

No. 15-274

---

IN THE  
**Supreme Court of the United States**

---

**WHOLE WOMAN'S HEALTH, ET AL.,**  
*Petitioners,*

v.

**JOHN HELLERSTEDT, M.D., COMMISSIONER OF THE  
TEXAS DEPARTMENT OF STATE HEALTH SERVICES,  
ET AL.,**  
*Respondents.*

---

*On Writ of Certiorari to the United States Court of  
Appeals for the Fifth Circuit*

---

**BRIEF OF *AMICI CURIAE* AMERICAN  
ASSOCIATION OF PRO-LIFE OBSTETRICIANS  
AND GYNCOLOGISTS, AMERICAN COLLEGE OF  
PEDIATRICIANS, CHRISTIAN MEDICAL &  
DENTAL ASSOCIATION, CATHOLIC MEDICAL  
ASSOCIATION AND PHYSICIANS FOR LIFE IN  
SUPPORT OF RESPONDENTS**

---

DAVID A. CORTMAN  
KEVIN H. THERIOT  
ALLIANCE DEFENDING  
FREEDOM  
1000 Hurricane Shoals  
Road, NE  
Suite D-1100  
Atlanta, GA 30043

STEVEN H. ADEN  
*Counsel of Record*  
ALLIANCE DEFENDING  
FREEDOM  
440 1st St., N.W., Suite 600  
Washington, DC 20001  
(202) 393-8690  
saden@ADFlegal.org

*Counsel for Amici Curiae*

---

## TABLE OF CONTENTS

TABLE OF AUTHORITIES .....	iii
INTEREST OF <i>AMICI CURIAE</i> .....	1
SUMMARY OF ARGUMENT.....	3
ARGUMENT	
I. HB2 APPROPRIATELY EXPRESSES TEXAS'S CONSTITUTIONAL INTEREST IN SAFEGUARDING WOMEN'S HEALTH AND MAINTAINING MEDICAL STANDARDS .....	4
A. Abortion, Like Many Outpatient Procedures, Carries Inherent Serious Risks .....	6
B. Drug-Induced Abortion Carries Greater Risks than Surgical Abortion.....	9
C. Recognizing these Risks, Texas has Taken Appropriate Steps to Safeguard Women's Health and Safety by Regulating Abortion in a Manner Consistent With Other Outpatient Procedures. ....	17
1. Texas's Prior Regulation of Abortion Facilities .....	17
2. Texas Reasonably Addressed a Record of Substandard Outpatient Abortion Practice. ....	19

3. HB2 Was Intended to Strengthen Protections for the Health and Safety of Women Seeking Abortions. ....	20
II. THE FIFTH CIRCUIT CORRECTLY APPLIED THE <i>CASEY</i> STANDARD TO UPHOLD HB2'S OUTPATIENT SURGERY AND ADMITTING PRIVILEGES REQUIREMENTS. ....	22
A. The Ambulatory Surgical Center Requirements Rationally Relate to Texas's Legitimate Interest in Upholding Consistent Standards for Outpatient Abortion Providers .....	27
B. The Admitting Privileges Requirement Rationally Relates to Texas's Legitimate Interest in Regulating Outpatient Abortion .....	30
CONCLUSION .....	36

## TABLE OF AUTHORITIES

### **Cases:**

<i>City of Akron v. Akron Center for Reproductive Health,</i> 462 U.S. 416 (1983).....	25
<i>City of Cleburne v. Cleburne Living Center,</i> 473 U.S. 432 (1985).....	24
<i>Gonzales v. Carhart</i> 550 U.S. 128 (2007).....	3, 5, 23, 24,25
<i>Greenville Women’s Clinic v. Bryant,</i> 222 F.3d 157 (4th Cir. 2000) .....	25
<i>Harris v. McRae,</i> 448 U.S. 297 (1980).....	27
<i>Karlin v. Foust,</i> 188 F.3d 446 (7th Cir. 1999) .....	26
<i>Mazurek v. Armstrong,</i> 520 U.S. 968 (1997).....	23, 24, 26, 27
<i>McCleskey v. Kemp,</i> 481 U.S. 279 (1987).....	26
<i>Personnel Administrator of Massachusetts v. Feeney,</i> 442 U.S. 256 (1979).....	27

<i>Planned Parenthood Association of Kansas City, Missouri, Inc. v. Ashcroft</i> , 462 U.S. 476, 504 (1983) .....	25
<i>Planned Parenthood Minnesota, North Dakota, South Dakota v. Rounds</i> , 686 F.3d 889 (8th Cir. 2012) .....	26
<i>Planned Parenthood of Greater Texas Surgical Health Services v. Abbott</i> , 748 F.3d 583 (5th Cir. 2014) .....	8, 9, 10, 30, 31
<i>Planned Parenthood of Southern Pennsylvania v. Casey</i> , 505 U.S. 833 (1992).....	5, 22-25, 29
<i>Planned Parenthood v. Humble</i> , 753 F.3d 905 (9th Cir. 2014) .....	26
<i>Planned Parenthood v. Schimel</i> , 806 F.3d 908 (7th Cir. 2015) .....	25, 26
<i>Roe v. Wade</i> , 410 U.S. 113 (1973).....	5, 17, 23, 25
<i>Simopoulos v. Virginia</i> , 462 U.S. 506 (2004).....	25, 28, 29
<i>Smith v. Doe</i> , 538 U.S. 84 (2003).....	26
<i>Tucson Woman’s Clinic v. Eden</i> , 379 F.3d 531 (9th Cir. 2004) .....	26

