IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS

PLANNED PARENTHOOD ARKANSAS & EASTERN OKLAHOMA, d/b/a PLANNED PARENTHOOD OF THE HEARTLAND and STEPHANIE HO, M.D., on behalf of themselves and their patients,

Plaintiffs,

v.

LARRY JEGLEY, Prosecuting Attorney for Pulaski County, in his official capacity, his agents and successors; MATT DURRETT, Prosecuting Attorney for Washington County, in his official capacity, his agents and successors,

Defendants.

No. 4:15CV784-JLH

This case assigned to District Judge Holmes
and to Magistrate Judge Harris

COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF

Plaintiffs Planned Parenthood Arkansas & Eastern Oklahoma, d/b/a Planned Parenthood of the Heartland ("PPH"), and Stephanie Ho, by and through their undersigned attorneys, bring this Complaint against the above-named Defendants, their employees, agents, delegates, and successors in office, and in support thereof allege the following:

I. PRELIMINARY STATEMENT

1. Plaintiffs bring this action seeking declaratory and injunctive relief on behalf of themselves and their patients under the United States Constitution and 42 U.S.C. § 1983, to challenge sections 1504(a) and (d) of Arkansas Act 577, Reg. Sess. (2015) ("Act 577" or "the Act"), codified at Ark. Code Ann. § 20-16-1501 *et seq.*, which, unless enjoined by this Court, will impair the health and safety of women seeking abortions in Arkansas and violate their

constitutional rights. The Act will go into effect on January 1, 2016 and a copy of it is attached hereto as Exhibit A.

2. Plaintiffs challenge two medically unnecessary requirements contained in the Act: (1) Section 1504(d) (the "contracted physician requirement") will require all physicians who provide medication abortion (i.e., an abortion using medication alone) to have a signed contract with a physician (the "contracted physician") who agrees to handle complications and emergencies and who maintains specific admitting privileges at a hospital, as described in the Act; and (2) Section 1504(a) (the "FPL mandate") will require that medication abortions be provided using an inferior, outdated protocol that appears on the final printed labeling ("FPL") for the medication.

3. Because PPH cannot comply – despite diligent efforts to do so – with the contracted physician requirement and because of the burdens of the FPL mandate, enforcement of the Act will result in a dramatic reduction of women's access to abortion in Arkansas. Today, abortions are available at three health centers in Arkansas: PPH offers medication abortion at its health centers in Fayetteville and Little Rock, and another provider offers surgical and medication abortion in Little Rock. Without relief from this Court, as of January 1, 2016, PPH will be forced to stop providing abortions entirely, leaving only one health center in the state, which will offer only surgical abortion. Due to this unnecessary law, women in Fayetteville will be forced to travel three hours each way to Little Rock to have a surgical abortion, and women statewide will lose access to a safe, early method of abortion using medications alone.

4. The requirements in the Act – which impose these burdens without any medical benefit – violate the constitutional rights guaranteed to Plaintiffs and their patients by the Fourteenth Amendment to the United States Constitution. Preliminary and permanent injunctive

relief is necessary to protect the health of Arkansas women and the constitutional rights of Plaintiffs and their patients.

II. JURISDICTION AND VENUE

5. Jurisdiction is conferred on this Court by 28 U.S.C. §§ 1331 and 1343(a)(3). Plaintiffs' claims for declaratory and injunctive relief are authorized by 28 U.S.C. §§ 2201 and 2202, by Rules 57 and 65 of the Federal Rules of Civil Procedure, and by the general legal and equitable powers of this Court.

6. Venue in this judicial district is appropriate under 28 U.S.C. § 1391.

III. THE PARTIES

A. Plaintiffs

7. Plaintiff PPH is a not-for-profit corporation headquartered in Iowa and licensed to do business in Arkansas. It operates two of the three abortion-providing health centers in the state, located in Little Rock and Fayetteville. PPH or predecessor organizations have provided high quality reproductive healthcare in Arkansas for more than thirty years. The healthcare services provided by PPH at its two Arkansas health centers include well-women exams, testing and treatment for sexually transmitted infections, provision of birth control and emergency contraception, HIV testing, pregnancy testing, screening for vaginal infections, and HPV vaccinations. PPH also provides medication abortions in Arkansas to women through 63 days of pregnancy as measured from the first day of the woman's last menstrual period ("LMP"). PPH brings this action on behalf of itself, its patients, and the physicians it employs to provide services to its patients.

8. Plaintiff Ho is a licensed family practice physician who provides medication abortions through 63 days LMP and other healthcare services to patients at PPH's Little Rock and Fayetteville health centers. Dr. Ho brings this action on behalf of herself and her patients.

