet T, Platais I. "False positive" urine pregnancy test reults after successful medication abortion. <u>Contraception</u>. 2021 Jun;103(6):400-403. doi: 10.1016/j.contraception.2021.02.004. Epub 2021 Feb 14.

 Journal Impact Factor: 2.335; Times Cited: 0; Role: Protocol review and editing, site administration of multicenter trial, data acquisition, manuscript preparation, editing and review.
- 12. Schlafer R, Saunders JB, Boraas CM, Kozhimannil KB, Mazumder N, Freese R. Maternal and neonatal among incarcerated women who gave birth in custody. <u>Birth</u>. 2021 Mar;48(1):122-131. doi: 10.1111/birt.12524. Epub 2020 Dec 27. Impact factor 3.689; Times cited 2; Role: Developed study concept and design, defined intellectual content, manuscript preparation, editing and review.
- 13. Thompson I, Sanders JN, Schwarz EB, **Boraas C**, Turok DK. Copper intrauterine device placement 6-14 days after unprotected sex. <u>Contraception</u>. 2019 Sep;100(3):219-221. doi: 10.1016/j.contraception.2019.05.015. Epub 2019 Jun 7. Impact factor 2.335; Times cited 4; Role: Protocol review and editing, grant writing and submission, site administration of multicenter trial, data acquisition, manuscript preparation, editing and review.
- 14. Raymond EG, Tan YL, Comendant R, Sagaidac I, Hodorogea S, Grant M, Sanhueza P, Van Pratt E, Gillespie G, **Boraas C**, Weaver MA, Platais I, Bousieguez M, Winikoff B. Simplified medical abortion screening: a demonstration project. <u>Contraception</u>. 2018 Apr;97(4):292-296. doi: 10.1016/j.contraception.2017.11.005. Epub 2017 Nov 21. PMID: 29170088

 Impact factor 2.335; Times cited 22; Role: Protocol review and editing, site administration of multicenter trial, data acquisition, manuscript preparation, editing and review.
- 15. **Boraas CM**, Chappell CA, Krajewski CM. Use of an Endotracheal Tube for Surgical Abortion Complicated by a Leiomyomatous Uterus: A Case Report. <u>J Med Case Rep</u>. 2017 August 25;11(1):236. doi: 10.1186/s13256-017-1408-y. PMID: 28838323. Impact factor 1.07; *Times cited 1; Role: Developed case report design, defined intellectual content, conducted literature search, data acquisition, manuscript preparation, editing and review.*

- 16. Paul J*, **Boraas CM**, Duvet M*, Chang JC. YouTube and the single-rod contraceptive implant: a content analysis. <u>J Fam Plann Reprod Health Care</u>. 2017 Jul;43(3):195-200. doi: 10.1136/jfprhc-2016-101593. Epub 2017 Jan 20. PMID: 28108504. *Impact factor 2.151*, *Times cited 11; Role: Developed study concept and design, defined intellectual content, manuscript preparation, editing and review.*
- 17. **Boraas CM**, Achilles SL, Cremer ML, Chappell CA, Lim SE, Chen BA. Synthetic osmotic dilators with adjunctive misoprostol for same-day dilation and evacuation: a randomized controlled trial. <u>Contraception</u>. 2016 Nov;94(5):467-472. PMID: 27241895. Impact factor 2.335; Times cited 10; Role: Developed study concept and design, defined intellectual content, conducted literature search, data acquisition, manuscript preparation, editing and review.
- 18. Rapkin RB, Achilles SL, Schwarz EB, Meyn L, Cremer M, **Boraas CM**, Chen BA. Self-Administered Lidocaine Gel for Intrauterine Device Insertion in Nulliparous Women: A Randomized Controlled Trial. <u>Obstet Gynecol</u>. 2016 Sep;128(3):621-8. doi: 10.1097/ACOG.000000000001596. PMID: 27500351. *Impact factor 4.982; Times cited 26; Role: Defined intellectual content, data acquisition, manuscript preparation, editing and review.*
- Akinsete OO, Sides T, Hirigoyen D, Cartwright C, Boraas C, Davey C, Pessoa-Brandao L, McLaughlin M, Kane E, Hall J, Henry K. Demographic, clinical, and virologic characteristics of African-born persons with HIV/AIDS in a Minnesota hospital. <u>AIDS Patient Care STDS</u>. 2007 May;21(5):356-65. PMID: 17518528.
 Impact factor 5.944; Times cited 36; Role: Data acquisition, manuscript preparation, editing and review.

Non-Peer-Reviewed Publications

- 1. Martins SL*, **Boraas CM.** Contraceptive counseling: an essential travel medicine service. <u>J Travel Med.</u> 2020 Jul 14;27(4):taaa023. doi: 10.1093/jtm/taaa023 *Role: Commentary preparation, editing and review.*
- 2. Miller KK*, Gewirtz O'Brien JR*, Sajady M, Argo T*, Chaisson N, **Boraas C.** Long Acting Reversible Contraception (LARCs): Beyond Birth Control. Minnesota Pediatrician monthly newsletter, February 2020. Available at: http://www.mnaap.org/long-acting-reversible-contraceptives-larcs-beyond-birth-control/Role: Manuscript preparation, editing and review.
- 3. **Boraas CM**, Schwarz EB. Contraceptive Choice for Women with Obesity. <u>Gynecology Forum</u>. 2012 May;17(4):20-3. *Role: Developed review design, conducted literature search, manuscript preparation, editing and review*.

