No. 13-51008

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

PLANNED PARENTHOOD OF GREATER TEXAS SURGICAL HEALTH SERVICES; PLANNED PARENTHOOD CENTER FOR CHOICE; PLANNED PARENTHOOD SEXUAL HEALTHCARE SERVICES; WHOLE WOMAN'S HEALTH; AUSTIN WOMEN'S HEALTH CENTER; KILLEEN WOMEN'S HEALTH CENTER; SOUTHWESTERN WOMEN'S SURGERY CENTER; WEST SIDE CLINIC, INCORPORATED; ROUTH STREET WOMEN'S CLINIC; HOUSTON WOMEN'S CLINIC, each on behalf of itself, its patients and physicians; ALAN BRAID, M.D.; LAMAR ROBINSON, M.D.; PAMELA J. RICHTER, D.O., each on behalf of themselves and their patients; PLANNED PARENTHOOD WOMEN'S HEALTH CENTER,
Plaintiffs-Appellees,

v.

ATTORNEY GENERAL GREGORY ABBOTT; DAVID LAKEY, M.D.; MARI ROBINSON, Executive Director of the Texas Medical Board,
Defendants-Appellants.

On Appeal from the United States District Court for the
Western District of Texas, Austin Division
Case No. 1:13-cv-00862-LY

BRIEF OF *AMICI CURIAE* AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS AND THE AMERICAN MEDICAL ASSOCIATION IN SUPPORT OF PLAINTIFFS-APPELLEES AND IN SUPPORT OF AFFIRMANCE

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Plaintiffs-Appellees,

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ATTORNEY GENERAL GREGORY ABBOTT; DAVID LAKEY, M.D.; MARI ROBINSON, Executive Director of the Texas Medical Board,
Defendants-Appellants.

CERTIFICATE OF INTERESTED PERSONS

Amici curiae, the American College of Obstetricians and Gynecologists and the American Medical Association, are non-profit organizations, with no parent corporations or publicly traded stock. Undersigned counsel of record certify that no persons and/or entities as described in the fourth sentence of Fifth Circuit Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

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• Alliance Defending Freedom • Bioethics Defense Fund • Family Research Council	Catherine Glenn Foster Alliance Defending Freedom

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STATEMENT OF INTEREST OF AMICI CURIAE

The American College of Obstetricians and Gynecologists (the "College" or "ACOG") and the American Medical Association ("AMA") submit this brief *amici curiae* in support of Appellees.[1]

ACOG is a non-profit educational and professional organization founded in 1951. The College's objectives are to foster improvements in all aspects of healthcare of women; to establish and maintain the highest possible standards for education; to publish evidence-based practice guidelines; to promote high ethical standards; and to encourage contributions to medical and scientific literature. The College's companion organization, the American Congress of Obstetricians and Gynecologists (the "Congress"), is a professional organization dedicated to the advancement of women's health and the professional interests of its members. Sharing more than 57,000 members, the College and the Congress are the leading professional associations of physicians who specialize in the healthcare of women.

The membership of the Texas District of the Congress includes 2,532 obstetrician-gynecologists who provide medical care to the women of Texas. The College and the Congress recognize that abortion is an essential health care service

[1] Pursuant to Federal Rule of Appellate Procedure 29, the parties have consented to the filing of this *amicus* brief. Also pursuant to Rule 29, undersigned counsel for *amici curiae* certify that: (1) no counsel for a party authored this brief in whole or in part; (2) no party or party's counsel contributed money that was intended to fund the preparation or submission of this brief; and (3) no person or entity—other than *amici curiae*, its members, and its counsel—contributed money intended to fund the preparation or submission of this brief.

and oppose laws regulating medical care that are unsupported by scientific evidence and that are not necessary to achieve an important public health objective.

The College has previously been granted leave to appear as *amicus curiae* in various courts throughout the country including the U.S. Supreme Court. In addition, the College's work has been cited frequently by the Supreme Court and other federal courts seeking authoritative medical data regarding childbirth and abortion.[2]

AMA is the largest professional association of physicians, residents and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups, seated in the AMA's House of Delegates, substantially all U.S. physicians, residents and medical students are represented in the AMA's policy making process. The objectives of the AMA are to promote the science and art of medicine and the betterment of public health. AMA members practice in all fields of medical specialization and in every state, including Texas.

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[2] *See, e.g., Stenberg v. Carhart*, 530 U.S. 914, 932-936 (2000) (quoting ACOG's *amicus* brief extensively and referring to ACOG as among the "significant medical authority" supporting the comparative safety of the abortion procedure at issue); *Hodgson v. Minnesota*, 497 U.S. 417, 454 n.38 (1990) (citing ACOG's *amicus* brief in assessing disputed parental notification requirement); *Simopoulos v. Virginia*, 462 U.S. 506, 517 (1983) (citing ACOG publication in discussing "accepted medical standards" for the provision of obstetric-gynecologic services, including abortions); *see also Gonzales v. Carhart*, 550 U.S. 124, 170-171, 175-178, 180 (2007) (Ginsburg, J., dissenting) (referring to ACOG as "experts" and repeatedly citing ACOG's *amicus* brief and congressional submissions regarding abortion procedure); *Greenville Women's Clinic v. Bryant*, 222 F.3d 157, 168 (4th Cir. 2000) (extensively discussing ACOG's guidelines and describing those guidelines as "commonly used and relied upon by obstetricians and gynecologists nationwide to determine the standard and the appropriate level of care for their patients").

