IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

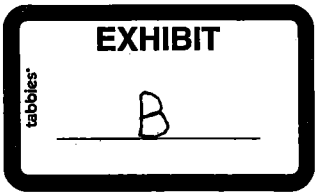
PLANNED PARENTHOOD OF GREATER TEXAS SURGICAL AND SEXUAL HEALTH SERVICES, and on behalf of its patients and physicians, *et al.*,	)	
Plaintiffs,	)	CIVIL ACTION
v.	)	
	)	CASE NO. 1:13-cv-862-LY
GREGORY ABBOTT, Attorney General of Texas, in his official capacity, *et al.*,	)	
Defendants.	)	

DECLARATION OF DR. PAUL M. FINE

Paul M. Fine, MD, declares and states the following:

1. I am board-certified in obstetrics and gynecology and a Fellow of the American Congress of Obstetricians & Gynecologists. I am a Professor in the Departments of Obstetrics & Gynecology and Urology at the Baylor College of Medicine in Houston, where I have been on the faculty since 1979. I am the Medical Director of Planned Parenthood Gulf Coast and Planned Parenthood Center for Choice, Inc., which is a Plaintiff in this case. I am also the Medical Director of Emergency Medical Services ("EMS") for three cities in Galveston County, Texas. A copy of my curriculum vitae is attached hereto as Exhibit 1.

2. I provide the following facts and opinions as an expert in obstetrics and gynecology; the provision of abortion, including medication abortion; the treatment of abortion complications; and general emergency medical services and transfers. The opinions expressed below are based on my years of experience in the field of obstetrics and gynecology; my



teaching, clinical, and research experience in abortion care; my involvement in the provision of emergency medical services; and my review of the medical literature.

3. I have nearly four decades of experience providing abortions, teaching abortion methods, and supervising the provision of abortion services in hospital and outpatient settings. I was involved in the original United States trials of mifepristone and misoprostol (the medications used for medication abortion, as explained below). I have been on staff at approximately twelve hospitals. I also treat and teach about the treatment of the rare complications that can occur after abortion.

4. I provide these opinions in support of Plaintiffs' Motion for a Preliminary Injunction against enforcement of Texas House Bill 2's requirements that:

- all physicians who perform abortions "have active admitting privileges at a hospital that is located not further than 30 miles from the location at which the abortion is performed or induced [] and provides obstetrical or gynecological health care services;" and
- "abortion-inducing drugs" may only be given, dispensed, provided, or administered by a physician in a way that "satisfies the protocol tested and authorized by the United States Food and Drug Administration as outlined in the final printed label of the abortion-inducing drug" and/or "in the dosage amount prescribed by the clinical management guidelines defined by the American Congress of Obstetricians and Gynecologists Practice Bulletin as those guidelines existed on January 1, 2013."

5. I believe these requirements are medically unnecessary, in that that they will not improve patient health and safety. In fact, they are contrary to the usual medical standard of care and will have serious negative consequences for women's health in Texas.

Abortion Methods and Their Safety

6. There are generally two methods of performing abortions used in the United States: surgically, using various methods depending on the gestational age of the fetus, or medically, by administering certain drugs. This latter method is available in Texas today through 63 days after the first day of the woman's last menstrual period ("LMP").

7. Surgical abortion involves the use of instruments to evacuate the contents of the uterus. Despite the term "surgical," it involves no incision into the woman's skin or other bodily membrane, and is not what a layperson might typically think of as "surgery." Surgical abortions are almost always performed in an outpatient setting, most often at a clinic or office. The procedure itself is typically performed in a room with an examination or operating table, on which the woman will lie on her back with her hips and knees flexed and thighs apart in the lithotomy position, most often with her feet or legs in stirrups. The woman may be given a sedative prior to the procedure. After adequate dilation of the woman's cervix, the physician will insert instruments through her vagina and cervix in order to empty the contents of the uterus. The procedure is short in duration, with a first-trimester abortion (up to 13.6 weeks LMP) typically lasting about five to eight minutes.

8. The types of complications that may occur following a surgical abortion include infection, bleeding, uterine perforation, and retained tissue. In the vast majority of cases, these types of complications can be, and are, resolved in an outpatient setting—that is, at the clinic where the abortion was performed—without the need for any hospital treatment.

9. Surgical abortion is analogous to other gynecological procedures that also routinely take place in outpatient settings in terms of risks, invasiveness, instrumentation, and duration. For example, first-trimester surgical abortions are nearly identical to diagnostic or therapeutic

dilation and curettage on a non-pregnant woman and surgical completion of spontaneous miscarriage; both of these procedures involve stretching open the cervix and removing the lining of the uterus and uterine contents by suction and/or sharp instruments. Surgical abortion is also comparable to non-gynecological outpatient surgical procedures in terms of risk, invasiveness, instrumentation, and duration. For example, abortion is comparable in these respects to colonoscopy with removal of polyps. All of these procedures can be, and are, safely performed by physicians without admitting privileges.

10. Up to nine weeks of pregnancy (or 63 days LMP), in addition to surgical abortion, Texas women today may choose to end their pregnancies using medications. Currently, the medications most commonly used for this purpose in the United States are mifepristone and misoprostol. Mifepristone (also known as "RU-486" or by its trade name Mifeprex) terminates a pregnancy by blocking progesterone, a naturally produced hormone that prepares the lining of the uterus for a fertilized egg and helps maintain pregnancy. Without progesterone, the pregnancy cannot continue and the lining of the uterus softens and breaks down and the embryo detaches from the uterine lining. Approximately 24 to 48 hours after the woman takes mifepristone, she takes the second drug, misoprostol (also known as a prostaglandin or by its trade name Cytotec) which causes the uterus to contract and expel the embryo or fetus and other products of conception. This same regimen is offered to women with gestational ages up to 9 weeks (through 63 days) LMP who have a spontaneous abortion (i.e., miscarriage) with retained tissue as alternative to surgical management with dilation & curettage ("D&C").