Chapters in Books

 Boraas CM. A 32-Year-Old HIV-positive woman requesting IUD. 2019. Office Gynecology: A Case-Based Approach, First Edition; Chelmow D, Karjane N, Ricciotti H, Young A, eds., Cambridge University Press, New York, NY. Role: Author 2. **Boraas CM** and Keder LM. Intrauterine Contraception Insertion and Removal. In Press. *Atlas of Pelvic Surgery and Anatomy, First Edition*; Huh W and Kim K, eds., McGraw Hill Professional, New York, NY.

Role: Author

3. **Boraas CM** and Keder LM. Contraceptive Implant Insertion and Removal. In Press. *Atlas of Pelvic Surgery and Anatomy, First Edition*; Huh, W. and Kim, K., eds, McGraw Hill Professional, New York, NY.

Role: Author

4. **Boraas CM** and Keder LM. Female Sterilization. In Press. *Atlas of Pelvic Surgery and Anatomy, First Edition*; Huh, W. and Kim, K., eds, McGraw Hill Professional, New York, NY. Role: Author

Presentations

Invited Oral Presentations at International Professional Meetings, Conferences, etc.

- 1. **Boraas CM,** Nardos R, Ghebre R, Pace S, Chojnacki M. Obstetrics and Gynecology Medicine Panel. University of Minnesota Global Health Course. May 6, 2021. Virtual.
- 2. **Boraas CM.** Current Contraception Overview. American Refugee Committee Staff Development Conference. March 18-26, 2013. Sangkhlaburi, Thailand.
- 3. **Boraas CM.** Long-Acting Reversible Contraception Implants. American Refugee Committee Staff Development Conference. March 18-26, 2013. Sangkhlaburi, Thailand.
- 4. **Boraas CM.** Long-Acting Reversible Contraception Intrauterine Devices. American Refugee Committee Staff Development Conference. March 18-26, 2013. Sangkhlaburi, Thailand.

Invited Oral Presentations at National Professional Meetings, Conferences, etc.

- 1. **Boraas CM**, Ojanen-Goldsmith A, Torgrimson-Rojerio B, Hassan A*. Time for Action: The impact of tear gas used by law enforcement on reproductive health. Society of Family Planning Annual Meeting. October 12, 2021. Virtual.
- 2. **Boraas CM**. Merck Nexplanon Extension Trial, Site Tips and Tricks. MK-8415-060 Lessons Learned Recruitment and Retention Meeting. May 5, 2021. Virtual.
- 3. **Boraas CM** and Rapkin RB. Surgical Miscarriage Management in the Office: You Can Do It. ACOG Annual Clinical Meeting. April 30-May 2, 2021. Virtual.
- 4. **Boraas CM**, Kaneshiro B, Raymond E, Grant M. No Test Medical Abortion. Society of Family Planning Webinar. January 6, 2021. Virtual.
- 5. Borchert K, Wipf H*, Roeske E*, Clure C*, Traxler S, **Boraas CM.** Pregnancy of Unknown Location in Abortion Care: Management and Outcomes. National Abortion Federation Conference. April 2018. Seattle, WA.

- 6. **Boraas CM.** Interviewing Basics. Fellowship in Family Planning Career Development Workshop. July 23-24, 2017. Chicago, IL.
- 7. **Boraas CM.** Searching for a Position. Fellowship in Family Planning Career Development Workshop. July 23-24, 2017. Chicago, IL.
- 8. **Boraas CM** and Rapkin RB. Surgical Miscarriage Management in the Office: You Can Do It. ACOG Annual Clinical Meeting. May 7, 2017. San Diego, CA.

Invited Oral Presentations at Local and Regional Professional Meetings, Conferences, etc.

- 1. **Boraas, CM.** Trauma-informed Gyn and Pregnancy Care: How we use Language in the Exam Room. University of Minnesota Department of Obstetrics. Gynecology and Women's Health Resident Curriculum Conference. February 14, 2022. Minneapolis, MN.
- 2. **Boraas, CM.** Contraception for the Medically Complex Patient. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference, February 14, 2022. Minneapolis, MN.
- Boraas, CM. Induced Abortion for Genetic Counselors. University of Minnesota Genetic Counselor Graduate Student Education Presentation. December 13, 2021. Minneapolis, MN.
- 4. **Boraas, CM.** Ectopic pregnancy and induced abortion. University of Minnesota Womens' Health Nurse Practitioner and Nurse Midwifery Education Presentation. September 17, 2021. Minneapolis, MN
- 5. **Boraas CM.** Dilation and Curettage Papaya Workshop. Simulation. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Bootcamp. June 21, 2021. St. Paul, MN.
- Boraas, CM. Induced Abortion for Genetic Counselors. University of Minnesota Genetic Counselor Graduate Student Education Presentation. December 14, 2020. Minneapolis, MN.
- 7. **Boraas, CM.** Breastfeeding Basics for the Ob/Gyn Resident. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. December 28, 2020. Minneapolis, MN.
- 8. **Boraas CM.** Introduction to Family Planning. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Bootcamp. June 22, 2020. St. Paul, MN.
- 9. **Boraas CM.** Dilation and Curettage Papaya Workshop. Simulation. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Bootcamp. June 22, 2020. St. Paul, MN.