SUMMARY OF ARGUMENT

Women should have access to all needed medical care—ranging from mammograms to prenatal visits to reproductive care—based on the latest medical developments and scientific facts. Women who live in Texas are no exception. Yet, Texas' House Bill ("H.B.") 2 imposes government regulation on abortion care that is not based on scientific facts or the best available medical knowledge. Putting aside the legal and constitutional infirmities presented by H.B. 2,[3] there is simply no medical basis to impose a local admitting privileges requirement on abortion providers or to limit medical abortion to specific regimens, especially when scientific progress has demonstrated that other regimens are safer and more effective. H.B. 2 does not serve the health of women in Texas, but instead jeopardizes women's health by restricting access to abortion providers and denying women well-researched, safe, evidence-based, and proven protocols for the provision of medical abortion.

For these and the reasons set forth below, *amici* urge this Court to set aside H.B. 2's admitting privileges requirement and, with respect to medical abortion, at a minimum, uphold the district court's prohibition on the enforcement of H.B. 2's medical abortion provisions "where a physician determines in appropriate medical

[3] Unless expressly discussed herein, *amici* do not express an opinion on all or other aspects of H.B. 2 or the district court's opinion.

judgment, such a procedure is necessary for the preservation of the life or health of the mother."[4]

ARGUMENT

I. H.B. 2's Privileges Requirement Does Not Serve the Health of Women in Texas.

Amici oppose legislative interference with the practice of medicine and a woman's relationship with her doctor, especially when legislative enactments—like H.B. 2's privileges requirement—do nothing to protect the health of women and are incongruous with modern medical practice. In contemporary medical practice, it is not only accepted, but expected, that a woman experiencing a rare complication from an abortion—or any other medical procedure—will receive care for that complication from a nearby hospital. The privileges requirement imposed by H.B. 2 does nothing to enhance the safety of, or healthcare provided to, women in Texas. There is no medically sound reason for Texas to impose a more stringent requirement on facilities in which abortions are performed than it does on facilities that perform other procedures that carry similar, or even greater, risks. Therefore, there is no medically sound basis for H.B. 2's privileges requirement.

Access to safe and legal abortion is an important aspect of women's health care. Abortion is one of the safest medical procedures performed in the United States. The risk associated with childbirth is approximately fourteen times higher

[4] ROA.1559.

than abortion.[5] Over 90% of abortions in the United States are performed in outpatient settings[6] and almost all complications that arise after an abortion can be, and are, treated on an outpatient basis. Hospitalization due to an abortion is rare. There is a less than 0.3% risk of major complications following an abortion that might need hospital care[7] and a recent study found that the risk of major complications from first trimester abortions by the aspiration method is even less—0.05%.[8] According to Texas vital statistics data as of 2011 (the most recent year for which data is available), since 2008, there have been *no* reported maternal deaths out of 227,912 abortions in Texas.[9]

Even though abortions rarely result in complications, H.B. 2 imposes more stringent requirements on facilities where abortions are performed than on other facilities—such as outpatient and Ambulatory Surgical Centers—at which riskier

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[5] Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215, 215 (Feb. 2012).

[6] Rachel Jones & Kathryn Kooistra, *Abortion Incidence and Access to Services in the United States, 2008*, 43 Persp. on Sexual & Reprod. Health 41, 46 (2011).

[7] Stanley K. 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] Tracy A. Weitz et al., *Safety of Aspiration Abortion Performed by Nurse Practitioners, Certified Nurse Midwives, and Physician Assistants Under a California Legal Waiver*, 103 Am. J. Pub. Health 454, 458 (Mar. 2013). Similarly, the risk of hospitalization from a medical abortion is 0.06%. Kelly Cleland et al., *Significant Adverse Events and Outcomes After Medical Abortion*, 121 Obstetrics & Gynecology 166, 169 (Jan. 2013).

[9] Tex. Dep't of State Health Servs., Ctr. for Health Statistics, *Vital Statistics Annual Reports* for 2008-2011, Table 33, Selected Characteristics of Induced Terminations of Pregnancy, *available at* http://www.dshs.state.tx.us/chs/vstat/annrpts.shtm (last visited Dec. 18, 2013). There was one death in 2008 out of 81,591 abortions (or a mortality rate of 0.001%). *Id.* In contrast, in that same year, there were 90 maternal deaths out of 405,242 live births (a mortality rate of 0.02%) or approximately 20 times the mortality rate of abortion procedures. *Id.* at Table 28, Infant, Neonatal, Fetal, Perinatal, and Maternal Deaths for 2008.

surgical procedures are performed, including those that use general anesthesia.[10] The common procedures performed at these facilities are not necessarily safer than abortion and, indeed, many pose greater risks.[11] For instance, the mortality rate of a colonoscopy (34.5 per 100,000[12]) is more than 40 times greater than that of abortion (0.67 or less per 100,000[13]). There is absolutely no medical reason to treat facilities that provide abortions differently than facilities at which procedures with similar or greater risks of complications are performed.

