

No. 15-274

IN THE
Supreme Court of the United States

WHOLE WOMAN'S HEALTH, *et al.*,
Petitioners,

v.

KIRK COLE, M.D., *et al.*,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

BRIEF FOR AMICI CURIAE AMERICAN COLLEGE
OF OBSTETRICIANS AND GYNECOLOGISTS,
AMERICAN MEDICAL ASSOCIATION, AMERICAN
ACADEMY OF FAMILY PHYSICIANS, AND
AMERICAN OSTEOPATHIC ASSOCIATION
IN SUPPORT OF PETITIONERS

KIMBERLY A. PARKER
Counsel of Record
SKYE L. PERRYMAN
EMILY L. STARK
JESSICA E. NOTEBAERT
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Ave., NW
Washington, DC 20006
(202) 663-6000
kimberly.parker@wilmerhale.com

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	iii
STATEMENT OF INTEREST OF AMICI CURIAE	1
INTRODUCTION AND SUMMARY OF ARGUMENT.....	4
ARGUMENT.....	5
I. H.B. 2'S ASC REQUIREMENT IMPOSES MEDICALLY UNNECESSARY DEMANDS ON ABORTION FACILITIES AND SERVES NO MEDICAL PURPOSE	5
A. Abortion Is An Extremely Safe Medical Procedure And No Medical Evidence Suggests That Abortion Would Be Safer If Performed In An ASC Setting	6
B. H.B. 2's ASC Requirement Imposes Medically Unnecessary Demands On Abortion Facilities	9
1. Abortion procedures do not require the full operating theater or external sterility precautions that are mandated by H.B. 2	10
2. Office-based surgery is common and Texas law does not require that facilities performing procedures with higher mortality rates than abortion meet the standards for ASCs	12

TABLE OF CONTENTS—Continued

	Page
II. H.B. 2’S PRIVILEGES REQUIREMENT DOES NOT SERVE THE HEALTH OF WOMEN IN TEXAS.....	14
A. Clinicians Are Denied Medical Privileges For Reasons Unrelated To Their Competency	15
B. H.B. 2’s Privileges Requirement Is Inconsistent With Accepted Medical Practice And Provides No Benefit To Patient Care Or Health Outcomes	16
CONCLUSION	21

TABLE OF AUTHORITIES

CASES

	Page(s)
<i>Planned Parenthood Southeast, Inc. v. Strange</i> , 33 F. Supp. 3d 1330 (M.D. Ala. 2014)	20
<i>Planned Parenthood of Wisconsin, Inc. v. Van Hollen</i> , 738 F.3d 786 (7th Cir. 2013)	19, 20
<i>Planned Parenthood of Wisconsin, Inc. v. Van Hollen</i> , No. 13-465, 2015 WL 1285829 (W.D. Wis. Mar. 20, 2015)	19, 20

STATUTORY PROVISIONS

22 Tex. Admin. Code §§ 192.1-192.6.....	14
25 Tex. Admin. Code	
§ 135.52.....	11
§ 139.56.....	18
Tex. Health & Safety Code Ann.	
§ 171.0031.....	19
§ 171.004.....	6
§ 245.004.....	5

LEGISLATIVE MATERIALS

Texas House Bill 2 (2013)	<i>passim</i>
---------------------------------	---------------

TABLE OF AUTHORITIES—Continued

Page(s)

EXECUTIVE MATERIALS

<i>Whether Abortion Facilities that are Exempt from Licensing Under Section 245.004 of the Health and Safety Code are Subject to Regulation by the Texas Department of Health Under Chapter 245, Op. No. GA-0212 (Tex. Att’y Gen. July 7, 2004), available at https://www.texasattorneygeneral.gov/opinions/opinions/50abbott/op/2004/htm/ga0212.htm#N_4_.....</i>	6
--	---

OTHER AUTHORITIES

ACOG, Committee on Health Care for Underserved Women, <i>Opinion Number 613, Increasing Access to Abortion</i> (2014), available at http://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/co613.pdf?dmc=1&ts=20150930T1613286031	5, 10
ACOG, Committee on Patient Safety & Quality Improvement, <i>Opinion Number 459, The Obstetric-Gynecologic Hospitalist</i> (2010), available at http://www.acog.org/-/media/Committee-Opinions/Committee-on-Patient-Safety-and-Quality-Improvement/co459.pdf?dmc=1&ts=20150930T1631363865	17
ACOG, <i>Frequently Asked Questions, Dilation and Curettage</i> (2012), available at http://www.acog.org/-/media/For-Patients/faq062.pdf?dmc=1&ts=20150930T1632419491	8