- 10. **Boraas CM.** Ectopic Pregnancy. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. June 22, 2020. Minneapolis, MN.
- 11. **Boraas CM.** Pregnancy of Unknown Location and Early Pregnancy Loss. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. May 4, 2020. Minneapolis, MN.
- Wise M*, Boraas CM. Veracept Phase II Trial. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Journal Club. May 4, 2020. Minneapolis, MN.
- 13. **Boraas CM.** Breech Vaginal Delivery. Simulation. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. February 24, 2020. Minneapolis, MN.
- 14. **Boraas, CM.** Global Maternal Mortality. University of Minnesota Global Pediatrics Education Presentation. February 6, 2020. Minneapolis, MN.
- Boraas CM. Important Conversations Challenging Patients, Language, Race and Racism. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. February 27, 2020. Minneapolis, MN.
- Boraas CM, Pacala K. Dilation and Curettage Papaya Workshop. Simulation. University of Minnesota Medical School Obstetrics and Gynecology Interest Group Skills Night. February 27, 2020. Minneapolis, MN.
- 17. **Boraas CM**, Finn K, McKegney C, Ball C. Highlighting work as an abortion provider. Lunch Lecture. Medical Students for Choice. University of Minnesota Medical School. January 13, 2020. Minneapolis, MN.
- 18. Gerwitz-O'Brien J*, Donlon T*, **Boraas, CM.** Advocacy in Action. Becoming a Doctor Course. University of Minnesota Medical School. January 8, 2020. Minneapolis, MN.
- 19. **Boraas, CM.** Contraception for Endocrine Fellows. University of Minnesota Endocrinology Fellows Education Presentation. November 21, 2019. Minneapolis, MN.
- Boraas, CM. Induced Abortion for Genetic Counselors. University of Minnesota Genetic Counselor Graduate Student Education Presentation. November 18, 2019. Minneapolis, MN.
- 21. **Boraas, CM.** Ectopic pregnancy and induced abortion. University of Minnesota Womens' Health Nurse Practitioner and Nurse Midwifery Education Presentation. September 13, 2019. Minneapolis, MN.
- 22. **Boraas CM.** Adolescent Gynecology. University of Minnesota Department of Pediatrics Resident Block Education Conference. August 9, 2019. Minneapolis, MN.

- Boraas CM. Breech Vaginal Delivery. Simulation. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. February 18, 2019. Minneapolis, MN.
- 24. **Boraas CM.** LARC Tips and Tricks. University of Minnesota Department of Obstetrics. Gynecology and Women's Health Resident Curriculum Conference. February 11, 2019. Minneapolis, MN.
- 25. Kummer L, **Boraas CM**, Chomilo N. Making an Impact through Advocacy. Becoming a Doctor Course. University of Minnesota Medical School. January 9, 2019. Minneapolis, MN.
- 26. **Boraas CM** and Flanagan S. Uterine Artery Embolization in Obstetric Hemorrhage. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Grand Rounds. December 18, 2018. Minneapolis, MN.
- 27. **Boraas CM.** Termination of Pregnancy in the Second Trimester. Fetal Diagnosis and Treatment Center. University of Minnesota Medical School. December 6, 2018. Minneapolis, MN.
- 28. **Boraas CM.** Contraception Overview. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Bootcamp. June 19, 2018. Minneapolis, MN.
- 29. **Boraas CM.** Introduction to Abortion. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Bootcamp. June 19, 2018. Minneapolis, MN.
- 30. **Boraas CM.** Cesarean Scar Pregnancy. Fairview Infusion Center Continuing Medical Education. May 25, 2018. Minneapolis, MN.
- 31. **Boraas CM.** Abortion Cervical Preparation. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. February 26, 2018. Minneapolis, MN.
- 32. **Boraas CM.** Dilation and Evacuation versus Induction of Labor for Termination of Pregnancy. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. February 26, 2018. Minneapolis, MN.
- 33. **Boraas, CM.** Ectopic pregnancy and induced abortion. University of Minnesota Womens' Health Nurse Practitioner and Nurse Midwifery Education Presentation. December 1, 2017. Minneapolis, MN.
- 34. **Boraas, CM.** Global Maternal Mortality: Focus on Delivery. University of Minnesota Department of Pediatrics Residency Block Education Presentation. Hennepin County Medical Center. November 17, 2017. Minneapolis, MN.
- 35. **Boraas CM.** Challenging Patient Encounters. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. October 30, 2017. Minneapolis, MN.