While hospital privileges should be awarded based on the competency of physicians, in some cases the requirements to obtain privileges are difficult, if not impossible, for a physician to meet, irrespective of the physician's technical competency. For example, some requirements may dictate that a physician reside in the local area, that the physician have a particular faculty appointment, or that the physician perform a certain number of procedures at the hospital annually. As

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[10] General anesthesia itself carries risks. *See, e.g.*, Michelle Harris & Frances Chung, *Complications of General Anesthesia*, 40 Clin. Plastic Surg. 503 (2013) (discussing risk of complications associated with general anesthesia, the most common of which are cardiovascular and respiratory complications); *see also* Barbara S. Gold, MD et al., *Unanticipated Admission to the Hospital Following Ambulatory Surgery*, 262 J. Am. Med. Assoc. 3008, 3008-10 (Dec. 1989) (finding that general anesthesia was one factor associated with an increased likelihood of post-surgery admission following ambulatory surgery).

[11] These procedures include, among others, colonoscopy, vasectomy, cystoscopy, colposcopy, subcutaneous implant placement, sigmoidoscopy, hemorrhoid banding, skin biopsy, abscess incision and drainage, dental extraction, joint injection, and eye surgery including LASIK.

[12] Cynthia W. Ko et al., *Complications of Colonoscopy: Magnitude and Management*, 20 Gastrointestinal Endoscopy Clinics of N. Am. 659, 659-71 (Oct. 2010).

[13] Raymond, *supra* note 5 at 216 (finding mortality rate of 0.6 per 100,000); Karen Pazol et al., Centers for Disease Control and Prevention, *Abortion Surveillance – United States, 2009*, Morbidity and Mortality Weekly Report 61:1-44, Table 25 (Nov. 23, 2012), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6108a1.htm (last visited Dec. 18, 2013) (finding national legal induced abortion case fatality rate for 2003-2009 of 0.67 per 100,000).

discussed more fully below, often qualified and competent physicians who perform abortions are not able to meet these and other similar requirements to obtain privileges.

H.B. 2 is also inconsistent with prevailing medical practices, which are focused on ensuring prompt medical care and do not require that each individual abortion provider have admitting privileges.[14] Therefore, it is important that the provider's facility have a plan to provide prompt emergency services and (if needed) transfer to a nearby emergency facility if complications occur,[15] something that Texas law already requires.[16] Indeed, in the rare instance when a woman experiences a complication after an abortion and seeks hospital-based care, under the prevailing medical practice, she is, and can be, appropriately treated by a trained emergency room physician or, if necessary, the hospital's on-call specialist. Emergency room physicians are trained to handle the rare complications from abortion the same way they are trained to handle complications arising from any

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[14] *See* Inst. of Med., *Crossing the Quality Chasm: A New Health System for the 21st Century*, 8-9 (Mar. 2001) (finding that patient care should be guided by certain rules, including that "[p]atients should receive care whenever they need it and in many forms, not just face-to-face visits … [and] that the health care system should be responsive at all times (24 hours a day, every day) and that access to care should be provided over the Internet, by telephone, and by other means in addition to face-to-face visits" and that "[c]linicians and institutions should actively collaborate and communicate to ensure an appropriate exchange of information and coordination of care.").

[15] ACOG, *Guidelines for Women's Health Care: A Resource Manual*, 433 (3d ed. 2007) ("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."); *see also* Nat'l Abortion Fed'n, *2013 Clinical Policy Guidelines*, 55 (Dec. 2012).

[16] 25 Tex. Admin. Code. § 139.56(a) (requiring a "readily accessible written protocol for managing medical emergencies and the transfer of patients requiring further emergency care to a hospital.").

other medical procedure. Thus, as the lower court recognized, the care a woman receives at the emergency room is independent of, and not contingent on, her abortion provider having admitting privileges.[17]

In fact, the transfer of care from the abortion provider to an emergency room physician is consistent with the developments in medical practice dividing ambulatory and hospital care in the medical field more broadly.[18] That is, throughout modern medical practice, often the same physician does not provide both outpatient and hospital-based care; rather, hospitals increasingly rely on "hospitalists" that provide care only in a hospital setting.[19] Continuity of care is achieved through communication and collaboration between specialized health care providers,[20] which does not depend on those providers having hospital privileges.

H.B. 2's privileges requirement will not assist women in the rare event they experience complications after being discharged and returning home. It is unlikely that the hospital at which a woman would seek treatment (*i.e.*, a hospital near her home) is the one at which her provider maintains privileges (*i.e.*, a hospital within 30 miles of the abortion provider's clinic). Texas is a large state and many women

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17 ROA.1541.

18 *See, e.g.*, ACOG, Comm. on Patient Safety & Quality Improvement, Op. 459, *The Obstetric Gynecologic Hospitalist*, July 2010.