B. Defendants

9. Defendant Larry Jegley is the Prosecuting Attorney in Pulaski County, where PPH's Little Rock health center is located. Defendant Jegley has the authority to criminally prosecute any person who violates the Act. Ark. Code Ann. § 20-16-1506(a). Defendant Jegley is sued in his official capacity.

10. Defendant Matt Durrett is the Prosecuting Attorney in Washington County, where PPH's Fayetteville health center is located. Defendant Durrett has the authority to criminally prosecute any person who violates the Act. *Id.* Defendant Durrett is sued in his official capacity.

IV. FACTUAL ALLEGATIONS

A. Medication Abortion Background and Practice at PPH Health Centers

11. Women seek abortions for a variety of medical, psychological, emotional, familial, economic, and personal reasons. Approximately one in three women in the United States will have an abortion by age 45.

12. Currently, and for over 7 years, Arkansas women in the first nine weeks of pregnancy (through 63 days LMP) have had the option of choosing a medication abortion, an extremely safe and effective procedure, at PPH's two Arkansas health centers. In fiscal year 2015 alone, PPH's physicians provided over 500 medication abortions at its Arkansas health centers. Over 300 of these abortions were performed at the Fayetteville health center.

13. A medication abortion involves a combination of two prescription pills: mifepristone and misoprostol. Mifepristone, commonly known as "RU-486" or by its

commercial name Mifeprex, works by blocking the hormone progesterone, which is necessary to maintain pregnancy, and by increasing the efficacy of the second medication in the regimen, misoprostol. Misoprostol, sometimes known by its brand name Cytotec, causes the uterus to contract and expel its contents.

14. Mifepristone is the only medication approved by the U.S. Food and Drug Administration ("FDA") for use as an abortifacient. It was approved in 2000 and as part of that approval, as with all medications, the FDA approved a final printed label. The FPL is an informational document that provides physicians with guidance about the use for which the drug sponsor requested and received FDA approval.

15. Based on the clinical trials submitted in support of the application for approval (which were completed prior to 1996 and involved fewer than 3000 women), the manufacturer proposed, and the FDA approved, an FPL for Mifeprex that reflects the regimen used in those trials. As with most drugs, the FDA did not test the drug itself.

16. Under this regimen, the patient takes 600 mg of mifepristone orally, returns to the health center approximately 36 to 48 hours later to take 400 micrograms ("μg") of misoprostol orally, and then returns approximately 14 days later for a follow-up visit. The clinical trials found this regimen to be safe and effective through 49 days LMP, and the FPL therefore reflects that regimen and that gestational age limit.

17. The FDA's regulatory authority with respect to drugs is limited to approving them for marketing; it does not regulate the practice of medicine. In approving mifepristone, the FDA did not authorize (or prohibit) the use of any particular regimen for administering it. The FDA has never required that prescribers of mifepristone follow any particular regimen and has never imposed a gestational age limit on its use.

18. It is standard medical practice for physicians to prescribe FDA-approved drugs in dosages and for indications that were not specifically approved or contemplated by the FDA, particularly when supported by adequate study. The practice of altering prescriptions to reflect clear, significant, generally accepted developments in medical research is referred to as "off-label" or "evidence-based" medicine. The American Medical Association ("AMA") has stated that up to 20% of all drugs are prescribed off-label and among some classes of cardiac drugs, off-label use can be as high as 46%.

19. By the time mifepristone was made available in the United States in 2000, newer research already showed that a different protocol other than the FPL mandate could be safely and effectively used later in pregnancy. Based on this research, from the time that mifepristone was approved, the overwhelming majority of abortion providers in the United States offered their patients a regimen different than the FPL mandate.

20. Today, the evidence-based regimen most commonly used across the country, including by Plaintiffs, involves 200 mg of mifepristone taken orally at the health center followed approximately 24 to 48 hours later by 800 μg of misoprostol, which the woman self-administers buccally (dissolving the pills between her cheek and gum) at a location of her choosing, most often at home. This regimen has been shown to be effective through at least 63 days LMP.

21. Women choose medication abortion for a variety of reasons. For some women, it offers important advantages over surgical abortion. In particular, some women have medical conditions that make medication abortion a significantly safer option, with a lower risk of both complications and failure than a surgical abortion. These conditions include extreme obesity, and anomalies of the reproductive and genital tract, such as large uterine fibroids, vaginismus,

cervical stenosis, genital mutilation, or an extremely flexed uterus, which make it difficult to access the pregnancy inside the uterus as part of a surgical abortion.

22. Many women choose medication abortion because they fear any procedure with surgical instruments. Victims of rape, or women who have experienced sexual abuse or molestation, may choose medication abortion to feel more in control of the experience and to avoid the trauma of having instruments placed in their vagina.

23. Additionally many women prefer medication abortion because it feels more natural, like a miscarriage, and/or because they can complete a medication abortion in the privacy of their homes, with the company of loved ones, and at a time of their choosing. Medication abortion with mifepristone and misoprostol is increasingly prevalent, chosen by more women each year.