- 36. **Boraas, CM,** Terrell, CA, Hutto, SL. Abortion Care at UMMC. University of Minnesota Medical Center ER Department Grand Rounds. September 28, 2017. Minneapolis, MN.
- 37. **Boraas, CM.** Contraception for Patients with Medical Conditions. Continuing Education Presentation. Planned Parenthood MN-ND-SD. August 8 and 12, 2017. St. Paul, MN.
- 38. **Boraas, CM**, Terrell, CA, Hutto, SL. Abortion Care at UMMC. UMMC Peri-operative Education Meeting. April 11, 2017. Minneapolis, MN.
- 39. **Boraas CM.** Mifepristone: Politics and Science in Practice, University of Minnesota Department of Obstetrics, Gynecology and Women's Health Grand Rounds. February 21, 2017. Minneapolis, MN.
- 40. **Boraas CM.** Breech Vaginal Delivery. Simulation. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. February 6, 2017. Minneapolis, MN.
- 41. **Boraas CM** and Ball CE. Family Planning Questions and Answers, Planned Parenthood MN-ND-SD Clinician Days. January 6, 2017. St. Paul, MN.
- 42. **Boraas CM.** Abortion Policy. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. September 12, 2016. Minneapolis, MN.
- 43. **Boraas CM.** Abortion Cervical Preparation. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. September 12, 2016. Minneapolis, MN.
- 44. **Boraas CM.** Dilation and Evacuation versus Induction of Labor for Termination of Pregnancy. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. September 12, 2016. Minneapolis, MN.
- 45. **Boraas CM.** Challenging Patient Encounters. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. August 29, 2016. Minneapolis, MN.
- 46. **Boraas CM.** Introduction to Abortion. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Bootcamp. June 20, 2016. Minneapolis, MN.
- 47. **Boraas CM.** Family Planning Update. University of Minnesota Department of Obstetrics, Gynecology and Women's Health and MN ACOG Autumn Seminar. November 20, 2015. Minneapolis, MN.
- 48. **Boraas CM.** Introduction to Abortion. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Bootcamp. June 23, 2015. Minneapolis, MN.

- 49. **Boraas CM** and Ball CE. Family Planning Questions and Answers. Planned Parenthood MN-ND-SD Clinician Days. October 1, 2014. St. Paul, MN.
- 50. **Boraas CM** and Eggleston K. Family Planning Questions and Answers. Planned Parenthood MN-ND-SD Clinician Days. September 30, 2014. St. Paul, MN.
- 51. **Boraas CM.** Family Planning in Conflict Settings. University of Pittsburgh Global Health and Underserved Lecture Series. February 10, 2014. Pittsburgh, PA.
- Boraas CM. Why Women 'Wait': Abortion in the Second Trimester. University of Illinois at Chicago Department of Obstetrics and Gynecology Grand Rounds. January 31, 2014. Chicago, IL.
- 53. **Boraas CM.** Abortion and Long-Term Health Outcomes: Examining the Evidence. University of Pittsburgh Department of Obstetrics, Gynecology and Reproductive Sciences Gynecology Conference. January 6, 2014. Pittsburgh, PA.
- 54. **Boraas CM.** Misoprostol in Gynecologic Practice. Magee-Womens Hospital Gynecology Conference. University of Pittsburgh. November 11, 2013. Pittsburgh, PA.
- 55. **Boraas CM.** Towards Equity: Reproductive Health along the Thai-Burma Border. University of Pittsburgh Department of Obstetrics, Gynecology and Reproductive Sciences Gynecology Conference. July 8, 2013. Pittsburgh, PA.
- 56. **Boraas CM.** Fit to be Tied: Sterilization in the USA. University of Pittsburgh Department of Obstetrics, Gynecology and Reproductive Sciences Gynecology Conference. February 22, 2013. Pittsburgh, PA.
- 57. **Boraas CM.** Health Reform 101: What's in it for Women? University of Pittsburgh Medical School Medical Students for Choice Lecture Series. November 2, 2012. Pittsburgh, PA.
- 58. **Boraas CM.** Health Reform 101: What's in it for Women? University of Pittsburgh Department of Obstetrics, Gynecology and Reproductive Sciences Gynecology Conference. October 22, 2012. Pittsburgh, PA.
- 59. **Boraas CM.** Maternal Mortality: The Promise of Progress. The Ohio State University Department of Obstetrics and Gynecology Grand Rounds. May 17, 2012. Columbus, OH.
- Boraas CM. Current Contraception Overview. Kilimanjaro Christian Medical College Department of Obstetrics and Gynecology Grand Rounds. March 10, 2011. Moshi, Tanzania.
- 61. **Boraas CM.** Morbidity and Mortality Report Case of the Lost IUD. The Ohio State University Department of Obstetrics and Gynecology Grand Rounds. September 2, 2010. Columbus, OH.

62. **Boraas CM.** Malaria in Pregnancy. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. August 27, 2010. Minneapolis, MN.

Peer-Reviewed Oral Presentations at National Professional Meetings, Conferences, etc.