19 *Id.*

20 *See* Inst. of Med., *supra* note 14 at 9, 62, and 133-134.

do not live within a 30-mile radius of a clinic. If these women needed emergency care, it would be inappropriate to transport them an additional distance to the hospital at which their abortion provider maintains privileges.[21] H.B. 2's privileges requirement is therefore not only out of step with modern medical practice, which contemplates provision of emergency care by specially trained hospital physicians at a hospital near the patient's residence, it also provides no benefit to women who may experience post-procedure complications.

II. Requiring Hospital Privileges Jeopardizes Women's Health By Restricting Access To Abortion Providers.

Amici oppose H.B. 2's privileges requirement because it jeopardizes women's health in Texas by imposing a legislative constraint on access to safe and legal abortion. H.B. 2's requirement that abortion providers obtain privileges at a local hospital will have the effect of restricting and/or delaying women's access to abortion providers, because, as the district court found, clinics will be forced to close or to stop providing abortion services.[22] A number of providers cannot satisfy H.B. 2's privileges requirement because, as noted above, they cannot obtain privileges for reasons that have nothing to do with the quality of care that they

[21] Indeed, H.B. 2 acknowledges that the prevailing practice is for a patient to receive emergency care at a facility near her home. Tex. Health & Safety Code § 171.0031(2)(B) (requiring that women be given "the name and telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion would be treated.").

[22] ROA.1542.

provide.[23]

Some academic hospitals will only allow medical staff membership from physicians who also qualify for and accept faculty appointments. Other hospitals include a requirement to perform a certain number of deliveries and/or a certain number of major obstetric or gynecological surgeries in order to be affiliated with the hospital. Physicians who specialize in performing abortions, a very safe procedure only rarely resulting in hospitalization, are not able to meet such requirements. Finally, certain hospitals require doctors to live within a certain distance of the hospital due to on-call requirements. However, the scarcity of abortion providers make these requirements difficult if not impossible to meet.[24]

The difficultly of obtaining privileges is not theoretical. In Texas, twelve of the 34 abortion clinics were forced to stop providing abortions because providers

[23] Am. Congress Obstetricians & Gynecologists, *Statement on State Legislation Requiring Hospital Admitting Privileges for Physicians Providing Abortion Services*, Apr. 25, 2013 (opposing legislation requiring abortion providers to have hospital admitting privileges and stating that such physicians should have a plan to ensure prompt emergency services in the case of a complication).

[24] In its Brief, the State argues that nondiscrimination statutes protect physicians from being denied privileges on religious grounds, Appellants' Br. 33-34, but nondiscrimination statutes do not necessarily prevent this treatment. Indeed, at least one such nondiscrimination statute, the Church Amendment, applies nationwide and it has not stopped religious hospitals from being clear that they would not grant privileges to an abortion provider. *See, e.g*, Akbar Ahmed, *Court file Shows Confusion Over Wisconsin Abortion Regulation Law*, Milwaukee-Wisconsin J. Sentinel (July 26, 2013) (quoting an email from Rita Hanson, Chief Medical Officer at Wheaton Franciscan stating "Wheaton Franciscan Healthcare is a ministry of the Catholic church. [] For that reason, if it's known to us that a doctor performs abortions and that doctor applies for privileges at one of our hospitals, our hospital board would not grant privileges" and quoting an unnamed spokeswoman for Columbia St. Mary's Health System as stating that the organization would deny privileges to physicians who provide abortions "as a matter of our Catholic identity.").

did not have privileges.[25] This is especially significant for the 275,000 women of reproductive age living in the lower Rio Grande Valley near the Texas-Mexico border.[26] Since H.B. 2 went into effect, the only two abortion clinics located in the Valley have been forced to close because the abortion providers have been unable to obtain hospital privileges, leaving women in the Valley without a provider in the four county wide area.[27]

Restrictions on abortion access will lead to increased patient loads on the remaining abortion providers and will inevitably prevent some women from obtaining an abortion altogether.[28] Some women who are still able to access abortion will be required to travel farther to do so, which is likely to lead to delay.[29] Surveys of women who delay obtaining abortions have found that the time needed to raise money, including for travel, is one of the principal sources of delay in women obtaining an abortion.[30] Not surprisingly, the delays associated with obtaining resources and making arrangements to travel to an abortion provider are

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[25] Daniel Grossman et al., *The Public Health Threat of Anti-Abortion Legislation*, XX Contraception XX (XX 2013) (published online Nov. 6, 2013), *available at* http://www.contraceptionjournal.org/article/S0010-7824(13)00660-4/abstract.