B. Challenged Provisions of the Arkansas Law

24. In its 2015 legislative session, the Arkansas General Assembly passed and Governor Asa Hutchinson signed into law Act 577, which places new restrictions on the provision of medication abortion. The Act's effective date is January 1, 2016.

25. Section 1504(a) of the Act requires a provider who provides or prescribes an "abortion-inducing drug" to ensure that the provision of this drug "satisfies the protocol authorized by the United States Food and Drug Administration, as outlined in the final printed labeling for the drug or drug regimen." Abortion-inducing drugs are defined as substances "prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman, with knowledge that the termination will with reasonable likelihood cause the death of the unborn child." The Act states that in the case of a medication abortion using mifepristone

and misoprostol, physicians must follow the dosage and administration instructions for both mifepristone and misoprostol that appear on the Mifeprex label.

26. The Act defines abortion-inducing drugs to include "off-label use of drugs known to have abortion-inducing properties, which are prescribed specifically with the intent of causing an abortion, such as misoprostol, Cytotec, and methotrexate." However, the Act's definition of abortion-inducing drug "does not apply to drugs that may be known to cause an abortion, but which are prescribed for other medical indications such as chemotherapeutic agents or diagnostic drugs." Arkansas does not mandate that any other medications be used only as described on the final printed label.

27. Section 1504(d) requires physicians who provide or prescribe abortion-inducing drugs to "have a signed contract with a physician who agrees to handle complications," and furthermore that "[t]he physician who contracts to handle emergencies shall have active admitting privileges and gynecological/surgical privileges at a hospital designated to handle any emergencies associated with the use or ingestion of the abortion-inducing drug." Additionally, every pregnant woman who is provided with abortion-inducing drugs "shall receive the name and phone number of the contracted physician and the hospital at which that physician maintains admitting privileges and which can handle any emergencies." The contracted physician requirement applies only to the provision of medication abortions, not surgical abortions

28. Anyone who violates the Act is guilty of a Class A misdemeanor. The Act also provides for civil remedies, including malpractice actions, against violators.

C. The Act's Requirements Are Medically Unnecessary

29. Legal abortion is one of the safest and most common procedures in contemporary medical practice. Medication abortion is an extremely safe and effective method of abortion, one

of the safest procedures in medical practice today. Major complications from medication abortion are extremely rare, and far rarer than those associated with pregnancy and childbirth. A recent study found that out of 233,805 medication abortions performed in the United States, only 0.16% of patients experienced a significant adverse event and fewer than six out of every 10,000 experienced complications resulting in hospital admission.

30. The evidence-based regimen used by Plaintiffs, and banned by the Act, is the current standard of care. More than two million American women have now safely had a medication abortion, the overwhelming majority of whom have used an evidence-based regimen, compared to the fewer than 3000 women who participated in the clinical trials submitted to the FDA in the mid-1990s.

31. The American College of Obstetricians and Gynecologists ("ACOG"), the AMA, the World Health Organization, and the Royal College of Obstetricians and Gynecologists have all endorsed the use of an alternative regimen through 63 days LMP. ACOG has declared that, "[b]ased on efficacy and the adverse effect profile, evidence-based protocols for medication abortion are superior to the FDA-approved regimen." Am. Coll. of Obstetricians & Gynecologists, *Practice Bulletin No. 143: Medical Management of First Trimester Abortion* 2 (Mar. 2014). That is why ACOG and the AMA both oppose FPL mandates like the Act's.

32. The contracted physician requirement is unnecessary because PPH's policies and protocols, as well as the skill and experience of its medical staff, ensure that patients receive the same level and quality of care in the event of a complication as they would if PPH had a contracted physician.

33. PPH employs two physicians who provide medication abortions at its Arkansas health centers. Dr. Ho, one of PPH's two physicians, is licensed to practice medicine in Arkansas. In addition to providing care to PPH's patients, she has a private practice as well.

34. Because the medications used in a medication abortion do not take effect immediately, there is no circumstance, except for an allergic reaction to mifepristone – which has never been reported – that would require a medication abortion patient to be transferred from a health center to a hospital. Indeed, PPH has never had to transfer a medication abortion patient from its health centers to a hospital. Rather, the rare complications that follow a medication abortion occur once a woman has gone home.

35. Because of this, upon discharge, all of PPH's medication abortion patients are provided with a phone number for a 24-hour hotline staffed by a registered nurse, which they can call regarding any complications, questions, and concerns that arise after they have left the health center. In most cases, the patients' questions and concerns can be addressed over the phone; many patients just need reassurance that their symptoms are normal and will subside. If a return visit to the health center is necessary, the patient is given an appointment. The nurse who answers the hotline is able to contact PPH physicians at all times, should the need arise.