11. Medication abortion requires no anesthesia or sedation. Many women take only over-the-counter medication to control whatever pain they experience. The bleeding and cramping the misoprostol causes occur only after the patient has left the clinic and is at home. The types of

complications that may occur following medication abortion include infection, bleeding, and retained tissue. In the vast majority of cases, these types of complications can be, and are, handled in an outpatient setting without the need for any hospital treatment.

12. Legal abortion is one of the safest medical procedures in the United States. The risk of death associated with childbirth is approximately fourteen times higher than that associated with abortion, and every pregnancy-related complication is more common among women having live births than among those having abortions.[1]

13. Although abortion is very safe and the risk of complications from an abortion is incredibly low, both the morbidity (risk of major complications) and mortality rates for abortion increase with advancing gestational age. Approximately 90 percent of all abortions performed in the United States occur during the first trimester and almost two-thirds (61 percent) occur at eight weeks LMP or less. Moreover, very early abortions (6 weeks gestation or less) have become more prevalent, essentially doubling from 14 percent of all abortions in 1992 to 30 percent in 2006.[2]

14. Because the risk of complications from abortion is so low, the vast majority of abortions are performed in an outpatient setting, usually in a clinic or office, and this can be done safely and effectively without any need for the performing physician to have admitting privileges at a local hospital. Over 90% of abortions in the United States are performed in outpatient settings.[3]

---

[1] Elizabeth Raymond & David Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstet. & Gynecol. 215, 216 (Feb. 2012).
[2] Karen Pazol, et al., Centers for Disease Control and Prevention (CDC), *Abortion surveillance – United States, 2006*, 58 Morbidity and Mortality Weekly Report 1–35 (2009); Sonya Gamble, et al., CDC, *Abortion surveillance – United States, 2005*, 57 Morbidity and Mortality Weekly Report 57: 1–32 (2008).
[3] Rachel Jones & Kathryn Kooistra, *Abortion Incidence and Access to Services in the United States, 2008*, 43 Persp. on Sexual & Reprod. Health 41, 46 (2011).

15. To effectively assess the risks related to abortion, it is important to put them in context. Women who seek abortions are pregnant, and pregnancy, itself, is risky. Three percent of all women who deliver vaginally have a prolonged hospital admission or early re-admission to the hospital. For cesarean delivery, the figure is three times higher, about 9%.[4] More than 30% of American women have a major abdominal operation (Cesarean) for delivery.[5]

16. By comparison, the risk of a woman experiencing some type of complication after an abortion is extremely low: only 2.5% of women obtaining first-trimester surgical abortions experience minor complications, which are handled at the health center.[6] The risk of a woman experiencing a complication that requires hospitalization is even lower: less than 0.3%, or ten times less than from a live vaginal birth.[7]

17. In terms of maternal mortality, which is thankfully a rare occurrence in this country, abortion is dramatically safer than continuing a pregnancy to term. The risk of death related to abortion overall is less than 0.7 deaths per 100,000 procedures, which is roughly comparable to the risk of death following a miscarriage. As I noted above, this is approximately fourteen times lower than the woman's risk of death in childbirth. By way of contrast, the risk of death from fatal anaphylactic shock following use of penicillin in this country is 2.0 deaths per 100,000 uses.[8]

---

[4] Patricia Hebert, et al., *Serious Maternal Morbidity After Childbirth: Prolonged Hospital Stays and Readmissions*, 94 Obstet. & Gynecol. 942, 944 (1999).
[5] Brady Hamilton, et al., *Births: Preliminary Data for 2011*, 61 Nat'l Vital Stat. Rep. 1, 2 (2012).
[6] Karen Meckstroth & Maureen Paul, *First-Trimester Aspiration Abortion, in* Management of Unintended and Abnormal Pregnancy 135, 136 (Maureen Paul, et al., eds., 2009).
[7] Stanley Henshaw, *Unintended Pregnancy and Abortion: A Public Health Perspective, in* A Clinician's Guide to Medical and Surgical Abortion 11, 21 (Maureen Paul, et al., eds., 1999).
[8] Alfred Neugut, et al., *Anaphylaxis in the United States: An Investigation into its Epidemiology*, 161 Archives of Internal Med. 15, 18 (2001).

Management of Abortion Complications and Lack of Need for Admitting Privileges

18. As I have stated above, most of the complications associated with abortion can be appropriately and safely managed by monitoring and/or treating the patient in the abortion clinic. For example, most cases of non-severe hemorrhage are managed in the clinic with uterotonic medications that increase the tone of the uterine muscle causing the uterus to contract and reduce or stop the bleeding. The woman can then be sent home with oral uterotonic medications to take for several more days. Women with mild infections are also usually treated on an outpatient basis with oral and/or injected antibiotics. In the case of a missed abortion or an incomplete abortion with retained tissue, the physician can provide the necessary follow-up treatment, which may involve administration of medicine or another suction procedure to empty the uterus, in the outpatient clinic.

19. It is extremely unlikely that a patient will experience a serious complication at the clinic that requires emergent hospitalization. If such a rare complication occurs, the patient needs to be transferred by ambulance to a hospital, but whether the abortion provider has admitting privileges at that hospital does not affect the quality of care that the patient receives. At the hospital, an emergency room physician will decide if it is necessary to involve an ob/gyn in the patient's care, and if so, he or she will contact the ob/gyn on call at that hospital, and that ob/gyn can admit the patient if necessary. All ob/gyns, regardless of whether they perform abortions, are qualified to manage the care of a patient experiencing a complication from an abortion, and to refer the patient, where necessary, to the appropriate subspecialist. Moreover, continuity of care can be maintained by direct telephone communication between the abortion provider and the emergency room physician, but does not require that the abortion provider have admitting privileges. This is standard medical practice and will ensure that the emergency room

physician is aware of the extent of the complication, prior treatment, and medication received. Additionally, when a patient is transported by ambulance from the clinic to the hospital, a copy of the clinic records is sent with the patient giving details of procedures performed, medications given, and events that transpired at the clinic.