[26] *Id.*

[27] *Id.*

[28] *Id.*

[29] *Id.*

[30] *See* Ushma D. Upadhyay et al., *Denial of Abortion Because of Provider Gestational Age Limits in the United States*, Am. J. Pub. Health (2013) (published online Aug. 15, 2013), *available at* http://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2013.301378; *see also* Linda A. Bartlett et al., *Risk Factors for Legal Induced Abortion-Related Mortality in the United States*, 103 Obstetrics & Gynecology 729 (Apr. 2004).

most prevalent among lower income women.[31] This is particularly problematic in Texas where 40% of women seeking abortions are at or below 100% of the Federal Poverty Guidelines and where many of these women already have to travel some distance to the nearest abortion provider.[32]

As one example, as a result of the closures of the only two clinics in the lower Rio Grande Valley, the closest abortion provider for the more than quarter of a million women of reproductive age living in that area is now 150 miles away and the closest ambulatory surgical center ("ASC") is 250 miles away. This distance adds approximately eight hours of travel time for women in the Valley, which is likely to be prohibitive for many women.[33] Even for women who do have the resources to travel, the travel required may force some women to delay their procedures until later in pregnancy, which, as discussed below, increases their exposure to complications and risks.[34] This is particularly problematic in Texas because after fifteen weeks of gestation an abortion must be performed in an ASC, and ASCs are located only in a few cities.

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[31] *See* Ushma D. Upadhyay et al., *Denial of Abortion Because of Provider Gestational Age Limits in the United States*, Am. J. Pub. Health (2013) (published online Aug. 15, 2013), *available at* http://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2013.301378; *see also* Grossman et al., *supra* note 25.

[32] ROA.370-71.

[32] *Id*.

[33] Grossman et al., *supra* note 25. Moreover, if a woman needs to obtain a medical abortion, Texas law would require a woman to travel these distances at least three times. *Id*.

[34] *Id*.

Delays in obtaining an abortion, such as those that are likely to occur as a result of H.B. 2, endanger women's health. While abortion procedures are among the safest medical procedures, the risk of complications associated with abortion procedures increases with the length of the pregnancy.[35] Medical studies consistently show that the mortality rate for abortion-related deaths in the first trimester, when almost nine in ten abortions are performed, is no more than four in one million abortions,[36] but increases to one death per 11,000 when an abortion is performed at 21 weeks or later.[37] Moreover, in some instances, the added burden imposed by the privileges requirement will prevent women from obtaining safe abortions altogether, which could lead some women to self-induce abortion. Indeed, Texas already has a higher-than-national average of attempts to self-induce an abortion and evidence suggests that such attempts will become more common under H.B. 2.[38] H.B. 2 presents risks to women's health by restricting and delaying access to safe abortion, and, accordingly, should be set aside.

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[35] Bartlett et al., *supra* note 30.

[36] Rachel Benson Gold & Elizabeth Nash, *TRAP Laws Gain Political Traction While Abortion Clinics – and the Women They Serve – Pay the Price*, 16 Guttmacher Pol'y Rev. 7 (Spring 2013) (citing Bartlett et al. *supra* note 30).

[37] Guttmacher Institute, *Facts on Induced Abortion in the United States* 2 (Oct. 2013), *available at* http://www.guttmacher.org/pubs/fb_indsuprauced_abortion.html; *see also* Karen Pazol et al., *Abortion Surveillance* (Nov. 23, 2012), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6108a1.htm?s_cid=ss6108a1_w#Tab25 (noting that complications are lowest early in pregnancy).

[38] Grossman et al., *supra* note 25; ROA.371-72; Rachel K. Jones, *How Commonly Do U.S. Abortion Patients Report Attempts to Self-Induce?*, 204 Am. J. Obstetrics & Gynecology 1 (2011).

III. The District Court's Limited Prohibition on Enforcement of Medical Abortion Provisions Should be Upheld.

H.B. 2 also binds physicians who administer medical abortions to an inferior protocol identified on the drug label approved by the Food and Drug Administration ("FDA") and to the dosage amount described in certain ACOG guidelines, denying Texas women the benefits of past, current, and future medical advancements. Although this Court has not been asked to review H.B. 2's broad ban on evidence-based medical abortion protocols, the State is challenging the district court's prohibition on the enforcement of H.B. 2's medical abortion provisions in situations when medical abortion would be significantly safer for the woman than any alternative procedure. A description of the current state of medical knowledge on a number of points—including various benefits associated with evidence-based medical abortion regimens and the existence of health conditions where medical abortion is preferred over surgical abortion—makes clear why this Court should uphold the district court's limited prohibition on enforcement.

The practice of medicine should be based on the latest scientific research and medical advances. Absent a substantial public health justification, legislatures should not interfere with patient care, medical decisions, and the patient-physician

relationship.[39] Laws that mandate a medical abortion treatment protocol that goes against best medical practice guidelines are dangerous to patient health.[40] Even laws that mandate a protocol that is valid at the time of the law's enactment are ill-advised because medical knowledge is not static.[41] As knowledge advances, medical treatments enshrined within such laws become outdated, denying patients the best evidence-based care.[42]

As a result of three decades of studies of various medical abortion regimens, a number of evidenced-based regimens have emerged that make medical abortion safer, faster, and less expensive, and that result in fewer complications as compared to the protocol approved by the FDA over 13 years ago. In October 2005, ACOG issued its Practice Bulletin No. 67 on the Medical Management of Abortion ("Practice Bulletin No. 67"), which concluded, among other things, that then-available good and consistent scientific evidence demonstrated that, as compared with the FDA-approved regimen, regimens using 200 mg of mifepristone orally and 800 µg of misoprostol vaginally were associated with better outcomes, fewer side effects, and lower cost for women with pregnancies up

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[39] ACOG, Statement of Policy, *Legislative Interference with Patient Care, Medical Decisions, and the Patient-Physician Relationship* (May 2013), *available at* http://www.acog.org/~/media/Statements%20of%20Policy/Public/2013LegislativeInterference.pdf.