36. In the exceedingly rare cases that the nurse determines that a patient who contacts the after-hours hotline should be treated or evaluated by a physician immediately, she or he will refer the patient to a local emergency room. All patients referred to the emergency room will be contacted by health center staff within 24 hours, and a physician at PPH will be notified.

37. The Act requires the contracted physician to have privileges at a hospital, but does not specify a location for that hospital. PPH patients come from all over the state of Arkansas, and even from other states. Consistent with the accepted standard of care, if any of these patients

were to experience a complication after returning home, they would be referred to a local hospital in their area, which is most likely not the hospital where a contracted physician would have privileges.

38. Emergency room physicians and on-call OB-GYNs are trained to treat any gynecological complications that may occur after a medication abortion.

39. The Act does not require PPH to involve, or even notify, its contracted physician in the event of a complication that requires hospital-based care.

40. If PPH does contact the contracted physician, unless he or she is a patient's personal OB-GYN, that physician will have no prior relationship with the patient and will rely entirely on information provided by PPH and/or the PPH physician who provided care to the patient. The contracted physician requirement does not increase patient safety and is medically unnecessary.

D. The Impact of the Act

41. Allowing the contracted physician requirement of the Act to go into effect will result in the elimination of medication abortion entirely in Arkansas. The two PPH health centers will no longer be able to offer medication abortion services because PPH cannot comply with the contracted physician requirement. Because PPH has no surgical abortion provider in Arkansas, it will be unable to offer abortion at all. Additionally, on information and belief, Little Rock Family Planning Services, the only other abortion provider in the state, intends to stop providing medication abortion if the Act goes into effect.

42. PPH has been trying, for several months, to find a physician with the requisite admitting privileges to contract with it and satisfy the Act, but has been unsuccessful. Many physicians PPH contacted did not want to contract with PPH because of fear of stigma and

harassment from being associated with an abortion provider, employers or partners did not want to be associated with an abortion provider, or because they do not support a woman's right to choose.

43. More than 300 women sought medication abortion at the Fayetteville health center in fiscal year 2015. The Act will completely eliminate abortion access in Fayetteville. Women who can now access abortion there will have to make the six hour roundtrip to Little Rock to access surgical abortion services. And they will have to make this 380-mile roundtrip more than once, or stay away from home for several days, because Arkansas law requires that a woman receive certain state-mandated information in-person and then wait at least 48 hours until she may have an abortion. Ark. Code Ann. § 20-16-1703.

44. Women will need to arrange the necessary funds, transportation, childcare or time off work required to travel these distances and make these separate trips. Especially for low-income women, women who have limited access to transportation, or women who are victims of abuse, these increased travel distances will, at a minimum, impose delays on their accessing care and, in some cases, will prevent them entirely from obtaining an abortion. While abortion is an incredibly safe procedure, its risk increases with gestational age, as does the cost of the procedure.

45. A complete ban on medication abortion in the state would substantially burden Arkansas women, particularly those women described above who have important personal reasons for choosing a medication abortion or have medical conditions that make medication abortion a significantly safer option. Some women with these medical conditions, moreover, could have other health complications arising out of, or exacerbated by, their being forced to

continue unwanted pregnancies. Such complications could threaten the life or the health of these women.

46. Even if the contracted physician requirement could be met or was enjoined, the FPL mandate would unduly burden women seeking abortions in Arkansas. Under the FPL mandate, medication abortion will be banned after 49 days LMP, when it would otherwise be available through 63 days LMP. As many women do not detect their pregnancies until around seven weeks LMP, these women would lose the option of medication abortion.

47. An FPL regimen also requires women to travel to a health center 4 separate times: (1) for state-mandated counseling; (2) to take the mifepristone; (3) to take the misoprostol (which, under current law, the woman can take at home); and (4) for a follow-up visit. In addition to the cost of the additional trip, as well as any time off work or child care needed, the FPL mandate also makes medication abortion a more expensive procedure, as tripling the mifepristone dosage adds significantly to the cost of the procedure.

48. Rather than promote women's health, the FPL mandate will harm women because, as compared with the evidence-based regimen used by Plaintiffs, the FPL regimen is less effective and has increased need for surgical intervention.

49. All of these burdens caused by the Act will come with no medical benefit whatsoever. To the contrary, eliminating the availability of abortion services in Fayetteville, and of medication abortion statewide, will harm women's health.

V. CLAIMS FOR RELIEF

COUNT I – RIGHT TO DUE PROCESS OF LAW

(Liberty/Privacy)

50. Plaintiffs hereby reaffirm and reallege each and every allegation made in paragraphs 1-49 above as if set forth fully herein.

51. The Act violates Plaintiffs' patients' rights to liberty and privacy as guaranteed by the Fourteenth Amendment to the United States Constitution by imposing an unconstitutional burden on their right to choose abortion.