- Faherty E*, Smith K, Boraas C, Lofgren S, Rothenberger M, and Enns E. Using mixed methods to identify and evaluate strategies to improve uptake of Expedited Partner Therapy for *chlamydia trachomatis* infection in Minnesota. Society for Medical Decision Making Virtual Meeting, October 18-20, 2021.
- 2. Martins SL* and **Boraas CM**. Willingness to use the 'male' birth control pill: Demographic and reproductive health correlates among a community-based sample of U.S. men. Annual Meeting of the Society for Pediatric and Perinatal Epidemiologic Research. June 21-22, 2021. Virtual.
- 3. Upadhyay U, Raymond E, Koenig L, Coplon L, Gold M, Kaneshiro B, **Boraas C**, Winikoff B. Safety and Efficacy of No-test Medication Abortion: A Retrospective Multi-Site Study. National Aboriton Federation Meeting. May 11-12, 2021. Virtual.
- 4. Anger H, Raymond E, Chong E, Haskell S, Grant M, **Boraas C**, Tocce K, Banks J, Coplon L, Shochet T, Platais I. Comparison of clinical outcomes among patients who did and did not have a screening ultrasound or pelvic exam prior to obtaining medicaion abortion services via direct-to-patient telemedicine. National Abortion Federation Meeting, May 11-12, 2021. Virtual
- 5. Sayarath M*, Gerwitz O'Brien J*, Shramko M*, Argo T*, Brown E, Mishra P, Boraas CM McRee, A. Assessing the Gap in Sexual and Reproductive Health Services among Hospitalized Adolescents. Works in Progress Session. Society of Adolescent Medicine Conference, March 11, 2020. San Diego, CA. Due to COVID-19 related conference cancellation, this invited presentation was not given.
- Borchert K, Wipf K*, Roeske E*, Clure C*, Traxler S, Boraas CM. Pregnancy of Unknown Location in Abortion Care: Management and Outcomes. National Abortion Federation Conference, April 23, 2018. Seattle, WA.
- 7. **Boraas CM**, Thompson I, Turok DK, Baldauf E, Borrero S, Schwarz EB, Sanders JN. Extending the window for insertion of the intrauterine device. American Society for Reproductive Medicine Scientific Congress, October 19, 2016. Salt Lake City, UT.
- 8. **Boraas CM**, Isley MM. Chlamydia and gonococcal infections and screening in women receiving intrauterine devices in a resident obstetrics and gynecology clinic. The Ohio State Department of Obstetrics and Gynecology Resident Research Day. October 2011. Columbus, OH.

Poster Abstract Presentations at National Professional Meetings, Conferences, etc.

1. Groene E*, **Boraas C**, Smith K, Lofgren S, Rothenberger M, Enns E. Offering Expedited Partner Therapy: a mixed methods study of Minnesota health providers. 2022 STD Prevention Conference. September 19-22, 2022. Virtual.

- 2. Keonig LR, Raymond EG, Gold M, **Boraas C**, Kaneshiro B, Winikoff B, Coplon L, Upadhyay UD. Time to Care Among Patients Who Receive Medication Abortion with History-Based Screening in the United States. Population Association of America Annual Meeting. April 6-9, 2022. Atlanta, GA.
- 3. Creinin M, Gawron L, Westhoff C, **Boraas CM**, Blumenthal P, Turok D. Phase 3 data of a novel low-dose copper intrauterine device with a nitinol frame: 1-year outcomes. ACOG Annual Clinical Meeting. April 30-May 2, 2021. Virtual.
- 4. Martins S*, Miller JJ*, Wise M*, Jafari N*, **Boraas CM.** Willingness to Use Novel Reversible Male-Controlled Contraceptive Methods in a Community-Based Sample of Adult Men. ACOG Annual Clinical Meeting. April 30-May 2, 2021. Virtual.
- 5. Wise M*, Martins S*, Tessier K, Traxler SA, **Boraas CM.** Success of Intrauterine Device Placement in Adolescents at Planned Parenthood. ACOG Annual Clinical Meeting. April 30-May 2, 2021. Virtual.
- 6. Miller JJ*, Martins S*, Mahoney MA*, Tessier K, Traxler SA, **Boraas CM**. Correlates of long acting reversible contraception uptake at 30 days following medication abortion. ACOG Annual Clinical Meeting. April 30-May 2, 2021. Virtual.
- 7. Faherty E*, **Boraas CM**, Smith K, Lofgren S, Rothenberger M, and Enns E. Expedited Partner Therapy for Sexually Transmitted Infections in Minnesota: A Mixed-Methods Review of Current Practices and Barriers to Implementation. ISPOR 2021, May 17-20, 2021. Virtual.
- 8. Gerwitz O'Brien J*, Shramko M*, Sayarath M*, Brown E, Argo T*, **Boraas CM**, McRee A. Missed Opportunities to Provide Comprehensive Sexual and Reproductive Healthcare among Hospitalized Adolescents. Society for Adolescent Health and Medicine Annual Meeting. March 10-12, 2021. Due to COVID-19 related conference cancellation, this peer-reviewed poster was presented in electronic format.
- 9. Henke L*, Martins S*, Bangdiwala A, **Boraas CM**. Barriers to Obtaining Long-Acting Reversible Contraception Among Low-Income Women. ACOG Annual Clinical Meeting, April 24-27, 2020, Seattle, WA. Due to COVID-19 related conference cancellation, this peer-reviewed poster was presented in electronic format.
- 10. Gerwitz O'Brien J*, Shramko M*, Sayarath M*, Argo T*, Brown E, Mishra P, Boraas CM McRee A. Missed Opportunities to Provide Comprehensive Sexual and Reproductive Healthcare among Hospitalized Adolescents. Pediatric Research, Education and Scholarship Symposium. April 24, 2020. Minneapolis, MN.
- 11. Argo T*, Gerwitz O'Brien J*, Miller KK*, Prince A, Bahr T*, **Boraas CM**, Chaisson N, Borman-Shoap E. No Missed Opportunities: A trainee-driven long acting reversible contraceptive workshop for pediatric primary care clinicians. Society of Adolescent Medicine Conference. March 11, 2020. San Diego, CA.