[40] *Id.*

[41] *Id.*

[42] *See id.*

to 63 days of gestation.[43] Practice Bulletin No. 67 also concluded that a patient could administer misoprostol safely and effectively, orally or vaginally, in her home,[44] eliminating the need for an additional visit to a health center and allowing the patient greater control over the time and place of her abortion. Thus, the state of scientific research and evidence, as of at least 2005, supported the use of certain alternative regimens over the FDA-approved regimen, which had been approved several years earlier.

Indeed, it is common for medical practice to advance beyond what is described on FDA drug labels. The FDA allows "off-label" use of registered products—meaning use that is not expressly provided for in an FDA-approved label—when existing medical evidence supports such use.[45] Accordingly, prescribing medication off-label "is common in every field of medicine, and in a

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[43] ACOG, Practice Bulletin No. 67, Medical Management of Abortion, 8 (Oct. 2005). ACOG's guidelines are designed to aid practitioners in making decisions about appropriate patient care, but do not dictate an exclusive course of treatment or procedure. *See id*. at 1. *See generally*, ACOG, *Reading the Medical Literature*, http://www.acog.org/Resources_And_Publications/Department_Publications/Reading_the_Medical_Literature (last visited Dec. 18, 2013) (describing in detail ACOG's methodical and comprehensive guideline development process).

[44] *See* ACOG, Practice Bulletin No. 67, Medical Management of Abortion, 8 (Oct. 2005).

[45] FDA Drug Bulletin, Vol. 12, No. 1, *Use of Approved Drugs for Unlabeled Indications*, 4-5 (Apr. 1982) (off-label use "may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature."). Although the FDA has regulatory authority over the manufacturers of drugs and medical devices, it does not regulate physicians and the practice of medicine as such. *Id*. Off-label use is also supported by the medical community. *See, e.g.*, Am. Medical Ass'n, Policy H-120.988 Patient Access to Treatments Prescribed by Their Physicians, *available at* https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fH-120.988.HTM (confirming the AMA's strong support for the proposition that "a physician may lawfully use an FDA approved drug product or medical device for an unlabeled indication when such use is based upon sound scientific evidence and sound medical opinion").

large number of fields most patients are prescribed at least one drug off-label."[46] For example, the FDA has only approved misoprostol for treatment of gastric ulcers,[47] yet the current FDA-approved label for mifepristone expressly instructs providers to use misoprostol in combination with mifepristone for medical abortions[48] and misoprostol is commonly used in obstetrics off-label for, among other things, cervical ripening, induction of labor, postabortion care, medical management of miscarriage, and treatment of postpartum hemorrhage.[49]

While H.B. 2 also permits the provision of "the abortion-inducing drug in the dosage amount prescribed by the clinical management guidelines defined by the [ACOG] Practice Bulletin as those guidelines existed on January 1, 2013,"[50] this too is problematic both because it selects only the dosage aspect of the evidence-based regimens described in the guidelines (and not the timing, location,

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[46] Alexander T. Tabarrok, *Assessing the FDA via the Anomaly of Off-label Drug Prescribing*, V(1) The Independent Review 25, 26 (Summer 2000) (collecting studies, including ones showing that 56% of cancer patients, 81% of AIDS patients, 80 to 90% of pediatric patients, and 23% of pregnant women have been prescribed at least one drug off-label). *See also* William F. Rayburn & Gayla L. Turnbull, *Off-Label Drug Prescribing on a State University Obstetric Service*, 40 J. of Reprod. Med. 186, 186-87 (Mar. 1995) (concluding that 23% of patients attending a prenatal clinic took one or more drugs for off-label indications); Marcio A. da Fonseca & Paul Casamassimo, *Old Drugs, New Uses*, 33 Pediatr. Dent. 67, 67 (Jan./Feb. 2011) (stating that as much as 50% of pediatric use of medications is considered off-label).

[47] Cytotec (misoprostol) FDA label, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2002/19268slr037.pdf.

[48] Mifeprex (mifepristone) FDA label approved in September 2000, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.pdf.

[49] Scott G. Petersen et. al, *Can We Use a Lower Intravaginal Dose of Misoprostol in the Medical Management of Miscarriage? A Randomized Controlled Study*, 53 Australian & New Zealand J. of Obstetrics and Gynecology 64, 64 (2013); ACOG, Practice Bulletin No. 107, Induction of Labor 2 (Aug. 2009); ACOG, Committee Opinion No. 427, Misoprostol for Postabortion Care 1 (Feb. 2009); ACOG, Practice Bulletin No. 76, Postpartum Hemorrhage 3-4 (Oct. 2006).