COUNT II – RIGHT TO DUE PROCESS OF LAW

(Bodily Integrity)

52. Plaintiffs hereby reaffirm and reallege each and every allegation made in paragraphs 1-49 above as if set forth fully herein.

53. The Act violates Plaintiffs' patients' rights to bodily integrity guaranteed by the Fourteenth Amendment to the United States Constitution by depriving women access to a safe and medically accepted non-surgical abortion procedure.

COUNT III – RIGHT TO DUE PROCESS OF LAW

(Right to Pursue Profession)

54. Plaintiffs hereby reaffirm and reallege each and every allegation made in paragraphs 1-49 above as if set forth fully herein.

55. The Act violates Plaintiffs' right to pursue their profession guaranteed under the Fourteenth Amendment to the United States Constitution because it makes Plaintiffs' ability to maintain their business and pursue their profession contingent entirely on the willingness of third parties to be publicly associated with and contracted with an abortion provider.

COUNT IV – RIGHT TO EQUAL PROTECTION

56. Plaintiffs hereby reaffirm and reallege each and every allegation made in paragraphs 1-49 above as if set forth fully herein.

57. The Act violates Plaintiffs' right to equal protection of the laws guaranteed by the Fourteenth Amendment to the United States Constitution, because it imposes requirements on medication abortion providers that it does not impose on other medical providers or medications without adequate justification.

VI. REQUEST FOR RELIEF

Plaintiffs respectfully request that this Court:

A. Issue a declaratory judgment that the contracting physician requirement and FPL mandate are unconstitutional and unenforceable;

B. Issue preliminary and permanent injunctive relief restraining Defendants and their employees, agents, and successors in office from enforcing the contracting physician requirement and the FPL mandate;

C. Grant Plaintiffs attorneys' fees, costs, and expenses pursuant to 42 U.S.C. § 1988; and;

D. Grant such other and further relief as this Court may deem just, proper, and equitable.

Dated: December 28, 2015

Bettina E. Brownstein (85019)
Bettina E. Brownstein Law Firm
904 West Second Street
Little Rock, Arkansas 72201
(501) 920-1764
bettinabrownstein@gmail.com

Helene T. Krasnoff*
PLANNED PARENTHOOD
FEDERATION OF AMERICA
1110 Vermont Ave., NW, Suite 300

Washington, DC 20005
(202) 296-4890
helene.krasnoff@ppfa.org

Maithreyi Ratakonda*
PLANNED PARENTHOOD
FEDERATION OF AMERICA
434 West 33rd Street
New York, NY 10001
(212) 261-4405
mai.ratakonda@ppfa.org

Attorneys for the Plaintiffs

**Application for admission pro hac vice pending*

EXHIBIT A

Stricken language would be deleted from and underlined language would be added to present law.
Act 577 of the Regular Session

State of Arkansas *As Engrossed: H2/25/15*
90th General Assembly **A Bill**
Regular Session, 2015 HOUSE BILL 1394

By: Representatives C. Fite, *Ballinger, Baltz, Bentley, Copeland, Cozart, Gates, M. Gray, Harris, Henderson, Lundstrum, D. Meeks, Payton, Petty, Rushing, B. Smith, Speaks, Sullivan, Vaught*
By: Senators Files, J. Hendren, Hester, Irvin, B. Johnson, Rapert

For An Act To Be Entitled

AN ACT TO ESTABLISH THE ABORTION-INDUCING DRUGS SAFETY ACT; AND FOR OTHER PURPOSES.

Subtitle

TO ESTABLISH THE ABORTION-INDUCING DRUGS SAFETY ACT.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. Arkansas Code Title 20, Chapter 16, is amended to add an additional subchapter to read as follows:

Subchapter 15 — Abortion-Inducing Drugs Safety Act

20-16-1501. Title.

This Act may be known and cited as the "Abortion-Inducing Drugs Safety Act."

20-16-1502. Legislative findings and purpose.

(a) The General Assembly finds that:

(1) The United States Food and Drug Administration approved the drug mifepristone, a first-generation progesterone receptor modulator, as an abortion-inducing drug with a specific gestation, dosage, and administration protocol;

(2) The United States Food and Drug Administration approved

mifepristone under the rubric of 21 C.F.R. § 314.520, also referred to as "Subpart H," which is the only Food and Drug Administration approval process that allows for postmarketing restrictions and provides for accelerated approval of certain drugs that are shown to be effective but "can be safely used only if distribution or use is restricted";

(3) The United States Food and Drug Administration does not treat Subpart H drugs in the same manner as drugs which undergo the typical approval process;