20. Even if the abortion provider had privileges at a local hospital, the provider often has little ability to control where the Emergency Medical Technicians ("EMTs") take the patient. The provider might prefer for the patient to go to the hospital where he or she has privileges or close relationships with other doctors, but in reality, the EMTs will take that patient to the closest hospitals as they determine the emergency warrants, following the EMS departmental written protocol, or where the family might request. And, if the emergency room where the provider seeks to send a patient is full and not accepting transfers, which can happen, then the patient will also be sent elsewhere.

21. The admitting privileges requirement is also unnecessary and irrelevant to providing optimal care because of the distances some women travel to obtain an abortion. Although abortion has a very low complication rate, the complications that can occur frequently arise only after a patient has left the clinic and returned home. If, after discharge from the abortion clinic, a woman who lives outside the area where she obtained her abortion experiences a complication that requires hospital treatment, it make no sense for her to travel to be treated at a hospital near the abortion clinic just because her abortion provider has admitting privileges there. She would go to the hospital emergency room that is closest to her home. In an emergency or potential emergency situation, no physician, or EMT, would countenance going further than necessary just to get to a hospital where her provider has privileges. For example, if a woman travels to Houston from Columbus, Wharton, Liberty, or Bay City for an abortion and experiences a

problem when she returns home, the fact the physician who performed the procedure has privileges at a Houston hospital would do her no good.

22. Similarly, if a patient who obtains a medication abortion experiences a complication that requires a hospital visit, the complication will never occur when the patient is in the clinic, but rather when she is away from the clinic, and most likely at home. For example, if a medication abortion patient experiences bleeding that requires a transfusion, which is the most common of the rare complications from a medication abortion, it will occur one to three weeks after the procedure. In those cases, a physician should refer that patient to the hospital nearest to her to make sure she is treated as quickly as possible.

23. It is my opinion that admitting privileges are also irrelevant to providing optimal care in the event of a complication because the physician who provides the abortion may not be the appropriate physician to manage the patient's care in the hospital, regardless of whether the physician has privileges there. Given that abortions have such a low complication rate, abortion providers may, depending on their practice, only rarely perform the types of surgeries, including laparoscopy, open laparotomy, and hysterectomy, that might be necessary to treat a complication requiring surgery, while the on-call ob/gyn at the hospital will have more experience doing these procedures and is also familiar with the systems in that hospital.

24. Moreover, the physician performing the abortion might not have the relevant expertise to treat the patient. For example, in the very rare case of uterine perforation with a vascular or bowel injury, it is critical that the patient be treated by the appropriate subspecialist (general or vascular surgeon). A woman with a cardiac or lung condition may need treatment from a cardiologist or pulmonologist. I rely on my colleagues to manage these complications and conditions, just as they rely on me to evaluate gynecologic pathology they might encounter

during surgery they perform. Given how specialized the practice of medicine has become, particularly in a hospital setting, such handoffs to the appropriate specialists are common and necessary across medicine.

25. In addition, in those rare cases when an abortion patient, after discharge, goes to a hospital emergency room because of concerns or complications, she can often be treated by the emergency room physician and released without being admitted. Emergency room physicians are qualified to initially evaluate and treat most complications that could arise after the abortion procedures that Plaintiffs perform, and when necessary, they have immediate access to consultation with the ob/gyn on-call. Such skills are the same as those needed for the treatment of spontaneous miscarriages, which are often treated in hospital emergency rooms. If additional care is necessary, the on-call physicians at those hospitals can provide it. Moreover, it is my experience that many of those women who visit ERs after an abortion do so because of concerns they are having about their symptoms in cases where the ER visit is not actually medically necessary. In those cases, the ER physician can evaluate, counsel, and release those patients.

26. Accordingly, the professional standards of the American Congress of Obstetricians & Gynecologists ("ACOG"), Planned Parenthood Federation of America ("PPFA"), and the National Abortion Federation ("NAF"), while recognizing that clinics that perform abortions should have arrangements in place for transferring patients who require emergency treatment, do not require that the physician performing abortions have admitting privileges at a hospital.[9] ACOG has explicitly stated on more than one occasion that admitting privileges are not

[9] *Guidelines for Women's Health Care: A Resource Manuel* 433 (Paula Hillard, et al., eds. 2007) (ACOG) ("Clinicians who perform abortions in their offices, clinics, or freestanding ambulatory care facilities should have a plan to provide prompt emergency services if a complication occurs and should establish a mechanism for transferring patients who require emergency treatment."); *2013 Clinical Policy Guidelines* 55 (NAF Dec. 2012) ("Protocols for the management of medical emergencies must be in place. These protocols must include indications for emergency transport and written, readily available directions for contacting external emergency assistance (i.e., an ambulance)."); Clinical Program Structure I-A-1, PPFA Manual of Medical Standards & Guidelines 12 (June 2012) (affiliates must have the "ability to transfer a client without delay to a hospital").

necessary to the provision of safe abortion care and has opposed laws that make abortion access contingent on the availability of such privileges.[10]

27. The admitting privileges requirement of HB 2 is particularly unnecessary because Texas law already requires that abortions at 16 weeks LMP or greater be performed in a licensed ambulatory surgical center ("ASC"). Under the regulations established by the Department of State Health Services, all ASCs are already required to have a written transfer agreement with a hospital *or* the physicians who perform procedures there must have admitting privileges at a local hospital. Thus, Texas law already regulates transfer of care arrangements for all abortions at 16 weeks or later. While I believe that these requirements are unnecessary for any abortion provider, there is no reason to place a more onerous requirement on doctors who perform abortions prior to 16 weeks, including providers who do no surgery at all (*e.g.*, provide only medication abortion), than is placed on providers of much more risky surgeries performed in ASCs, as I discuss below.