[50] H.B. 2 Sec. 171.063(b).

and route of administration of misoprostol) and because it binds future care to a particular point in time in the past. In fact, the ACOG guidelines that existed on January 1, 2013, Practice Bulletin No. 67, were published *eight* years ago.[51] Since then, medical knowledge has continued to develop and advance, and the result of H.B. 2 will be to deny patients the benefits of those advancements.

Indeed, since ACOG Practice Bulletin No. 67 was published in 2005, more recent studies have shown that vaginal, sublingual, *and* buccal routes of misoprostol administration increase efficacy and increase the gestational age range for use as compared with the FDA-approved regimen[52] and that misoprostol can be safely self-administered at home.[53] Data also indicate that the overall risk of serious infection with medical abortion is very low and that buccal administration of misoprostol may result in a lower risk of serious infection compared with vaginal administration.[54] Research in medical care is always continuing; for medical abortion, continued research demonstrates advances every year, with the

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[51] ACOG periodically, but not continually, updates its guidelines to keep up with the ever-evolving nature of the practice of medicine. ACOG reviews its Practice Bulletins every 18 to 24 months to assess currency and accuracy, and will reaffirm a Bulletin unless it contains information that is incorrect or harmful. When ACOG's review indicates that advances in the medical evidence warrant a revision to the document, ACOG will begin a process for revising a Practice Bulletin that takes up to 24 months to complete.

[52] *See* Cleland et al., *supra* note 8 at 166; Eric A. Schaff, *Mifepristone: Ten Years Later*, 81(1) Contraception 1, 1-7 (Jan. 2010) ("Schaff, *Mifepristone*").

[53] *See* Thoai D. Ngo et al., *Comparative Effectiveness, Safety and Acceptability of Medical Abortion at Home and in a Clinic: A Systematic Review*, 89 Bull World Health Organ. 360 (concluding that home-based self-administration of misoprostol as part of mifepristone-misoprostol medical abortion was safe and effective under the conditions in place in the included studies).

[54] Cleland et al., *supra* note 8 at 166-71; Mary Fjerstad et al., *Rates of Serious Infection After Changes in Regimens for Medical Abortion*, 361 N. Eng. J Med. 145, 145-151 (Oct. 2009).

development of newer, evidence-based regimens that make medical abortion safer, faster, less expensive, and result in fewer side effects, and that are superior to the FDA-approved regimen.[55] In fact, evidence-based regimens through at least 63 days of gestation are safer and more effective than the FDA-approved regimen up to 49 days of gestation.[56] As with any medical care, treatments that are safer and more effective are medically preferable. Unfortunately, because of H.B. 2, physicians in Texas now face punishment should they apply these and other medical advances and knowledge when caring for their patients. Moreover, were ACOG to publish a revised Practice Bulletin based on the most up to date and best medical evidence, under H.B. 2 physicians will be punished for following the protocols outlined in the updated Bulletin by virtue of the fact that the Bulletin would not have existed "as of January 2013."[57]

H.B. 2's restriction on the regimens that can be used for medical abortions is harmful to women. The law is flatly at odds with AMA and ACOG's missions to foster improvements in all aspects of health care for women. There is also no

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[55] *See* Regina Kulier et al., *Medical Methods for First Trimester Abortion*, Cochrane Database of Systematic Reviews, Issue 11 (2011); Schaff, *Mifepristone supra* note 52.

[56] After 49 days of gestation, the efficacy of the FDA-approved regimen declines significantly, and the likelihood of continuing pregnancy increases. Mitchell D. Creinin & Irving M. Spitz, *Use of Various Ultrasonographic Criteria to Evaluate the Efficacy of Mifepristone and Misoprostol for Medical Abortion*, 181 Am. J. Obstetrics & Gynecology 1419, 1419-24 (1999). However, regimens using vaginal, sublingual and buccal misoprostol provide efficacy rates up to 63 days of gestation that exceed the approximately 92% efficacy of the FDA-approved regimen up to 49 days of gestation. Irving M. Spitz et al., *Early Pregnancy Termination with Mifepristone and Misoprostol in the United States*, 338 New Eng. J. Med. 1241, 1241-1247 (Apr. 1998); Kulier et al., *supra* note 55; Schaff, *Mifepristone supra* note 52; Cleland et al., *supra* note 8 at 166-71.

[57] *See* Grossman et al., *supra* note 25.

substantial public health justification underlying H.B. 2's restriction on medical abortion. Although concerns about serious, rare, and deadly infection with clostridial bacteria in women having medical abortion has been raised, it has since become evident that there is no specific connection between clostridial organisms and medical abortion.[58] As noted above, good and consistent scientific evidence supports the use of evidence-based protocols over the FDA-approved regimen.[59]

H.B. 2's restriction on the regimens that can be used for medical abortions is especially harmful to those women with certain medical conditions that make first-trimester medical abortions (even after 49 gestational days) recommended over other abortion methods, such as aspiration. Those conditions include certain

[58] Investigators have found these organisms also are associated with other obstetric and gynecological procedures, including spontaneous abortion, term delivery, surgical abortion, and medical procedures for cervical dysplasia. *See* A. L. Cohen et al., *Toxic Shock Associated with Clostridium Sordellii and Clostridium Perfringens After Medical and Spontaneous Abortion*, 110 Obstetrics & Gynecology 1027 (Nov. 2007); Christine S. Ho et al., *Undiagnosed Cases of Fatal Clostridium-Associated Toxic Shock in Californian Women of Childbearing Age*, 201 Am. J. Obstetrics & Gynecology 459 (2009).