TABLE OF AUTHORITIES—Continued

	Page(s)
ACOG, <i>Frequently Asked Questions, Induced Abortion</i> (2015), available at http://www.acog.org/-/media/For-Patients/faq043.pdf?dmc=1&ts=20150930T1633507149	8
ACOG, <i>Guidelines for Women’s Health Care: A Resource Manual</i> (4th ed. 2014)	7, 10, 17
ACOG, <i>Patient Education Pamphlets: Colposcopy</i> (2013).....	12
ACOG, <i>Patient Education Pamphlets: Endometrial Hyperplasia</i> (2012).....	12
ACOG, <i>Patient Education Pamphlets: Loop Electrosurgical Excision Procedure</i> (2013).....	12
ACOG, <i>Practice Bulletin Number 143, Medical Management of First-Trimester Abortion</i> (2014), available at http://www.acog.org/-/media/Practice-Bulletins/Committee-on-Practice-Bulletins---Gynecology/Public/pb143.pdf?dmc=1&ts=20150930T1644381068	10
ACOG, <i>Statement of Policy, Legislative Interference with Patient Care, Medical Decisions, and the Patient-Physician Relationship</i> (2013), available at http://www.acog.org/-/media/Statements-of-Policy/Public/2013LegislativeInterference.pdf?dmc=1&ts=20150930T1625461514	5
Allen, Rebecca H., et al., <i>Pain Relief for Obstetric and Gynecologic Ambulatory Procedures</i> , 40 <i>Obstetrics & Gynecology Clinics N. Am.</i> 625 (2013)	13

TABLE OF AUTHORITIES—Continued

	Page(s)
American Society for Gastrointestinal Endoscopy, <i>Complications of Colonoscopy</i> , 74 J. Gastrointestinal Endoscopy 745 (2011).....	14
Dennis, Amanda, et al., <i>Barriers to and Facilitators of Moving Miscarriage Management Out of the Operating Room</i> , 47 Persp. on Sexual & Reprod. Health 141 (2015)	13
Godfrey, Emily M., et al., <i>Early Pregnancy Loss Needn't Require a Trip to the Hospital</i> , 58 J. Fam. Prac. 585 (2009)	13
Grazer, Frederick M. & Rudolph H. de Jong, <i>Fatal Outcomes from Liposuction: Census Survey of Cosmetic Surgeons</i> , 105 Plastic & Reconstructive Surgery 436 (2000)	14
Grimes, David A., et al., <i>Abortion Facilities and the Risk of Death</i> , 13 Fam. Plan. Persp. 30 (1981).....	9
Grimes, David A., et al., <i>Comparative Risk of Death from Legally Induced Abortion in Hospitals and Nonhospital Facilities</i> , 51 Obstetrics & Gynecology 323 (1978).....	9
Grossman, Daniel, et al., <i>The Public Health Threat of Anti-Abortion Legislation</i> , 89 Contraception 73 (2014).....	16
Institute of Medicine, <i>Crossing the Quality Chasm: A New Health System for the 21st Century</i> (2001)	16, 18

TABLE OF AUTHORITIES—Continued

	Page(s)
Joyce, Theodore, <i>The Supply-Side Economics of Abortion</i> , 365 <i>New Eng. J. Med.</i> 1466 (2011)	8
Lohr, Patricia A. & Richard Lyus, <i>Dilatation and Evacuation</i> , in <i>Abortion Care</i> 88 (Sam Rowlands ed., 2014).....	12
National Abortion Federation, <i>2015 Clinical Policy Guidelines</i> (2015)	17
Nichols, Mark, et al., <i>A Comparative Study of Hysteroscopic Sterilization Performed In-Office Versus a Hospital Operating Room</i> , 13 <i>J. Minimally Invasive Gynecology</i> 447 (2006)	13
Paul, Maureen, <i>Office Management of Early Induced Abortion</i> , 42 <i>Clinical Obstetrics & Gynecology</i> 290 (1999)	9, 12
Peacock, Lisa M., et al., <i>Transition to Office-Based Obstetric and Gynecologic Procedures: Safety, Technical, and Financial Considerations</i> , 58 <i>Clinical Obstetrics & Gynecology</i> 418 (2015).....	8, 9, 13
Prine, Linda W. & Honor MacNaughton, <i>Office Management of Early Pregnancy Loss</i> , 84 <i>Am. Fam. Physician</i> 75 (2011)	9
Raymond, Elizabeth G. & David A. Grimes, <i>The Comparative Safety of Legal Induced Abortion and Childbirth in the United States</i> , 119 <i>Obstetrics & Gynecology</i> 215 (2012)	6, 7

TABLE OF AUTHORITIES—Continued

	Page(s)
Rock, John A. & Howard W. Jones III, <i>TE Linde's Operative Gynecology</i> (10th ed. 2011)	8, 11
Soffen, Kim, <i>How Texas Could Set National Template for Limiting Abortion Access</i> , N.Y. Times, Aug. 19, 2015, http://www.nytimes.com/2015/08/20/upshot/how-texas-could-set-national-template-for-limiting-abortion-access.html?_r=0	18
Texas Department of State Health Services, <i>2014 Healthy Texas Babies: Data Book</i> (2014)	7
Texas Department of State Health Services, <i>Vital Statistics Annual Reports</i> , http://www.dshs.state.tx.us/chs/vstat/annrpts.shtm (last updated Sept. 14, 2015)	7, 8, 13
Upadhyay, Ushma D., et al., <i>Incidence of Emergency Department Visits and Complications After Abortion</i> , 125 <i>Obstetrics & Gynecology</i> 175 (2015).....	7, 18
Urman, Richard D., et al., <i>Safety Considerations for Office-Based Obstetric & Gynecologic Procedures</i> , 6 <i>Revs. Obstetrics & Gynecology</i> e8 (2013).....	13
Weitz, Tracy A., et al., <i>Safety of Aspiration Abortion Performed by Nurse Practitioners, Certified Nurse Midwives, and Physician Assistants Under a California Legal Waiver</i> , 103 <i>Am. J. Pub. Health</i> 454 (2013).....	8