(4) As approved by the United States Food and Drug Administration and as outlined in the final printed labeling of mifepristone, an abortion by mifepristone consists of three (3) two-hundred (200) mg tablets of mifepristone taken orally, followed by two (2) two-hundred (200) mcg tablets of misoprostol taken orally, through forty-nine (49) days from the first day of the woman's last menstrual period;

(5) The patient is to return for a follow-up visit in order to confirm that a complete termination of pregnancy has occurred;

(6) This United States Food and Drug Administration-approved protocol is referred to as the "Mifeprex regimen";

(7) This treatment requires three (3) office visits by the patient, and the dosages may only be administered in a clinic, medical office, or hospital and under supervision of a physician;

(8) The final printed labeling of Mifeprex outlines the United States Food and Drug Administration-approved dosage and administration of both drugs in the Mifeprex regimen, namely mifepristone and misoprostol;

(9) When the United States Food and Drug Administration approved the Mifeprex regimen under Subpart H, it did so with certain restrictions such as the requirement that the distribution and use of the Mifeprex regimen must be under the supervision of a physician who has the ability to assess the duration of pregnancy, diagnose ectopic pregnancies, and provide surgical intervention or has made plans to provide surgical intervention through other qualified physicians;

(10) One (1) of the restrictions imposed by the United States Food and Drug Administration as part of its Subpart H approval is a written agreement that must be signed by both the physician and patient;

(11) In that agreement, the woman, along with the physician, attests to the following, among other statements:

(A) "I believe I am no more than 49 days (7 weeks) pregnant";

(B) "I understand that I will take misoprostol in my provider's office two days after I take Mifeprex (Day 3)"; and

(C) "I will do the following: return to my provider's office in 2 days (Day 3) to check if my pregnancy has ended. My provider will give me misoprostol if I am still pregnant";

(12) The United States Food and Drug Administration concluded that available medical data did not support the safety of home use of misoprostol, and it specifically rejected information in the Mifeprex final printed labeling on self-administering misoprostol at home;

(13) Court testimony in Planned Parenthood Cincinnati Region v. Taft, 459 F. Supp. 2d 626 (S.D. Oh. 2006), by Planned Parenthood and other abortion providers demonstrates that providers routinely fail to follow the United States Food and Drug Administration-approved protocol for the Mifeprex regimen, as it is outlined in the Mifeprex final printed labeling and that providers are administering a single oral dose of two-hundred (200) mg of mifepristone, followed by a single vaginal or buccal dose of eight-tenths (.8) mg misoprostol, through sixty-three (63) days of the woman's last menstrual period, without medical supervision and without follow-up care;

(14) The use of mifepristone presents significant medical risks to women, including without limitation abdominal pain, cramping, vomiting, headache, fatigue, uterine hemorrhage, viral infections, and pelvic inflammatory disease;

(15) Abortion-inducing drugs are associated with an increased risk of complications relative to surgical abortion and the risk of complications increases with advancing gestational age, and, in the instance of the Mifeprex regimen, with failure to complete the two-step dosage process;

(16)(A) In July 2011, the United States Food and Drug Administration reported two thousand two hundred and seven (2,207) adverse events in the United States of America after women used the Mifeprex regimen for the termination of pregnancy.

(B) Among those were fourteen (14) deaths, six hundred and twelve (612) hospitalizations, three hundred and thirty-nine (339) blood transfusions, and two hundred and fifty-six (256) infections, including

forty-eight (48) severe infections;

(17)(A) Off-label or so-called evidence-based use of the Mifeprex regimen may be deadly.

(B) To date, fourteen (14) women have reportedly died after administration of the Mifeprex regimen, with eight (8) deaths attributed to severe bacterial infection.

(C) All eight (8) of those women administered the regimen in an off-label or evidence-based manner advocated by abortion providers.

(D) The United States Food and Drug Administration has not been able to conclude whether off-label use led to the eight (8) deaths; and

(18) Medical evidence demonstrates that women who use abortion-inducing drugs incur more complications than those who have surgical abortions.

(b) Based on the findings in subsection (a), it is the purpose of this subchapter to:

(1) Protect women from the dangerous and potentially deadly off-label use of abortion-inducing drugs, such as, but not limited to the Mifeprex regimen; and

(2) Ensure that physicians abide by the protocol tested and approved by the United States Food and Drug Administration for such abortion-inducing drugs, as outlined in the drug labels.

20-16-1503. Definitions.

As used in this subchapter:

(1)(A) "Abortion" means the act of using or prescribing any instrument, medicine, drug, or any other substance, device, or means with the intent to terminate the clinically diagnosable pregnancy of a woman, with knowledge that the termination by those means will with reasonable likelihood cause the death of the unborn child.