[59] That there have been eight infection-related deaths reported to the FDA that involved the vaginal and buccal administration of misoprostol versus no infection-related deaths reported to the FDA that involved the FDA-approved regimen is of no import because the regimen approved by the FDA has been disfavored and not widely used for many years. *See FDA's Mifepristone U.S. Postmarketing Adverse Events Summary through 04/30/2011*, http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf (summarizing reported adverse events); Melanie M.J. Wiegerinck et al., *Medical Abortion Practices: A Survey of National Abortion Federation Members in the United States*, 78 Contraception 486, 488 (2008) (finding that in 2001"[t]he combination of 200 mg mifepristone followed by home use of 800 mcg vaginally administered misoprostol, commonly referred to as the alternative or evidence-based regimen, was used by 83% of facilities. The FDA approved regimen…was used in only 4% of facilities."). According to the aforementioned FDA adverse report data, through April 2011, approximately 1.52 million women used mifepristone in the U.S., resulting in a fatality rate due to infection of 0.0005 percent, which is extremely low. Given the infrequent use of the FDA approved regimen, one would not expect to see any deaths associated with the small set of women that have received medical abortion that followed the FDA approved regimen.

uterine anomalies and a stenotic (narrow) cervix.[60] Appellants have incorrectly stated that "[b]efore the FDA approved the Mifeprex regimen in 2000, abortion patients could not obtain any drug-induced abortions, no matter how impractical or risky a surgical abortion might be for any individual patient."[61] In fact, prior to 2000, medical abortions using other drug regimens, that did not include mifepristone, were recommended in lieu of aspiration or other instrumental methods for patients with the medical conditions described above.[62] The passage of H.B. 2 imposes a new prohibition on the use of non-mifepristone regimens since those regimens, too, are not approved by the FDA. As a result, women whose gestation exceeds 49 days and who have medical conditions that require medical abortion, are unable to obtain a medical abortion despite strong medical need, leaving them worse off than they would have been before 2000.

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60 Eric A. Schaff et al., *Methotrexate and Misoprostol When Surgical Abortion Fails*, 87(3) Obstetrics & Gynecology 450-452 (Mar. 1996) ("Schaff, *Methotrexate*"); Mitchell D. Creinin et al., *Medically Induced Abortion in a Woman With a Large Myomatous Uterus*, 175(5) Am. J. Obstetrics & Gynecology 1379-80 (Nov. 1996); *see also* ROA.1551 (stating that such conditions may arise in "women who are extremely obese, have uterine fibroids distorting normal anatomy, have a uterus that is very flexed, or have certain uterine anomalies [and] when a woman has a condition known as stenotic cervix-a cervix with an abnormally small opening, often caused by scarring from prior surgeries [or when] a woman has undergone female genital mutilation.").

61 Appellants' Br. 34.

62 *See* Schaff, *Methotrexate supra* note 60; Creinin et al., *supra* note 60. Methotrexate is FDA-approved for treatment of certain cancers, psoriasis, and rheumatoid arthritis. Methotrexate Injection, USP FDA label, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/011719s117lbl.pdf. Misoprostol is FDA-approved for use relating to gastric ulcers. Cytotec (misoprostol) FDA label, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2002/19268slr037.pdf. Practice Bulletin No. 67 concludes that "[m]ifepristone-misoprostol regimens using 200 mg of mifepristone orally and 800 µg of misoprostol vaginally are generally preferred to regimens using methotrexate and misoprostol or misoprostol only for medical abortion." ACOG, Practice Bulletin No. 67 at 8.

In light of the foregoing, and while reaffirming its opposition to H.B. 2's medical abortion provisions as a whole, *amici* urge this Court to uphold the district court's limited prohibition on the enforcement of the medical abortion provisions "where a physician determines in appropriate medical judgment, such a procedure is necessary for the preservation of the life or health of the mother."[63] The district court's limited prohibition would, at least, provide physicians some additional flexibility in the limited, but important, circumstances when the life or health of the patient may require administration of medical abortions through evidence-based protocols.

CONCLUSION

For the foregoing reasons, *amici* urge the Court to uphold the district court's decision.

[63] ROA.1559.

December 19, 2013

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because this brief contains 6,416 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in 14-point font size and Times New Roman type style.

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CERTIFICATE OF SERVICE

I hereby certify that, on December 19, 2013, I electronically filed the foregoing Brief of *Amici Curiae* American College of Obstetricians and Gynecologists and the American Medical Association in Support of Plaintiffs-Appellees and In Support of Affirmance with the Clerk of Court by using the CM/ECF system, which will send a notice of electronic filing to counsel for the parties and *amici curiae*:

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