STATEMENT OF INTEREST OF AMICI CURIAE

The American College of Obstetricians and Gynecologists (the “College” or “ACOG”), the American Medical Association (“AMA”), the American Academy of Family Physicians (“AAFP”), and the American Osteopathic Association (“AOA”) submit this amici curiae brief in support of Petitioners.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 the health care 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, including 2,532 obstetrician-gynecologists in Texas, the College and the Congress are the leading professional associations of physicians who specialize in the health care of women.

The College and the Congress recognize that abortion is an essential health care service and oppose laws regulating medical care that are unsupported by scien-

¹ No counsel for a party authored this brief in whole or in part and no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of the brief. No person or entity other than amici or their counsel made a monetary contribution to the preparation or submission of this brief. Emails from the parties granting consent to the filing of this brief are on file with the Clerk of the Court.

tific evidence and that are not necessary to achieve an important public health objective.

The College has previously appeared as *amicus curiae* in various courts throughout the country, including this Court. In addition, the College's work has been cited by numerous courts seeking authoritative medical data regarding childbirth and abortion.

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 policymaking 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. This Court and the federal Courts of Appeal have cited the AMA's publications and *amicus curiae* briefs in cases implicating a variety of medical questions.

AAFP is headquartered in Leawood, Kansas, and is the national medical specialty society representing family physicians. Founded in 1947 as a not-for-profit corporation, its 120,900 members are physicians and medical students from all 50 states, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, and the Uniformed Services of the United States. The AAFP seeks to improve the health of patients, families, and communities by advocating for the health of the public and serving the needs of members with professionalism and creativity.

AOA, established in 1897, is the national professional association for the more than 110,000 osteopathic physicians (Doctors of Osteopathic Medicine or DOs) and medical students enrolled in accredited colleges of osteopathic medicine in the United States. This includes more than 3,500 osteopathic physicians who practice in the specialty of obstetrics and gynecology. The AOA is recognized by the United States Department of Education as the accrediting agency for colleges of osteopathic medicine. Since 1943, the AOA's American Osteopathic Board of Obstetrics and Gynecology has offered a program of specialty and subspecialty board certification for osteopathic obstetricians and gynecologists. The AOA is dedicated to promoting public health, to encouraging scientific research, and to maintaining and improving high standards of osteopathic medical education.

INTRODUCTION AND SUMMARY OF ARGUMENT

Reproductive healthcare is essential to a woman's overall health, and access to abortion is an important component of reproductive healthcare. When state legislatures enact laws that restrict access to abortion without any valid medical justification, they jeopardize women's health. Texas is one of a number of states that has enacted such legislation.

Passed in 2013, Texas House Bill ("H.B.") 2 requires that the majority of abortion providers in Texas conform to the standards of ambulatory surgical centers (the "ASC requirement"), notwithstanding that the legal abortions performed in Texas prior to the passage of H.B. 2 met or exceeded safety expectations for outpatient medical procedures. H.B. 2 also requires that abortion providers obtain admitting privileges at local hospitals (the "privileges requirement") without regard to the many reasons, unrelated to a clinician's technical competence, that can make it difficult or impossible to obtain such privileges.

H.B. 2's ASC requirement and privileges requirement are contrary to accepted medical practice and are not based on scientific evidence. They fail to enhance the quality or safety of abortion-related medical care and, in fact, impede women's access to such care by imposing unjustified and medically unnecessary burdens on abortion providers. Accordingly, without this Court's review, H.B. 2 would deprive women in Texas of quality, evidence-based medical care and their recognized rights under the U.S. Constitution.

For these and the reasons discussed more fully below, amici curiae, leading medical societies whose policies represent the considered judgments of the many

physicians in this country, urge the Court to grant Petitioners' request for a writ of certiorari so that the Court may consider the compelling question of whether H.B. 2 withstands constitutional muster.²

ARGUMENT

The Court's review of the decision below is critical to ensuring that women in Texas are not deprived of access to abortion care. Patient safety is of paramount importance to amici, but H.B. 2's ASC and privileges requirements do nothing to protect the health and safety of women and are incongruous with modern medical practice. Women's access to high-quality, evidence-based abortion care should not be limited by laws enacted under the guise of patient safety but that, in fact, harm women's health.³

I. H.B. 2'S ASC REQUIREMENT IMPOSES MEDICALLY UNNECESSARY DEMANDS ON ABORTION FACILITIES AND SERVES NO MEDICAL PURPOSE

H.B. 2's requirement that abortion facilities⁴ meet the standards for ASCs is devoid of any medical or sci-

² The history of legal challenges to H.B. 2 is set forth at Pet. 4-15.