(B) An act under subdivision (1)(A) of this section is not an abortion if the act is performed with the intent to:

(i) Save the life or preserve the health of the unborn child;

(ii) Remove a dead unborn child caused by spontaneous abortion;

(iii) Remove an ectopic pregnancy; or

(iv) Treat a maternal disease or illness for which the prescribed drug is indicated;

(2)(A) "Abortion-inducing drug" means a medicine, drug, or any other substance prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman, with knowledge that the termination will with reasonable likelihood cause the death of the unborn child.

(B) "Abortion-inducing drugs" includes off-label use of drugs known to have abortion-inducing properties, which are prescribed specifically with the intent of causing an abortion, such as misoprostol, Cytotec, and methotrexate.

(C) This definition does not apply to drugs that may be known to cause an abortion, but which are prescribed for other medical indications such as chemotherapeutic agents or diagnostic drugs.

(D) Use of drugs to induce abortion is also known as a medical, drug-induced, or chemical abortion;

(3) "Adverse event" means an undesirable experience associated with the use of a medical product in a patient, including without limitation an event that causes:

(A) Death;

(B) Threat to life;

(C) Hospitalization;

(D) Disability or permanent damage;

(E) Congenital anomaly or birth defect, or both;

(F) Required intervention to prevent permanent impairment or damage;

(G) Other serious important medical events, including without limitation:

(i) Allergic bronchospasm requiring treatment in an emergency room;

(ii) Serious blood dyscrasias;

(iii) Seizures or convulsions that do not result in hospitalization; and

(iv) The development of drug dependence or drug abuse;

(4) "Final printed labeling" means the United States Food and

Drug Administration-approved informational document for an abortion-inducing drug which outlines the protocol authorized by the United States Food and Drug Administration and agreed upon by the drug company applying for United States Food and Drug Administration authorization of that drug;

(5) "Gestational age" means the time that has elapsed since the first day of the woman's last menstrual period;

(6) "Mifeprex regimen" means the abortion-inducing drug regimen that involves administration of mifepristone or the brand name "Mifeprex" and misoprostol which is the only abortion-inducing drug regimen approved by the United States Food and Drug Administration and is also known as the RU-486 regimen or simply RU-486;

(7) "Mifepristone" means the first drug used in the Mifeprex regimen;

(8) "Misoprostol" means the second drug used in the Mifeprex regimen;

(9) "Physician" means any person licensed to practice medicine in this state including medical doctors and doctors of osteopathy; and

(10) "Unborn child" means the offspring of human beings from conception until birth.

20-16-1504. Unlawful distribution of abortion-inducing drug.

(a)(1) It shall be unlawful to knowingly give, sell, dispense, administer, or otherwise provide or prescribe an abortion-inducing drug to a pregnant woman to induce an abortion or enabling another person to induce an abortion, unless the person who gives, sells, dispenses, administers, or otherwise provides or prescribes the abortion-inducing drug is a physician and the provision or prescription of the abortion-inducing drug satisfies the protocol authorized by the United States Food and Drug Administration, as outlined in the final printed labeling for the drug or drug regimen.

(2) In the case of the Mifeprex regimen, the final printed labeling for Mifeprex includes the United States Food and Drug Administration-approved dosage and administration instructions for both mifepristone and misoprostol.

(b) Because the failure and complication rates from medical abortion increase with advancing gestational age, because the physical symptoms of medical abortion can be identical to the symptoms of ectopic pregnancy, and

because abortion-inducing drugs do not treat ectopic pregnancies but rather are contraindicated in ectopic pregnancies, the physician giving, selling, dispensing, administering, or otherwise providing or prescribing the abortion-inducing drug shall first examine the woman and document in the woman's medical chart prior to giving, selling, dispensing, administering, or otherwise providing or prescribing the abortion-inducing drug the following information without limitation:

(1) Gestational age; and

(2) Intrauterine location of the pregnancy.

(c) Every pregnant woman to whom a physician gives, sells, dispenses, administers, or otherwise provides or prescribes any abortion-inducing drug shall be provided with a copy of the drug's label.

(d)(1) The physician who gives, sells, dispenses, administers, or otherwise provides or prescribes the abortion-inducing drug shall have a signed contract with a physician who agrees to handle complications and be able to produce that signed contract on demand by the patient or by the Department of Health.

(2) The physician who contracts to handle emergencies shall have active admitting privileges and gynecological/surgical privileges at a hospital designated to handle any emergencies associated with the use or ingestion of the abortion-inducing drug.

(3) Every pregnant woman to whom a physician gives, sells, dispenses, administers, or otherwise provides or prescribes any abortion-inducing drug shall receive the name and phone number of the contracted physician and the hospital at which that physician maintains admitting privileges and which can handle any emergencies.

(e)(1) The physician who gives, sells, dispenses, administers, or otherwise provides or prescribes any abortion-inducing drug, or an agent of the physician, shall schedule a follow-up visit for the woman for approximately fourteen (14) days after administration of the abortion-inducing drug to confirm that the pregnancy is completely terminated and to assess the degree of bleeding.