Contemporary Medical Practice and Admitting Privileges

28. In my opinion, the admitting privileges requirement in HB 2 is completely at odds with the reality of contemporary medical practice around the country, including the trend of dividing ambulatory and hospital care. Indeed, hospitals now typically have their own dedicated staff physicians, and in many cases, only those physicians who have truly hospital-based practices actually have and maintain admitting privileges.

---

[10] *See Statement on State Legislation Requiring Admitting Privileges for Physicians Providing Abortion Services*, ACOG, Apr. 25, 2013, available at http://www.acog.org/About_ACOG/News_Room/News_Releases/2013/Hospital_Admitting_Privileges_for_Physicians_Providing_Abortion_Services ("ACOG opposes laws or other regulations that require abortion providers to have hospital admitting privileges."); ACOG, Analysis of the Possible FDA Mifepristone Restrictions (July 27, 2000) at 3 ("Privileges at a hospital are not necessary for prescribing [medication abortion] safely. . . . The prescribing physician does not need to be in the emergency room or to be the admitting physician if a patient requires follow-up emergency care. Women experiencing miscarriages and spontaneous abortions frequently require the same services and care and appropriately receive this case at their physicians' offices.").

29. The admitting privileges requirement is at odds with the development of inpatient "hospitalists," who are hospital-based physicians who provide only inpatient care. For example, obstetrician/gynecologist hospitalists, called "laborists," now practice providing only inpatient obstetric care during delivery, while a community obstetrician provides prenatal care and treats the pregnant woman as an outpatient.[11] This in-hospital "laborist" would also provide ob/gyn consultation and care to the emergency room physician as needed for care of a patient having an abortion complication.

30. Similarly, even where a hospital's staff physicians are not solely hospitalists, if a pregnant woman experiences a complication, like pre-eclampsia, that requires emergency care, she will often be cared for in the hospital by the physician on call and not her regular physician. In fact, if the nearest hospital to the woman is one where her ob/gyn does not have privileges, the physician who cares for her in an emergency may not even be affiliated with the physician who provides her prenatal care.

31. It is extremely common for physicians to cover for each other and refer to other physicians as necessary to treat the patient. It is also well understood in medicine that while a physician must be properly trained and qualified to perform the procedures he or she performs, he or she need not be properly trained and qualified to handle all of the potential consequences and complications of those procedures. All physicians, at some point, must (and should) refer their patients to another specialist, or a subspecialist, to ensure quality of care.

32. In fact, referring a patient to an emergency room to handle complications, where the outpatient provider lacks admitting privileges, is common throughout outpatient medicine even outside the abortion context. I treat patients who have come to our hospital because of complications from non-abortion gynecological surgeries performed in outpatient settings, and

[11] *The Role of Laborist in Patient Care*, available at http://www.oblaborist.org/ (last visited June 5, 2013).

we provide high quality care to those patients without a need for the surgeon who performed the procedure to have admitting privileges. For example, hysteroscopy and diagnostic dilation and curettage on nonpregnant women and surgical management of spontaneous abortion ("miscarriage") are frequently performed in outpatient settings, and if there are complications, such as a uterine perforation, during such a procedure, the patient will be transferred to the hospital ER and may need follow-up surgery. Similarly, there has been an increase in physicians' use of anesthesia, even general anesthesia, in outpatient clinic or office settings. Complications from general anesthesia are much more common than complications from abortion, and when patients experiencing those complications must be transferred to the ER, they will receive high quality care at the hospital. It is not necessary for the physician who performs the outpatient procedure or administers the anesthesia to have admitting privileges at the hospital. Certified nurse anesthetists frequently provide general anesthesia in the office or clinic setting and they obviously do not have admitting privileges.

33. Physicians frequently perform surgeries in ambulatory surgery centers ("ASCs") that are generally more complicated and riskier that abortions. In the field of gynecology, those procedures can include laparoscopy, laparoscopic hysterectomy, and vaginal hysterectomy. Such procedures also usually involve general anesthesia with the patient paralyzed and intubated under the care of either an anesthesiologist or certified nurse anesthetist, which by itself is also much riskier than office-type procedures such as abortion and miscarriage management. In this regard, it appears that House Bill 2 singles out physicians who perform abortions by imposing an unnecessary admitting privileges requirement, while physicians who provide riskier treatments in an outpatient setting are not required by the State to have admitting privileges.

34. Due to the trends in granting privileges, there is an increasing divide between ambulatory and hospital-based care, which means that more and more outpatient providers must hand off the care of their patients experiencing complications at the hospital door. This is not patient abandonment, but the way that good medicine is practiced today.

35. Furthermore, I understand that HB 2 requires doctors who perform abortions to have "active admitting privileges," but I do not understand which of two meanings "active" might have in this context, given my understanding of the terminology surrounding hospital staff and admitting privileges.

36. On the one hand, the word "Active" is a term of art used in the bylaws of most hospitals to delineate a particular category of medical staff ("staff"), usually the highest level of membership in a hospital's staff. This is the case at Ben Taub Hospital, where I have privileges, and it is also true in many other hospitals in Texas, including those twelve hospitals where I have been on staff. In order to have admitting privileges, a physician must be a member of the hospital's staff. Physicians who are "Active" members of the hospital staff are allowed to vote on hospital issues and hold office at the hospital, while a physician who is a "Courtesy" staff member can usually admit patients to the hospital, but is not permitted to vote or hold office at the hospital. Becoming an "Active" staff member is more difficult, and often a physician is not eligible to become a member of the "Active" staff unless (s)he has "Provisional" staff status for an extended period of time (such as one year), after which time the hospital engages in peer review of the physician's work to decide whether to invite him or her to join the hospitals "Active" staff.