³ See ACOG, Comm. on Health Care for Underserved Women, *Opinion Number 613, Increasing Access to Abortion* 3 (2014) (explaining that the College opposes medically unnecessary physical plant and admitting privileges requirements); ACOG, *Statement of Policy, Legislative Interference with Patient Care, Medical Decisions, and the Patient-Physician Relationship* (2013).

⁴ Under Texas law, the term "abortion facility" applies to providers of abortions, such as outpatient clinics, that are not hospitals, ASCs, or physicians' offices (unless the office performs more than fifty abortions in any twelve-month period). Tex. Health &

entific purpose.⁵ Texas has argued that abortion procedures would be safer if performed in ASCs,⁶ but there is no scientific or medical evidence to support this view. To the contrary, mandating that abortion facilities meet ASC standards deprives women of access to reproductive health care and is inconsistent with appropriate and accepted medical practice.

A. Abortion Is An Extremely Safe Medical Procedure And No Medical Evidence Suggests That Abortion Would Be Safer If Performed In An ASC Setting

Abortion is one of the safest medical procedures performed in the United States. Nationally, the risk of death resulting from an abortion is exceptionally low—0.6 per 100,000 (or 0.0006 percent).⁷ In Texas, publicly

Safety Code Ann. § 245.004; *Whether Abortion Facilities that are Exempt from Licensing Under Section 245.004 of the Health and Safety Code are Subject to Regulation by the Texas Department of Health Under Chapter 245*, Op. No. GA-0212, at n.4 (Tex. Att’y Gen. July 7, 2004). In this brief, amici use the terms “facilities” and “clinics” interchangeably.

⁵ Amici are aware that, in 2003, Texas enacted a law providing that abortions at sixteen weeks’ gestational age and later be performed only in ASCs or hospitals. Tex. Health & Safety Code Ann. § 171.004. Amici confine their statements here to abortions occurring prior to sixteen weeks’ gestational age, which were performed legally in clinics and physicians’ offices prior to the enactment of H.B. 2.

⁶ Pet. App. 25a (“The Texas Legislature’s stated purpose for enacting these provisions was to raise the standard and quality of care for women seeking abortions and to protect the health and welfare of women seeking abortions.”); Resp. C.A. Br. 13, 35-36.

⁷ Raymond & Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 *Obstet-*

available data suggests that the rate is even lower. According to Texas vital statistics data, 993,844 abortions have been performed between 2001 and 2013 (the years for which data is available online).⁸ Only five deaths were reported in this thirteen-year period, accounting for a mortality rate of 0.5 per 100,000 (or 0.0005 percent).⁹ From 2009 through 2013, there were zero reported deaths in 360,059 abortions performed in Texas.¹⁰ The risk of major complications from the procedure is similarly low. A recent study found an approximately 0.2 percent risk of major abortion complications that might require hospital care, surgery, or blood transfusion.¹¹ Another study found that the risk of ma-

rics & Gynecology 215, 216 (2012); *see also* ACOG, *Guidelines for Women's Health Care: A Resource Manual* 719 (4th ed. 2014).

⁸ The calculations in the text accompanying this note and several subsequent notes are based on annual abortion statistics compiled by the Texas Department of State Health Services in its *Vital Statistics Annual Reports*, <http://www.dshs.state.tx.us/chs/vstat/annrpts.shtm> (last updated Sept. 14, 2015).

⁹ *Id.*

¹⁰ *Id.* By contrast, the maternal mortality rate has been increasing since at least 2007. *See* Tex. Dep't of State Health Servs., *2014 Healthy Texas Babies: Data Book* 14 (2014). In 2011 (the latest year graphed by DSHS), the average maternal mortality rate was 24.4 per 100,000 live births (or 0.0244 percent); for black women, that rate was 67.3 per 100,000 (or 0.0673 percent). *Id.* In comparison, there were no abortion-related deaths in Texas in 2011. Similarly, one nationwide study found that the mortality risk associated with childbirth is approximately fourteen times higher than the risk associated with abortion. Raymond & Grimes, *supra* n.7, at 216.

¹¹ Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 *Obstetrics & Gynecology* 175, 176, 181 (2015) (using 2009-2010 data from California).

major complications (uterine perforation, infection, and hemorrhage) from first trimester abortions by the aspiration method, the most common method for obtaining an abortion in Texas, is even lower—0.05 percent.¹²

Outpatient clinics and physicians' offices are safe places to obtain abortions.¹³ In the five years during which Texas had no reported abortion-related deaths, the overwhelming majority of abortions—83 percent—were performed in these settings, not in ASCs or hospitals.¹⁴ From 2001 to 2013, when Texas statistics reflected an exceedingly low mortality rate of 0.5 per 100,000 abortions (or 0.0005 percent), 91 percent of abortions were performed in abortion facilities or physicians' offices.¹⁵ Nationally, 95 percent of abortions are performed in nonhospital settings.¹⁶ There is no medically sound reason to assume that abortions performed in a hospital or ASC setting would be safer than those

¹² 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 (2013) (using 2007-2011 data from California); DSHS, *Vital Statistics Annual Reports*, *supra* n.8.

¹³ See ACOG, *Frequently Asked Questions, Induced Abortion 1* (2015); ACOG, *Frequently Asked Questions, Dilation and Curettage 1* (2012); see also Rock & Jones, *TE Linde's Operative Gynecology* 783 (10th ed. 2011).