(2) The physician or agent of physician shall make all reasonable efforts to ensure that the woman returns for the scheduled appointment.

(3) A brief description of the efforts made to comply with this

subsection, including without limitation the date, time, and identification by name of the person making such efforts, shall be included in the woman's medical record.

20-16-1505. Reporting.

(a) If a physician provides an abortion-inducing drug to another for the purpose of inducing an abortion as authorized in § 20-16-1504, and if the physician knows that the woman who uses the abortion-inducing drug for the purpose of inducing an abortion experiences an adverse event, the physician shall provide a written report of the adverse event within three (3) days of the event to the United States Food and Drug Administration via the Medwatch reporting system and to the Arkansas State Medical Board.

(b)(1) The board shall compile and retain all reports it receives under this section.

(2)(A) All reports received by the board are public records open to inspection under the Arkansas Freedom of Information Act, § 25-19-101 et seq.

(B) The board shall not release to any person or entity the name or any other personal identifying information regarding a person who:

(i) Uses an abortion-inducing drug to induce an abortion; and

(ii) Is the subject of a report received by the board under this section.

20-16-1506. Criminal penalties.

(a) A person who intentionally, knowingly, or recklessly violates a provision of this subchapter is guilty of a Class A misdemeanor.

(b) A criminal penalty may not be assessed against the pregnant woman upon whom the drug-induced abortion is performed.

20-16-1507. Civil remedies and professional sanctions.

(a) In addition to whatever remedies are available under the common or statutory law of this State, failure to comply with the requirements of this subchapter shall provide a basis for:

(1) A civil malpractice action for actual and punitive damages;

(2) A professional disciplinary action under § 16-114-201 et seq.; and

(3) Recovery for the woman's survivors for the wrongful death of the woman under § 16-62-102.

(b) A civil liability may not be assessed against the pregnant woman upon whom the drug-induced abortion is performed.

(c) When requested, the court shall allow a woman to proceed using solely her initials or a pseudonym and may close any proceedings in the case and enter other protective orders to preserve the privacy of the woman upon whom the drug-induced abortion was performed.

(d) If judgment is rendered in favor of the plaintiff, the court shall also render judgment for a reasonable attorney's fee in favor of the plaintiff against the defendant.

(e) If judgment is rendered in favor of the defendant and the court finds that the plaintiff's suit was frivolous and brought in bad faith, the court shall also render judgment for reasonable attorney's fee in favor of the defendant against the plaintiff.

20-16-1508. Construction.

(a) This subchapter does not create or recognize a right to abortion.

(b) It is not the intention of this subchapter to make lawful an abortion that is currently unlawful.

20-16-1509. Right of intervention.

The General Assembly, by joint resolution, may appoint one (1) or more of its members, who sponsored or cosponsored this subchapter in his or her official capacity, to intervene as a matter of right in any case in which the constitutionality of this law is challenged.

20-16-1510. Effective date.

This subchapter takes effect on January 1, 2016.

/s/C. Fite

APPROVED: 03/20/2015

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Planned Parenthood Arkansas & Eastern Oklahoma, d/b/a Planned Parenthood of the Heartland, et al.

(b) County of Residence of First Listed Plaintiff Pulaski
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
See attached.

DEFENDANTS

Prosecuting Attorney for Pulaski County, Lamb, Kegley, et al.

County of Residence of First Listed Defendant Pulaski
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
42 U.S.C 1983

Brief description of cause:
Sections of Ark. Code Ann. § 20-16-1501 et seq. violate Plaintiffs' and their patients' constitutional rights

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $ TRO and/or Preliminary Injunction

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE DOCKET NUMBER

DATE 12/28/15

SIGNATURE OF ATTORNEY OF RECORD Bettina E. Brownstein

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

Attachment to Civil Cover Sheet: Planned Parenthood Arkansas & Eastern Oklahoma, d/b/a Planned Parenthood of the Heartland, et al. v. Larry Jegley, Prosecuting Attorney for Pulaski County, et al.

Plaintiffs' Attorneys:

Bettina E. Brownstein (85019)
Bettina E. Brownstein Law Firm
904 West Second Street
Little Rock, Arkansas 72201
(501) 920-1764
bettinabrownstein@gmail.com

Helene T. Krasnoff*
PLANNED PARENTHOOD
FEDERATION OF AMERICA
1110 Vermont Ave., NW, Suite 300
Washington, DC 20005
(202) 296-4890
helene.krasnoff@ppfa.org

Maithreyi Ratakonda*
PLANNED PARENTHOOD
FEDERATION OF AMERICA
434 West 33rd Street
New York, NY 10001
(212) 261-4405
mai.ratakonda@ppfa.org

**Application for admission pro hac vice pending*