37. On the other hand, the phrase "active admitting privileges" might be used to describe admitting privileges that are current and up-to-date (and not, *e.g.*, lapsed or suspended). In this

usage, a physician who is a Courtesy staff member with admitting privileges at a hospital may have "active admitting privileges," in the sense that (s)he could admit patients, but (s)he would not be a member of the "Active" medical staff under the hospital's bylaws.

38. While any admitting privileges requirement is medically unnecessary and inconsistent with the standard of care, interpreting the word "active" to mean that physicians who perform abortions must become full members of the hospital staff at the highest level of participation, as opposed to requiring abortion providers to have "current" privileges that allow him or her to admit patients, would be especially problematic. It would mean that a physician could not perform abortions unless (s)he has the capacity to vote on hospital-related issues—a requirement that has absolutely no connection whatsoever to patient welfare or competent medical practice. And it would also make the admitting privileges requirement substantially more burdensome, in that fewer doctors could become members of a hospital's "Active" staff, and even those that could potentially do so would be unable to do so for some time.

Medication Abortion Practice Today Using Evidence-Based Medicine

39. Clinical testing of mifepristone began abroad in 1982, and the drug was licensed in France and China in 1988. In 1996, a U.S.-based organization filed a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA"), requesting approval of mifepristone for distribution in the United States. The FDA does not itself test medications. Rather, it reviews studies submitted by the applicant (known as "clinical trials"). In the case of mifepristone, the clinical trials involved fewer than 3000 women who took 600 mg of mifepristone orally and returned to the clinic approximately 36 to 48 hours later to take 400 μg of misoprostol orally. Those trials (in which, as I noted above, I was involved) showed that that regimen was safe and effective for abortions through 49 days LMP.

40. In September 2000, the FDA approved the NDA, and as part of that approval, as with all medications, approved a Final Printed Labeling ("FPL"), which is an informational document that provides physicians with guidance about the use for which the drug sponsor requested and received FDA approval. The mifepristone label, therefore, describes the regimen used in the clinical trials.[12] Mifepristone is the only medication that has received FDA approval for marketing as an abortion-inducing drug, and therefore, the only medication with an FPL describing an abortion regimen. The FDA has never required that mifepristone be used in a specific dosage, within a specific gestational age range, or following a specific regimen.

41. By the time that mifepristone was made available in the United States, newer research had been conducted showing that a lower dosage of mifepristone (200 mg) combined with a different dosage of misoprostol (800 µg), which the woman administered herself by placing the pills in her vagina (i.e., vaginal administration) was an equally safe regimen and was effective through 63 days LMP. This research also showed that changing the route of misoprostol administration decreased side effects. Based on this research, from the time that mifepristone medication abortion became available in the United States, the overwhelming majority of abortion providers offered their patients an evidence-based regimen different from the one on the FPL through 63 days LMP. The regimens used have changed over time in response to further research.

42. For more than the past five years, the evidence-based regimen most commonly used across the country, including in Texas, involves 200 mg of mifepristone taken orally at the clinic, followed approximately 24 to 48 hours later by 800 µg of misoprostol, which the woman self-

[12] The FPL says that Day One, the patient reads the Medication Guide, signs the Patient Agreement, and receives three 200 mg tables of Mifeprex, taken orally at the health care facility; Day Three, the patient returns to the health care facility and, unless the abortion has already occurred, receives two 200 mg of misoprostol taken orally; and Day 14, approximately fourteen days after the mifepristone was administered, the patient returns to the health facility to confirm that a complete termination of pregnancy has occurred.

administers at home by placing it in her buccal pouch (i.e., between her cheek and gum). This evidence-based regimen is very safe and highly effective through 63 days LMP with results superior to and side effects fewer than the FDA FPL regimen which, unfortunately, is based on outdated studies from the mid 1990s (which I participated in).

43. The practice of developing new protocols, using different dosages, or using medications for entirely different uses than for which they were approved by the FDA when they are supported by adequate study, is not unique to mifepristone. This practice is common in medicine and is called "off-label" or "evidence-based" use. The American Medical Association has stated that up to 20 percent of all drugs are prescribed off-label and among some classes of cardiac drugs, off-label use can be as high as 46 percent.[13] For example, this is how aspirin came to be used to prevent heart attacks and Wellbutrin, approved by the FDA as an anti-depressant, came to be used as a smoking cessation drug. Misoprostol, the second drug used in the medication abortion regimen, is another example. It was approved by the FDA as a drug to reduce the incidence of gastric ulcers in patients taking non-steroidal anti-inflammatory drugs such as ibuprofen and is labeled for that use. However, besides being routinely used as part of medication abortion, it is widely used in obstetrics to ripen the cervix prior to induction of labor and also to stop postpartum hemorrhage.

44. In almost all such cases, the label for the drug never reflects even the most common, accepted "off-label" uses. That is because only the manufacturer of a drug (in the case of mifepristone, there is only one manufacturer) can apply to have a drug relabeled, the process is very expensive (the manufacturer has to submit and perhaps conduct new research to support the

[13] AMA National Task Force on CME Provider/Industry Collaboration Fact Sheet, On-Label and Off-Label Usage of Prescription Medicines and Devices (available at http://www.ama-assn.org/resources/doc/cme/fact-sheet-4.pdf).

application and pay a large application fee), and there is simply no incentive for the manufacturer to do so, as off-label use is so prevalent and so rarely restricted.