¹⁴ DSHS, *Vital Statistics Annual Reports*, *supra* n.8.

¹⁵ *Id.*

¹⁶ Rock & Jones, *supra* n.13, at 783; Peacock et al., *Transition to Office-Based Obstetric and Gynecologic Procedures: Safety, Technical, and Financial Considerations*, 58 Clinical Obstetrics & Gynecology 418, 427 (2015); see also Joyce, *The Supply-Side Economics of Abortion*, 365 New Eng. J. Med. 1466, 1466-1467 (2011) (94 percent).

performed in an abortion clinic or office. Indeed, scientific literature suggests that the safety of abortions performed in an office setting is equivalent to the safety of those performed in a hospital setting.¹⁷ There is, thus, no medical basis to mandate that abortion clinics meet the standards for ASCs.

B. H.B. 2's ASC Requirement Imposes Medically Unnecessary Demands On Abortion Facilities

Requiring that an abortion clinic meet the standards for ASCs is medically unnecessary because of the nature and relative simplicity of abortion procedures and because the complication rate associated with these procedures is exceptionally low. ASCs are meant to provide environments in which invasive surgeries historically performed in hospitals can be performed outside a hospital-based setting. Abortion procedures, however, do not require an incision into a woman's body and do not entail exposure of sterile tissue to the external environment, and performance of such procedures does not require a hospital-based or related outpatient setting.

¹⁷ Paul, *Office Management of Early Induced Abortion*, 42 *Clinical Obstetrics & Gynecology* 290, 292 (1999); Peacock, *supra* n.16, at 427 (“[F]irst-trimester aspiration abortions performed in an office are as safe as those performed in hospitals.” (citing Prine & MacNaughton, *Office Management of Early Pregnancy Loss*, 84 *Am. Fam. Physician* 75 (2011))); *see also* Grimes et al., *Abortion Facilities and the Risk of Death*, 13 *Fam. Plan. Persp.* 30, 31 (1981); Grimes et al., *Comparative Risk of Death from Legally Induced Abortion in Hospitals and Nonhospital Facilities*, 51 *Obstetrics & Gynecology* 323, 324 (1978).

1. Abortion procedures do not require the full operating theater or external sterility precautions that are mandated by H.B. 2

The physical plant requirements mandated by H.B. 2 are not necessary for abortion procedures.¹⁸ For example, an operating room—which is mandatory under H.B. 2—is unnecessary for abortions. First, an increasingly large percentage of abortion patients are opting for medication abortion (*i.e.*, taking prescription pills that cause abortion), rather than surgical abortions. No designated procedure space is required for these abortions because they involve taking pills to induce pregnancy termination, which then typically occurs at home.¹⁹

Second, even surgical abortions do not require an operating room. To conduct first-trimester surgical abortions, clinicians will have the patient recline on an examination table fitted with stirrups, taking the same position as for many gynecological exams. The number of personnel involved is minimal; little is required by way of equipment. These procedures are not commonly

¹⁸ Current ACOG guidelines, which (in contrast to the Texas regulations) provide evidence-based information to practitioners based on well-accepted medical practice, already recommend physical plant standards for clinics and offices. *See* ACOG, *Guidelines for Women's Health Care*, *supra* n.7, at 142-143. They oppose, however, facility requirements, including those that require facilities to meet the physical plant standards of hospitals, that are enacted under the guise of patient safety but that impose medically unnecessary requirements designed to reduce access to abortion. ACOG, *Opinion Number 613*, *supra* n.3, at 3.

¹⁹ *See* ACOG, *Practice Bulletin Number 143, Medical Management of First-Trimester Abortion 2-3* (2014) (providing current evidence-based guidelines for medication abortion).

performed using general anesthesia, so designated space for equipment storage associated with general anesthesia is not generally required.²⁰ Surgical abortions simply do not require the size, layout, or equipment of a full operating theater.

Moreover, many of the burdensome construction requirements contained in the ASC regulations that are designed to maintain a sterile environment, such as restricted-access surgical suites, one-way traffic flow patterns, scrub equipment, and special ventilation units, are unnecessary in abortion clinics.²¹ This is because clinicians performing abortions access the uterus through the vagina, which is known as a “clean-contaminated field” and is not naturally a sterile space. Therefore, “[r]outine sterile precautions (*e.g.*, drapes, caps, masks, and gowns) are unnecessary”²² under accepted medical practice for abortions. Indeed, accepted medical practice requires only that the clinician use sterile instruments and employ a “no-touch” technique,

²⁰ In any event, as noted below, Texas law does not require other procedures that require even general anesthesia to be performed in a facility that meets ASC standards. *See infra* n.27 and accompanying text.

²¹ One specific example of a structural element designed to maintain a highly sterile environment in ASCs that is unnecessary in the abortion context is the requirement that ASCs have operating rooms with ceilings that are “monolithic from wall to wall ... , smooth and without fissures, open joints, or crevices and with a washable and moisture impervious finish.” 25 Tex. Admin. Code § 135.52(f)(5)(C). While such a requirement may be advisable for procedures where sterile body tissue is exposed, abortions are not such procedures and such stringent construction regulations are unnecessary.