- 12. Argo T*, Miller KK*, Bahr T*, Prince A, **Boraas CM**, Chaisson N, Borman-Shoap E, Gerwitz O'Brien J*. No Missed Opportunities: A trainee-driven long acting reversible contraceptive workshop for pediatric primary care clinicians. Minnesota American Academy of Pediatrics Conference. May 3, 2019. Minneapolis, MN.
- 13. Borchert K, Wipf K*, Roeske E*, Clure C*, Traxler S, **Boraas CM**. Pregnancy of Unknown Location in Abortion Care: Expectant Management and Ectopic Pregnancy Outcomes. National Abortion Federation Conference. May 6, 2019. Chicago, IL.
- Raymond E, Tan Y, Comendant R, Sagaidac I, Platais I, Grant M, Sanhueza P, Van Pratt E, Bousiequez M, Gillespie G, Boraas CM, Weaver M. Simplified Medical Abortion Screening: A Pilot Study. National Abortion Federation Conference. April 23, 2017. Montreal, Canada.
- 15. Paul J*, Duvet M, **Boraas CM**. YouTube and the contraceptive implant: a content analysis. North American Forum on Family Planning. October 11, 2014. Miami, FL.
- 16. Lewis L*, **Boraas CM**, Dunn SA, Krans EE. Postpartum contraceptive intention and initiation among opioid dependent women. North American Forum on Family Planning. October 11, 2014. Miami, FL.
- 17. **Boraas CM**, Achilles SL, Cremer ML, Chappell CA, Chen BA. Dilapan-S with adjunctive misoprostol for same-day dilation and evacuation: a randomized controlled trial. North American Forum on Family Planning. October 11, 2014. Miami, FL.
- 18. Rapkin RB, Achilles SL, **Boraas C**, Cremer M, Schwarz EB, Chen BA. Self-administered lidocaine gel for intrauterine device insertion in nulliparous women: a randomized controlled trial. ACOG Annual Clinical Meeting. April 28, 2014. Chicago, IL.
- 19. **Boraas CM**, Isley MM. Chlamydia and gonococcal infections and screening in women receiving intrauterine devices in a resident obstetrics and gynecology clinic. North American Forum on Family Planning. October 23, 2012. Denver, CO.
- 20. **Boraas CM**. Emergency contraception knowledge, attitudes and practices A survey of future providers in Minnesota and Guatemala. Global Health Council Conference. 2006. Washington, DC.
- 21. **Boraas CM**, Asante L, Heloo B. Female condom knowledge, attitudes and practices in Ghana's highest HIV prevalence regions. Global Health Education Consortium.

TEACHING AND CURRICULUM DEVELOPMENT

University of Minnesota

Course List

Undergraduate Courses

Annual speaker, The Future Physician II: The Life and Work of a Physician

2016-2020

Professional Medical Courses

Becoming a Doctor II: Making an Impact Through Advocacy Facilitator

2019-present

Obstetrics and Gynecology Core Clerkship Problem-Based Learning Facilitator
Obstetrics and Gynecology Preceptor, Rural Physicians Associate Program
Obstetrics and Gynecology Core Clerkship Attending Physician
2017-present
2017-present

Participation two times per academic year (4 week rotation) as a faculty problem-based learning mentor for the third-year students during the clerkship in Obstetrics and Gynecology. I also present a one-hour lecture on the clinical aspects of abortion and contraception approximately four times per year to the entire clerkship. Additionally, students can spend one day with me on at Planned Parenthood MN-ND-SD or Whole Woman's Health learning about reproductive choice and counseling, medical and surgical abortion, and contraceptive counseling.

Advanced Family Planning Elective Attending Physician

2015-present

The purpose of this elective is to learn more about the subspecialty of family planning. During the two-four week elective, students will be present in several clinical settings, including Planned Parenthood MN-ND-SD, Whole Woman's Health, Women's Health Specialists clinic, and the operating room for D&E procedures. The student also makes a presentation on a topic from the current medical literature to the family planning faculty and staff.

Curriculum Development

Post Graduate Medical Education

Global Pediatrics Curriculum

2019-present

Developed lectures for pediatrics providers about maternal morbidity and mortality.

Global Obstetrics Simulation for Pediatrics Residents

2017-prese

Developed a yearly simulation curriculum for delivery of a baby in the case of emergency for Pediatrics residents.