45. In the case of mifepristone, extensive research demonstrates that the alternative evidence-based regimens are every bit as safe as – and indeed, superior to – the regimen that appears on the FPL. In contrast to the approximately 2500 women who participated in the clinical trials, more than one million American women have now safely used an alternative, evidence-based mifepristone regimen to terminate their pregnancies.

46. The alternative evidence-based regimens are more effective, with both a lower rate of ongoing pregnancies and fewer surgical interventions necessary to complete the procedure. There are also fewer side effects such as nausea and vomiting. The FPL regimen has been shown to result in an ongoing pregnancy in approximately one percent of cases, and as many as eight percent of women following the FPL regimen will have a surgical procedure following the medications. Using much larger data sets, the off-label, evidenced-based regimen described above that most providers, including in Texas, use will result in ongoing pregnancy in only 0.5 percent of cases, and only two percent of women have had a surgical procedure following the medications.[14] Given its superiority, there is no medical or empirical basis for banning the off-label, evidence-based use, and certainly none for requiring the less effective FPL in its place.

47. The alternative regimens have a number of other advantages. *First*, they are effective for longer in pregnancy, allowing medication abortions to be performed at least through 63 days LMP and many more women to avail themselves of that method, thus avoiding an undesired surgical procedure. Those additional weeks are significant because many women do not detect their pregnancies until close to 49 days LMP. *Second*, self-administration of misoprostol (which

[14] The reasons why a woman may have a surgical procedure include ongoing pregnancy, bleeding (often due to retained tissue), and patient request.

has been studied and proven safe) eliminates a trip to the clinic for the misoprostol, allows the woman greater control over the timing of the procedure, and ensures that she experiences the bleeding and cramping that follows in a location of her choosing and with her husband, partner, or other supporting loved ones present. *Third*, the lower mifepristone dosage reduces the cost of the procedure significantly. *Fourth*, the alternative regimens have lower incidence of side effects than the regimen that appears on the FPL, as mentioned above.

48. These advantages of, and the safety of, the alternative evidence-based regimens are widely acknowledged. In fact, ACOG, the World Health Organization, and the Royal College of Obstetricians and Gynecologists have all endorsed use of an evidence-based alternative regimen through 63 days.

49. Mifepristone medication abortion is also increasingly prevalent. For example, of those women eligible for either surgical or medication abortion (meaning that they had a gestational age of 63 days LMP or less and no other contraindication) at a Planned Parenthood health center nationwide, in 2008, an estimated 53 percent of them (more than 97,000 women) chose to have a mifepristone medication abortion rather than a surgical procedure. I believe that this is representative of Texas as well; about that time, over 50% of eligible patients at Planned Parenthood in Waco chose medication abortion. Currently, at Planned Parenthood Center for Choice, although we offer abortions throughout the entire first trimester and into the second trimester, approximately 1/3 of all of our abortion patients choose medication abortion (which is only offered through 63 days), which is about 10 to 12 women per day, five days a week.

50. Far more than many other medical procedures, abortion has a very private, emotional component to it. Women seeking abortions are trying to manage their feelings about an unwanted pregnancy. In my experience, women have many different and personal reasons for

deciding to terminate a pregnancy that is not right for them. Issues regarding her age, economic situation, familial situation (including her children and her partner), and emotional and physical health all may play a part in both why a woman is having an abortion and why she chooses the procedure that she does.

51. Based on my own extensive experience and the literature, it is my opinion that once women are counseled about both medication and surgical abortion, most demonstrate a strong and clear preference for the type of procedure that they choose and are satisfied with that method. I believe that women know their own needs and desires and choose the abortion method that is best for them.

52. One of the most common reasons that women choose medication abortion is that they feel that it allows them to exert a greater degree of personal control over the procedure and over their bodies, compared to a surgical abortion. Many women like that they have an active role in the process of a medication abortion, which they also find more "natural."

53. As explained above, in a medication abortion, the woman takes the mifepristone at the clinic, but the contents of the uterus will be expelled later. This means that patients can undergo the procedure largely at a time and location of their choice, most often in their own homes. For many women, this feels more private than being surrounded by the clinic staff. It also means that they can have the support of the people they want around them. At many clinics, partners, family, and friends are not allowed into the procedure rooms when a woman has a surgical abortion.

54. Some women fear the invasive nature of a surgical abortion or the loss of control that comes from sedation or anesthesia. For women with these anxieties, medication abortion is highly preferable. Additionally, some Texas physicians do the medication abortion out of their

regular office, eliminating the need for the woman to pass through a crowd of harassing protesters often found outside of abortion clinics. There are also some women – particularly those who have been victims of rape, sexual abuse, or molestation – for whom having to lie on the table and have instruments inserted into their vaginas is particularly traumatic. In my experience, medication abortion is particularly beneficial for these women where products of conception is not required as evidence for criminal prosecution.

55. Some women have a medical condition that can make first-trimester surgical abortion extremely difficult – and in some cases, impossible. These circumstances include situations that make it difficult for the provider to access the pregnancy inside the uterus. Such cases may include women who are extremely obese, have uterine fibroids distorting normal anatomy, have a uterus that is very flexed, or have certain uterine anomalies, such as a bicornate uterus (a malformation where the upper portion forms two "horns" making the uterus appear somewhat heart-shaped). For these women, surgical abortion poses much higher risks of failed abortion, as well as complications such as perforation of the uterus. Medication abortion, therefore, is a significantly safer choice.

56. Another circumstance where medication abortion may be significantly safer is when it is very difficult to dilate the woman's cervix. This occurs when women have a condition called a stenotic cervix (an abnormally small cervical opening, often caused by scarring from prior surgeries). It may also happen when a woman has undergone female genital mutilation. Forcing some of these women to have surgical rather than medication abortions would put them at greater risk of damage to their cervix as well as other complications, such as uterine perforation.