²² Rock & Jones, *supra* n.13, at 784.

“which ensures that the tips of instruments never contact non-sterile surfaces before entering the uterus.”²³

The Respondents’ argument before the Fifth Circuit—that the external sterility requirements for ASCs are necessary for abortion procedures because “surgical abortion involves invasive entry into the uterus,”²⁴—ignores the fact that unlike some other obstetric and gynecological procedures (such as cesarean deliveries and abdominal hysterectomies), surgical abortions do not involve exposure of the uterus to the external environment. For this reason (among others), ensuring the sterility of the portion of the surgical instruments that make contact with the uterus is sufficient to achieve the sterility needed for the procedure. In short, there has never been a substantial argument in any accepted scientific or medical literature that further sterility precautions would improve the already exceptionally low complication rate associated with abortions.

2. Office-based surgery is common and Texas law does not require that facilities performing procedures with higher mortality rates than abortion meet the standards for ASCs

Office-based surgery is common and for many gynecological procedures it is the prevailing practice.²⁵

²³ Lohr & Lyus, *Dilatation and Evacuation*, in *Abortion Care* 88, 95 (Rowlands ed., 2014); see also Paul, *supra* n.17, at 293-294.

²⁴ See Pet. App. 31a; Resp. C.A. Br. 13.

²⁵ See, e.g., ACOG, *Patient Education Pamphlets: Colposcopy* (2013); ACOG, *Patient Education Pamphlets: Endometrial Hyperplasia* (2012); ACOG, *Patient Education Pamphlets: Loop*

For example, incomplete miscarriages are commonly treated in office settings via uterine aspiration, which is the same procedure as that used for the majority of induced abortion procedures covered by H.B. 2.²⁶

Texas permits physicians to perform surgical and other procedures in an office setting, including surgical procedures with complication and mortality rates simi-

Electrosurgical Excision Procedure (2013); Allen et al., *Pain Relief for Obstetric and Gynecologic Ambulatory Procedures*, 40 *Obstetrics & Gynecology Clinics N. Am.* 625, 631-640 (2013) (colposcopy, cervical biopsy, cervical dilation and uterine aspiration, IUD insertion, endometrial biopsy, hysteroscopy); Nichols et al., *A Comparative Study of Hysteroscopic Sterilization Performed In-Office Versus a Hospital Operating Room*, 13 *J. Minimally Invasive Gynecology* 447, 449 (2006); Peacock, *supra* n.16 (hysteroscopy, IUD retrievals, sterilization, uterine evacuation (including dilation and aspiration), among other procedures); Urman et al., *Safety Considerations for Office-Based Obstetric and Gynecologic Procedures*, 6 *Revs. Obstetrics & Gynecology* e8, e14 (2013) (“There is no evidence to substantiate office-based gynecologic procedures being inherently unsafe. On the contrary, gynecologists can perform procedures in the office setting in a safe, effective, efficient, patient-centered fashion.”).

²⁶ Allen, *supra* n.25, at 632 (uterine aspiration is used for induced abortion and treatment of miscarriages and can be done in office setting); Dennis et al., *Barriers to and Facilitators of Moving Miscarriage Management Out of the Operating Room*, 47 *Persp. on Sexual & Reprod. Health* 141, 141, 143 (2015) (office-based treatment for miscarriage “is equally safe or safer, quicker, more cost-effective and more acceptable to some women” than hospital-based care; technical aspects of miscarriage management and induced abortion are the same); Peacock, *supra* n.16, at 427-428 (vacuum curettage is used for abortion and miscarriage management and can be performed in office setting); DSHS, *Vital Statistics Annual Reports*, *supra* n.8; see also Godfrey et al., *Early Pregnancy Loss Needn’t Require a Trip to the Hospital*, 58 *J. Fam. Prac.* 585, 588 (2009) (vacuum aspiration appropriate for office setting).

lar to or higher than those posed by abortion. Texas law authorizes physicians to perform procedures in their offices—including procedures involving general anesthesia, which are generally riskier than procedures (such as the vast majority of abortions) that do not require general anesthesia—without meeting ASC standards.²⁷ For example, no law requires colonoscopies or liposuction to be performed in an ASC or hospital setting and the mortality rate for both procedures is higher than abortion. The mortality rate for colonoscopy is 0.007 percent.²⁸ The mortality rate for liposuction is around 0.02 percent.²⁹ There is no medical purpose or principled reason for Texas legislation requiring abortion facilities, but not other medical facilities that perform similar or even riskier outpatient procedures, to meet heightened ASC standards.

II. H.B. 2’S PRIVILEGES REQUIREMENT DOES NOT SERVE THE HEALTH OF WOMEN IN TEXAS

H.B. 2’s requirement that abortion providers maintain admitting privileges at a local hospital adds no medical benefit to the treatment of Texas women and is contrary to current medical practice. As with the ASC requirement, the Texas legislature’s claimed purpose for the privileges requirement is “to raise the standard

²⁷ See 22 Tex. Admin. Code §§ 192.1-192.6.