Fellowship in Family Planning, Director

2016-present

I serve as the future director of the family planning fellowship for graduated obstetrics and gynecology residents. This position has involved developing clinical, research and advocacy curriculum, which was approved by the University of Minnesota Board of Regents in Fall 2016. Application is currently under review by the national office of the Fellowship in Family Planning.

Ryan Residency in Abortion and Family Planning, Director

2015-present

I serve as the director of the family planning rotation for second year residents. This involves teaching and supervising the resident at Planned Parenthood in performing surgical abortions up to 23 6/7 weeks and medical abortions up to 10 0/7 weeks and in the operating room for D&E procedures up to 23 6/7 weeks. I also supervise office hysteroscopic sterilization and OR laparoscopic and hysteroscopic sterilization procedures. For residents who choose not to perform abortions, their education includes learning about early pregnancy counseling and decision making as well as performing ultrasounds for pregnancy dating.

Undergraduate Medical Education

Consultant, Endocrine and Reproductive Health Course Consultant, Diversity, Equity and Inclusion Thread

2021-present 2021-present

Nationally Available Published Curricula

Boraas, CM. Invited Lecturer *Obstetric Emergencies: Focus on Delivery.* Clinical Tropical Medicine & Online Global Health Curriculum. Editors Kristina Krohn, Brett

Hendel-Paterson, and William Stauffer. Available at

https://med.umn.edu/dom/education/global-medicine/courses-certificates/online/glob al-health-curriculum. The entire curriculum consists of 7 modules with over 180 hours of online material, including reviews and assessments. Pair with the in-person course, the curriculum qualifies participants to sit for the CTropMed and DTMH. With over 1300 unique enrollees from 47 states and over 28 countries, this curriculum helps providers learn how to address health disparities across the globe. Curriculum originally launched 2006, converted to online in 2010, and last updated in 2021.

Boraas, CM. Maternal Mortality. GPEDS (Global Pediatric Education Series) for Medical Students. Clerkship Directors: Winter J, Danich E, Howard C. This Virtual Medical Student Clerkship consists of 4 modules (approximately 25 hours) of online content covering topics in global child health. Available for enrollment September 2020.

Boraas, CM. Maternal Mortality. GPEDS 2.0 (Global Pediatric Education Series). Editors Winter J, Danich E, Howard C. Available at globalpeds.umn.edu/gpeds. Curriculum consists of 4 modules (approximately 25 hours) of online content on global child health that serves as the primary global health curriculum for pediatric residents at multiple institutions. The content is also available to individual subscribers for CME credit. Curriculum originally launched May 2014, Updated November 1, 2019.

ADVISING AND MENTORING

Undergraduate Student Activities

Research Mentor, B.A. Candidate	01/2021-06/2023		
Graduate Student Activities			
PhD Candidate	06/2022-present		
MPH Candidate	06/2022-6/2023		
MPH Candidate	06/2022-6/2023		
TRACT TL1 Program Mentor, PhD Candidate	07/2020-06/2022		
Master's Theses Directed MS in Medical Device Innovation Candidate MPH Candidate	06/2022-12/2022 09/2015-12/2015		
Professional Student Activities			

Twin Cities Medical Society Public Health Advocacy Fellowship Mentee	Jun 2020-2021
Medical student research advisees	Jul 2015-2018
Medical student advisees	Jul 2015-2018
Clinical Supervision	

3rd year medical students on Education in Pediatrics Along the Curriculum, 2017-present 3rd and 4th year medical students on OB/GYN clerkship rotations at Women's Health Specialists, 2015 – present

3rd and 4th year medical students on family planning elective rotations at Women's Health Specialists and community sites, 2015 – present

Residents Supervised

Clinical Supervision, 1st year residents on general gynecology rotations at Women's Health Specialists, 2015 – present

Clinical Supervision, 4th year residents on general gynecology rotations at Women's Health Specialists, 2015 – present

Clinical Supervision, 2nd year residents on general obstetrics rotations at UMMC L&D (The Birthplace), 2015 – present

Clinical Supervision, 3rd year residents on general obstetrics rotations at UMMC L&D (The Birthplace), 2015 – present

Clinical Supervision, 2nd year residents on family planning rotation at Planned Parenthood Minnesota, North Dakota, South Dakota, 2014 – present

Post Doctoral Fellows Supervised

Adolescent Health Fellowship September 2018 - June 2021

Post-doctoral Fellowship May 2019 - May 2020

Other Mentoring Activities

Faculty Advisor 2016-present

University of Minnesota Obstetrics and Gynecology Interest Group

Faculty Advisor 2016-present

University of Minnesota Medical Students for Choice

CLINICAL SERVICE

Clinical Leadership Accomplishments

Associate Medical Director, Planned Parenthood MN-ND-SD 2014-present

Clinical Service Responsibilities

Obstetrics, Gynecology, Midwifery and Family Planning Division 2015-present

Attending Physician Consulting Physician

Clinics: 2 half days per week, 2015-present OR: 1 half day per week, 2015-present

Planned Parenthood MN-ND-SD

2014-present

Clinics: 2 half days per week, 2016-present; 3 half days per week, 2015-2016; 4 half days per week