The Texas Law's Unnecessary and Burdensome Limits on Medication Abortion

57. HB 2 would significantly decrease the availability of medication abortion in Texas with no patient benefit. In fact, as I explain below, the new restrictions on medication abortion in HB 2 would reverse decades of medical advances for Texas women and threaten their health.

58. Under the Act, physicians face administrative and criminal penalties, including possible license revocation, if they "give, sell, dispense, administer, provide, or prescribe an abortion-inducing drug" to a patient unless "the provision, prescription, or administration . . . satisfies the protocol tested and authorized by the United States Food and Drug Administration as outlined in the final printed label of the abortion-inducing drug." Tex. Health & Safety Code §§ 171.063(a), 171.064. The only exception to this prohibition is that:

> A person may provide, prescribe, or administer the abortion-inducing drug in the dosage amount prescribed by the clinical management guidelines defined by the American Congress of Obstetricians and Gynecologists Practice Bulletin as those guidelines existed on January 1, 2013.

Id. § 171.063(b).

59. I do not understand what this law means when it says that doctors may "provide, prescribe, or administer" abortion-inducing drugs in the "dosage amount prescribed by" the ACOG guidelines. ACOG has a Practice Bulletin of Clinical Management Guidelines related to Medical Management of Abortion which was adopted in 2005 and reaffirmed in 2011 and which is attached hereto as Exhibit 2. This Bulletin does not "prescribe" any specific "dosage amount," but does list the following among its highest level of recommendations, which are "based primarily on good and consistent scientific evidence":

- Compared with the FDA-approved regimen, mifepristone-misoprostol regimens using 200 mg of mifepristone orally and 800 µg of misoprostol vaginally are associated with a decreased rate of continuing pregnancies, decreased time to expulsion, fewer side effects, improved complete abortion

rates, and lower cost for women with pregnancies up to 63 days of gestation based on LMP.

- A patient can administer misoprostol safely and effectively, orally or vaginally, in her home as part of a medical abortion regimen.

60. The ACOG recommendation quoted above is not limited to a "dosage amount" – it is a regimen that uses a different route of administration for the misoprostol than the FPL (vaginal rather than oral), as well as a different gestational age limit (63 rather than 49 days LMP). But it is not clear if H.B. 2 allows anything other than the "dosage amounts" in the ACOG recommendation – meaning that a doctor would have to follow the route of administration and the gestational age limit on the FPL (i.e., oral misoprostol and a 49 day limit).

61. While H.B. 2 seems to say this, it seems it cannot possibly mean this, as 200 mg mifepristone orally, followed by 800 µg of misoprostol orally (which is the route of administration for the misoprostol on the FPL) is a completely untested regimen that has never been endorsed by ACOG, and no study that I am aware of has considered such a regimen. It would be irresponsible of physicians to experiment with an untested regimen on patients, and therefore, this reading would render the ACOG exception meaningless. Presumably, the Legislature meant to allow something with the ACOG exception, but it is not clear.

62. Moreover, it makes no sense as a matter of medicine that the Legislature would endorse only the dosage amount in the ACOG recommendation. If it believed that ACOG makes good medical recommendations, why not allow everything AGOC has recommended, including use through 63 days LMP and self-administration of misoprostol? And why limit me to the Practice Bulletin as it existed in January 2013? Bulletins such as these are often updated with newer, more comprehensive research, but the Legislature seems to have said that only any

recommendations from prior to January 2013 are good, freezing medical practice in time, and denying me and my patients the best medical practices available in the future.

63. If the ACOG exception not does not allow vaginal or buccal administration of misoprostol and limits provision of mifepristone to 49 days, or if there is no clarification of what it means, women will be left with only the FPL regimen – as many physicians would not want to risk the significant penalties for violating the Act. This would be a huge disservice to Texas women as it would result in a ban on medication abortion entirely after 49 days LMP because, as I noted above, mifepristone is the only abortion-inducing drug that has a FPL related to abortion and the regimen on the FPL is limited to 49 days.

64. If H.B. 2 does ban medication abortion after 49 days LMP, it will have taken away a safe option using medication alone – if a woman with a gestational age past 49 days LMP chooses abortion, she must have a surgical procedure. There is no medical reason for this because, as I describe above, hundreds of thousands of American women have safely had mifepristone medication abortions with gestational ages of 50 through 63 days LMP. Indeed, mifepristone medication abortion has been shown to be safe and effective, and is beginning to be provided, through 70 days LMP. Rather than protecting women's health, the Act actively harms women by depriving them of advances in medicine made over the past twenty years.

65. For those women I identified above with specific medical conditions that make surgical abortion significantly more risky, the Act's ban after 49 days LMP is much worse. It will mean that they will be subjected to significant – and unnecessary – health risks.

66. For women with gestational ages through 49 days LMP, the Act does not ban medication abortion entirely, but leaves them with an inferior protocol and places significant barriers in their path. That is because unless the ACOG exception allows self-administration of

misoprostol, in order to have a medication abortion under the new rules, a woman would be required to make three or four separate trips to her provider over the course of two weeks. This is because Texas Health & Safety Code § 171.012 requires that the "physician who is to perform the abortion" provide certain information to the woman in person at least 24 hours before the procedure unless she lives more than 100 miles from an abortion provider (visit 1). The woman must return at least 24 hours later to take the mifepristone (visit 2) and two days later to take the misoprostol (visit 3), which, unless the ACOG exception allows for self-administration, must each be administered by a physician because they are each an "abortion-inducing drug" under the Act's definitions. *See* Tex. Health & Safety Code §§ 171.061(2), 171.063(a)(1).[15] Finally, the Act requires "[t]he physician who gives, sells, dispense, administers, provides, or prescribes the abortion-inducing drug" to do certain things at the follow-up visit, which must be "not more than 14 days after administration or use of the drug" (visit 4). *Id.* § 171.063(3).