²⁸ Am. Soc’y for Gastrointestinal Endoscopy, *Complications of Colonoscopy*, 74 J. Gastrointestinal Endoscopy 745, 747 (2011). For a discussion of the mortality rate associated with abortion, see *supra* notes 7-10 and accompanying text.

²⁹ Grazer & de Jong, *Fatal Outcomes from Liposuction: Census Survey of Cosmetic Surgeons*, 105 Plastic & Reconstructive Surgery 436, 441 (2000).

and quality of care for women seeking abortions and to protect the health and welfare of women seeking abortions.”³⁰ But abortion providers may be denied admitting privileges for reasons unrelated to the quality of care they provide, and the privileges requirement does not improve the health and safety of women.

A. Clinicians Are Denied Medical Privileges For Reasons Unrelated To Their Competency

Obtaining privileges can be difficult, if not impossible, for a clinician, irrespective of the clinician’s technical competence. For example, some academic hospitals will only allow medical staff membership for clinicians who also qualify for and accept faculty appointments. Other hospitals require that clinicians admit a certain number of patients, or perform a certain number of deliveries or major obstetric or gynecological surgeries in order to be affiliated with the hospital. Providers who specialize in performing abortions are frequently unable to meet such requirements because abortion is a very safe procedure only rarely resulting in hospitalization. These factors result in a denial of privileges that has nothing to do with a provider’s competence.

The difficulty of obtaining privileges is not theoretical; the Fifth Circuit credited evidence that clinicians at Petitioner’s clinic in McAllen have been denied privileges for reasons unrelated to screening clinicians for competency.³¹ But the real-life impact of the privileges

³⁰ Pet. App. 25a; Resp. C.A. Br. 13.

³¹ Pet. App. 70a-71a (“With respect to the admitting privileges requirement, Whole Woman’s Health presented considerable evidence that Plaintiff Dr. Lynn and three unidentified physicians

requirement is far more wide-ranging than the effect on the McAllen clinic. In Texas, after the enactment of H.B. 2, a significant percentage of abortion clinics were forced to stop providing abortions because providers did not have privileges.³² Requiring that clinicians obtain hospital privileges—when such privileges may be denied for any number of reasons having nothing to do with a clinician’s competency or the quality of care that he or she provides—does not promote the wellbeing of Texas women.

B. H.B. 2’s Privileges Requirement Is Inconsistent With Accepted Medical Practice And Provides No Benefit To Patient Care Or Health Outcomes

H.B. 2 is also inconsistent with prevailing medical practices, which focus on ensuring prompt medical care and continuity of care and do not require that each individual abortion provider has admitting privileges.³³ Instead of requiring that clinicians who perform abortions have admitting privileges at a local hospital, ac-

working at the McAllen facility were unable to obtain admitting privileges at local hospitals for reasons other than their competence.”). There was also evidence in the record on appeal that a clinician from Petitioner’s El Paso clinic was denied privileges for reasons unrelated to clinical competence, but the Fifth Circuit found it unnecessary to consider this evidence in reaching its decision. *Id.* at 72a & n.44.

³² Grossman et al., *The Public Health Threat of Anti-Abortion Legislation*, 89 *Contraception* 73, 74 (2014).

³³ See Inst. of Med., *Crossing the Quality Chasm: A New Health System for the 21st Century* 8-9 (2001) (recommending that health care be available 24 hours a day and that “[c]linicians and institutions should actively collaborate and communicate to ensure an appropriate exchange of information and coordination of care”).

cepted medical practice requires that an abortion provider's facility have a plan to provide prompt emergency services and (if needed) to transfer a patient to a nearby emergency facility if complications occur.³⁴ This practice ensures that, in the rare instance when a woman experiences a complication during or immediately after an abortion and seeks hospital-based care,³⁵ consistent with prevailing medical practice, she can be treated appropriately by a trained emergency-room clinician or the hospital's on-call specialist. The care provided by that emergency-room clinician or on-call specialist is not contingent on the woman's abortion provider having admitting privileges.

In fact, the transfer of care from the abortion provider to an emergency-room clinician is consistent with the increasing practice for inpatient and outpatient care to be provided by different practitioners.³⁶ That is, throughout modern medical practice, often the same clinician does not provide both outpatient and hospital-based care; rather, hospitals increasingly rely on "hospitalists" who provide care only in a hospital setting.³⁷ Continuity of care is achieved through communication

³⁴ ACOG, *Guidelines for Women's Health Care*, *supra* n.7, at 720 ("Clinicians who perform abortions ... 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."); Nat'l Abortion Fed'n, *2015 Clinical Policy Guidelines* 42 (2015).

³⁵ *See supra* n.11 and accompanying text.

³⁶ *See, e.g.*, ACOG, Comm. on Patient Safety & Quality Improvement, *Opinion Number 459, The Obstetric-Gynecologic Hospitalist* (2010) (reaffirmed 2012).

³⁷ *Id.*

and collaboration between specialized health care providers,³⁸ which do not depend on those providers having hospital privileges.