2014-2015

Whole Woman's Health 2014-present

Clinics: 2 half days per week, 2016-present; 1 half day per week, 2015-2016; 3 half days per week, 2014-2015

PROFESSIONAL SERVICE AND PUBLIC OUTREACH

Service To The Discipline/Profession/Interdisciplinary Area(s)

Editorships/Journal Reviewer Experience

Journal Reviewer, Obstetrics and Gynecology	2017-present
Recognized as Top 10% Peer Reviewer	2020
Journal Reviewer, Contraception	2013-present

Organization of conferences, workshops, panels, symposia

Member, University of Minnesota Department of Obstetrics, Gynecology and Women's Health and MN ACOG Joint Autumn Seminar Planning Committee 2016

Role: Organized educational themes and curricula, recruited speakers.

Member, University of Minnesota Department of Obstetrics, Gynecology and Women's Health and MN ACOG Joint Autumn Seminar Planning Committee 2015
Role: Organized educational themes and curricula, recruited speakers.

note: Organized educational themes and carriodia, re-

National Committee Memberships

Member, Society of Family Planning Research Implementation Interest Group	2021-present	
Member, M-POWER Advisory Committee	2021-present	
Member, No Test Medication Abortion Safety and Outcomes Working Group	2021-present	
Member, Complex Family Planning Fellowship Core Education Working Group	2021-present	
Member, Complex Family Planning Fellowship Education Committee	2020-2021	
Member, Society of Family Planning Program Committee	2019-2020	
Member, North American Forum on Family Planning Scientific Committee	2018-2020	
Member, Society of Family Planning Audit Committee	2016-2018	
Member, ACOG Online Learning in Ob-Gyn Advisory Committee	2014-present	
Member, ACOG Global Health Committee	2015-present	
Member, Fellowship in Family Planning Guide to Learning Revision Subcommittee, 2016-2018		

State Committee Memberships

Member, Minnesota Medical Association Health Equity Task Force	2020
Member, Minnesota PRAMS Advisory Committee	2017-present
Member, Reproductive Health Access Project, MN cluster	2017-present
Member, MN ACOG Advisory Council	2016-present
Member, MN ACOG Legislative Committee	2015-present

Public Advocacy

Physician Advocate, Minnesota ACOG Day at the Capitol	3/8/2022
Physician Advocate, Minnesota Medical Association Day at the Capitol	3/4/2020
Member, Minnesota Doctors for Health Equity	2018-present
Physician Advocate, Minnesota Medical Association Day at the Capitol	2/13/2019
Physician Advocate, Minnesota Medical Association Day at the Capitol	3/14/2018
Physician Advocate, Minnesota Medical Association Day at the Capitol	2/15/2017
Speaker, Press Conference on MN H.F. 411/S.F. 281, Physician's Integrity Act	1/23/2017
Physician Advocate, Minnesota Medical Association Day at the Capitol	3/23/2016

Service to the University/Medical School/Department

University of Minnesota

University-wide Service

Member, Medical School Faculty Advisory Committee 2022-present

Judge, Global Health Case Competition Faculty, Walter H. Judd Fellowships Selection Committee Faculty, Center for Global Health and Social Responsibility Chair, Students' International Health Committee Representative, Center for Health Interprofessional Programs Vice President, Student Senate, University of Minnesota School of Publ	2022 2018 2016-present 2002-2008 2002-2004 ic Health, 2003
Medical School Service and Intercollegiate Service	
Participant, Master Mentor Program Member, Medical School Admissions Committee	2017-present 2007-2008, 2018-present
Member, Learning Environment Rounds Member, Essentials of Modern Medicine Curriculum Initiative Member, Med2010 Education Initiative Representative, Student Council Representative, Education Council	2017-present 2007-2008 2007-2008 2004-2008 2004-2008
Department/Unit Service	
Member, ARTS Committee Member, Residency Program Evaluation Committee Member, Clinical Competency Committee Member, Education Council Member, Residency Interview Committee Moderator, Research Day M Health Fairview Service Member, UMMC Obstetric Case Review Committee Member, Perinatal Loss Policy Committee	2020-present 2016-present 2016-present 2016-present 2016, 2019 2022-present 2021-present
Member, Termination of Pregnancy Policy Committee	2020-present
University of Pittsburgh	
Medical School Service and Intercollegiate Service Fellow Advisor, Medical Students for Choice	2012-2014
The Ohio State University Department/Unit Service	
Resident Supervisor, Columbus Free Clinic Resident Advisor, Obstetrics and Gynecology Interest Group	2010-2012 2009-2012
St. Olaf College, Northfield, MN University-wide service Co-Founder, Helping Overcome Poverty through Education (H.O.P.E.)	2000-2001
Community Outreach Activities	
Family Planning Consultant, Teen Annex Clinic	2021-present
Family Planning Consultant, Teen Affilex Cliffic Family Planning Consultant, Alight Mentor, Upward Bound, St. Paul, MN Global Health Volunteer, Mano a Mano Organization, St. Paul, MN	2019-present 2004-2008 2004-2008