67. Today, some Texas women who choose medication abortion make three visits (for the mandatory counseling, to take the mifepristone, and for a follow-up), but others travel to the abortion provider only once (if she lives further than 100 miles from an abortion provider) or twice (for the counseling visit and to take the mifepristone) if they are able to arrange their follow-up appointment, involving an ultrasound or a blood test, at a location nearer to their homes. There is no medical justification for requiring women to return to a health center to take the misoprostol, and there is none for requiring a physician – and certainly not the same physician – to administer it. Medications prescribed by physicians are routinely and safely administered by other trained health professionals.

[15] It is not clear to me if this could be a different physician or must be same physician she saw for the first two visits.

68. Not only is there no medical reason, but it is also contrary to good medical practice, to require women to make three or four trips to the health center to obtain a medication abortion. In particular, requiring that the woman visit the health center to take the misoprostol *harms* women because it is unpredictable when the misoprostol will take effect and how long the bleeding will last. Some women will begin to bleed and cramp as soon as 30 minutes after they take the misoprostol. Others may not start bleeding for hours. For some women, the bleeding will last an hour or two. For others, it could be much longer. It is far better for women to experience these symptoms in the comfort of her own home, with her family or partner, rather than in a car (possibly while driving) or bus while they are traveling home from the health center, which in Texas could involve great distances.

69. In this way, requiring the FPL regimen would take away the major advantage that propels many women to choose medication abortion in the first place – that they can time these symptoms and be in a comfortable place with the support of loved ones of their choosing when they occur. Requiring the FPL would also significantly increase the cost of the procedure both because the woman will have to take two extra mifepristone pills, each of which cost approximately $80, and because the provider will have to staff the extra visits.

70. It will impose other burdens too, which for some women would be costly. In my experience, it is hard for many women to access the clinic, so making them come in four times in a two-week period – for the 24-hour counseling meeting, to take the mifepristone, to take the misoprostol, and for the follow-up visit – would be very difficult for many of them. This is especially true for young women, low-income women, women who are victims of domestic violence, women with child care responsibilities, and women with job commitments, as each trip to the clinic will require additional travel and time away from home, children, and work.

71. If faced with a more expensive, less private option that requires four trips to the health center – and especially if the procedure is limited to 49 days LMP, many women will no longer have the option of, or choose, medication abortion. And if too few women choose it, it is foreseeable that many providers will simply stop providing it.

72. Perhaps most importantly, all of these changes and burdens on women come with absolutely no medical benefit flowing from them. For all of these reasons, I believe that the medication abortion restrictions in H.B. 2 do not advance women's health in any way. To the contrary, HB 2 turns back the clock on more than 20 years' worth of research and experience, and I believe that it would have a significant negative impact on the health of Texas women.

Access to Legal Abortion Is Vital to the Protection of Public Health

73. As I mentioned above, women seek abortions for a variety of medical, familial, economic, and personal reasons. More than 60% of women who seek abortions are mothers who have decided that they cannot parent another child at this time,[16] and 66% plan to have children when they are older, financially able to provide necessities for them, and/or in a supportive relationship with a partner so their children will have two parents.[17] Approximately one in three women in this country will have an abortion in their lifetimes.[18]

74. It is extraordinarily important for women to have meaningful access to legal abortion. Women of childbearing age who do not have access to the procedure face significantly increased risks of death and poor health outcomes. For example, when women are forced to travel long distances for care, many will delay obtaining an abortion until they can find the money or arrange transportation. While abortion is a safe procedure, the risks from abortion increase as

[16] Rachel Jones, et al., *Characteristics of U.S. Abortion Patients, 2008*, Guttmacher Inst. 1, 8 (2010).
[17] Stanley Henshaw & Kathryn Kost, *Abortion Patients in 1994-1995: Characteristics and Contraceptive Use*, 28 Fam. Plan. Persp. 140, 144 (1996).
[18] Rachel Jones & Megan Kavanaugh, *Changes in Abortion Rates Between 2000 and 2008 and Lifetime Incidence of Abortion*, 117 Obstet. & Gynecol. 1358, 1365 (2011).

the pregnancy advances. Thus, delaying abortions until later in pregnancy increases the risks of complications.[19]

75. When legal abortion is unavailable or difficult to access, some women turn to illegal, and unsafe, methods to terminate unwanted pregnancies.[20]

76. Other women, deprived of access to legal abortion, forgo the abortions they would have obtained if they could and, instead, carry unwanted pregnancies to term. These women are exposed to increased risks of death and major complications from childbirth, and they and their newborns are at risk of complications during pregnancy and after delivery.[21]

77. There is a nationwide shortage of physicians willing to provide abortions to the women who need it. HB 2 imposes medically unnecessary and hard-to-satisfy restrictions on physicians who are currently willing to provide abortions to women in Texas, increasing the obstacles and correspondingly diminishing the number of providers. It will, therefore, be extremely harmful to the health and well-being of women in Texas.

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

Dated: September 25, 2013

Paul M. Fine, MD

[19] Linda Bartlett, et al., *Risk Factors for Legal Induced Abortion-Related Mortality in the United States*, 103 Obstet. & Gynecol. 729, 735 (2004).
[20] Daniel Grossman, et al., *Self-Induction of Abortion Among Women in the United States*, 18 Reprod. Health Matters 136 (2010).
[21] Jessica Gipson, et al., *The Effects of Unintended Pregnancy on Infant, Child, and Parental Health: A Review of the Literature*, 39 Stud. Fam. Plan. 18 (2008).