Prior to the enactment of H.B. 2, Texas law adequately required compliance with prevailing medical practice by requiring that abortion facilities have protocols to ensure that patients could be transferred to a hospital in the rare event of an emergency requiring hospital treatment.³⁹ There is no medical basis on which to conclude that women's health would be advanced by requiring that clinicians obtain privileges. Doing so is inconsistent with prevailing medical practice and imposes unnecessary restrictions on the ability of clinicians to provide abortion care.

Nor does H.B. 2's privileges requirement assist Texas women in the rare event that they experience complications after being discharged and returning home. As with any emergency, it is likely that a woman would seek treatment at a hospital near her home.⁴⁰ Given the juxtaposition of H.B. 2's requirement that an abortion provider maintain privileges at a hospital within thirty miles of her clinic with the fact that the average Texas county is 111 miles from an abortion clinic,⁴¹ it is unlikely that the hospital at which a woman

³⁸ See Inst. of Med., *supra* n.33, at 9, 62, 133-134.

³⁹ 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”).

⁴⁰ Upadhyay, *supra* n.11, at 176.

⁴¹ Soffen, *How Texas Could Set National Template for Limiting Abortion Access*, N.Y. Times, Aug. 19, 2015,

seeks emergency medical care will be the hospital at which her provider maintains privileges. It would be inappropriate to transport women an additional distance to the hospitals at which their abortion providers maintain privileges.⁴²

Noting the lack of scientific basis for the privileges requirement, several federal courts—with the exception of the Fifth Circuit—have recently recognized that requiring privileges provides no medical benefit to women who undergo abortion procedures. For example, the Seventh Circuit upheld a district court’s preliminary injunction of a Wisconsin statute containing a privileges requirement that is nearly identical to the Texas requirement, and the United States District Court for the Western District of Wisconsin recently permanently enjoined enforcement of that requirement.⁴³ The Seventh Circuit found, in the preliminary injunction record, “no evidence that women who have complications from an abortion recover more quickly or more completely or with less pain or discomfort if their

http://www.nytimes.com/2015/08/20/upshot/how-texas-could-set-national-template-for-limiting-abortion-access.html?_r=0.

⁴² 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 Ann. § 171.0031(a)(2)(B) (requiring that a woman 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”).

⁴³ See *Planned Parenthood of Wis., Inc. v. Van Hollen (Van Hollen I)*, 738 F.3d 786, 798 (7th Cir. 2013), *cert. denied*, 134 S. Ct. 2841 (2014); *Planned Parenthood of Wis., Inc. v. Van Hollen (Van Hollen II)*, No. 13-465, 2015 WL 1285829, at *42 (W.D. Wis.), *appeal docketed sub nom. Planned Parenthood of Wis., Inc. v. Schimel*, No. 15-1736 (7th Cir. Apr. 6, 2015).

physician has admitting privileges at the hospital to which the patient is taken for treatment of the complications.”⁴⁴ The district court similarly concluded, after a full trial on the merits of the plaintiffs’ challenge to the admitting privileges requirement, that the state failed to “demonstrat[e] through credible evidence a link between the admitting privileges requirement and a legitimate health interest.”⁴⁵

In setting aside Alabama’s privileges requirement, the United States District Court for the Middle District of Alabama found that mandating that abortion providers have admitting privileges “falls outside the range of standard medical practice for complication care” for abortion procedures and “would, in reality, undermine the State’s goal of continuity of care” because women in Alabama would lose local access to the clinics forced to close under the privileges requirement.⁴⁶ As these courts recognized, laws like H.B. 2 limit or delay access to care while providing no benefit to patient care.

⁴⁴ *Van Hollen I*, 738 F.3d at 793.

⁴⁵ *Van Hollen II*, 2015 WL 1285829, at *1. Specifically, the district court determined, largely on the basis of neutral expert testimony, that complication rates from abortion are extremely low and there was no evidence in the record that a clinician’s having admitting privileges at a local hospital would improve abortion outcomes, increase continuity of care, increase the quality of care provided to women undergoing abortions, or increase accountability for providers of abortion. *See id.* at *14-25.

⁴⁶ *Planned Parenthood Se., Inc. v. Strange*, 33 F. Supp. 3d 1330, 1372 (M.D. Ala.), *supplemented by* 33 F. Supp. 3d 1381 (M.D. Ala.), *and amended by* No. 2:13cv405-MHT, 2014 WL 5426891 (M.D. Ala. Oct. 24, 2014).

* * *

H.B. 2 does nothing to further the safety of abortions or the competency of those performing them in Texas. Indeed, legal abortions performed in Texas prior to H.B. 2 met or exceeded safety expectations for outpatient medical procedures. H.B. 2 is an unnecessary regulation that presents risks to women's health by restricting and delaying access to safe abortion. Accordingly, amici urge the Court to grant the petition for a writ of certiorari in order to review whether H.B. 2 can withstand constitutional scrutiny.

CONCLUSION

For the foregoing reasons, amici urge the court to grant the petition for a writ of certiorari.

Respectfully submitted.

KIMBERLY A. PARKER
Counsel of Record
SKYE L. PERRYMAN
EMILY L. STARK
JESSICA E. NOTEBAERT
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Ave., NW
Washington, DC 20006
(202) 663-6000
kimberly.parker@wilmerhale.com

OCTOBER 5, 2015