<i>Washington v. Glucksberg</i> , 521 U.S. 702 (1997).....	5
<i>Whalen v. Roe</i> , 429 U.S. 589, 597 (1977).....	24
<i>Whole Woman’s Health v. Cole</i> , 790 F.3d 563 (5th Cir. 2015) .....	9, 29
<i>Whole Woman’s Health v. Lakey</i> , 46 F. Supp. 3d 673 (W.D. Tex. 2014) .....	passim
<i>Williamson v. Lee Optical</i> , 348 U.S. 483 (1955).....	25
<i>Women’s Health Center of West County, Inc. v. Webster</i> , 871 F.2d 1377 (8th Cir. 1989) .....	26
<i>Women’s Medical Professional Corporation v. Baird</i> , 438 F.3d 595 (6th Cir. 2006) .....	26
 <b><u>Legislative Materials:</u></b>	
21 C.F.R. § 314.520 .....	11
42 C.F.R. § 416.41(b).....	32
25 Tex. Admin. Code § 135.5 .....	29
25 Tex. Admin. Code § 139.1 .....	18, 19
25 Tex. Admin. Code § 139.40 .....	21, 30

47 Fed. Reg. 34082, 34086 .....	32
Senate Committee on Health & Human Services, <i>Bill Analysis, Texas H.B. 2</i> , 83d Legislature, 2d C.S. (2013) .....	passim
Texas Health & Safety Code § 171.004 .....	18
Texas Health & Safety Code § 171.063 .....	10
Texas Health & Safety Code § 245.010 .....	19, 21
Texas Health & Safety Code § 245.004 .....	19
Texas Health & Safety Code § 243.010 .....	21

**Other Authorities:**

A. Filippini, <i>et al.</i> , <i>Acute Hemolytic Anemia with Acanthocytosis Associated with High-dose Misoprostol for Medical Abortion</i> , 50 Ann. Emerg. Med. 289 (2006) .....	17
Accreditation Council of Graduate Medical Education (ACGME), <i>Program Requirements for Graduate Medical Education in Emergency Medicine</i> , eff. Jul. 1, 2013 <a href="http://www.abim.org/certification/policies/combinedim/comccm.aspx">http://www.abim.org/certification/policies/combinedim/comccm.aspx</a> .....	33
<i>ACOG Practice Bulletin 67: Med. Management of Abortion</i> (Oct. 2005, reaffirmed 2011) .....	15
American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAASF) <i>Surgical Standards</i> 13.0, available at <a href="http://">http://</a>	

www.aaaasfsurveyors.org/asf_web/PDF%20FILE S/ASC%20Standards%20and%20Checklist%20V ersion%2013.pdf .....	31
C. Pallardy and S. Becker, <i>50 Things to Know About the Ambulatory Surgery Center Industry, Becker's ASC Review</i> (Jul. 20, 2013), t http://www.beckerasc.com/lists/50-things-to- know-about-the-ambulatory-surgery-center- industry.html .....	28
Center for Studying Health System Change, <i>Hospital Emergency On-Call Coverage: Is There A Doctor in the House?</i> (November 2007), http://www.hschange.com/CONTENT/956/.....	33
Centers for Disease Control, <i>National Health Statistics Reports: Ambulatory Surgery in the United States, No. 11</i> (Jan. 28, 2009, revised Sept. 4, 2009).....	8
Danco Laboratories, LLC, <i>Risk Evaluation and Mitigation Strategy (REMS)</i> , available at http://www.accessdata.fda.gov/drugsatfda_docs/r ems/Mifeprex_2011-0608_REMS%20DOCUMEN T. pdf.....	14
E. Hakim-Elahi, et al., <i>Complications of First Trimester Abortion: A Report of 170,000 Cases</i> , 76 Obstet. Gynecol. 129 (1990).....	6
F. Cittadini, et al., <i>A Case of Toxic Shock Due to Clandestine Abortion by Misoprostol Self- administration</i> , 10 J. Forensic Sci. 59 1662 (2014) .....	17



FDA, *Approved Risk Evaluation and Mitigation Strategies (REMS)*, available at <http://www.accessdata.fda.gov/scripts/cder/remis/index.cfm>..... 14

FDA, *CDER Drug and Biologic Accelerated and Restricted Distribution Approvals*, June 30, 2015, available at <http://www.fda.gov/downloads/Drugs/Development/ApprovalProcess/HowDrugsareDevelopedandApproved/DrugsandBiologicApprovalReports/NDAandBLAApprovalReports/UCM404466.pdf>..... 11

FDA, *Mifeprex Approval Letter to Population Council* dated Sep. 28, 2000, [http://www.accessdata.fda.gov/drugsatfda\\_docs/appltr/2000/20687appltr.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/appltr/2000/20687appltr.pdf)..... 12, 15

FDA, *Mifeprex (mifepristone) Information*, May 17, 2015, available at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111323.htm>..... 14

FDA, *Mifeprex Medication Guide*, available at [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2011/020687s014lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020687s014lbl.pdf) ..... 12

FDA, *Mifeprex Questions and Answers*, Feb. 24, 2010, available at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111328.htm>..... 13

FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/2011* (July 2011) ..... 15-16

Henshaw, S.K. and Finer, L.B., <i>The Accessibility of Abortion Services in the U.S., 2001</i> , 35 Perspectives on Sexual and Reproductive Health 16 (2003) .....	16
<i>Incidence of Emergency Department Visits and Complications After Abortion</i> , 125 Obstet. Gynecol. (2015) .....	9
M. Chen and M. Creinin, <i>Mifepristone with Buccal Misoprostol for Medical Abortion</i> , 126 Obst. & Gyn. 12 (2015).....	10
M. Fischer et al., <i>Fatal Toxic Shock Syndrome Associated with Clostridium Sordelli after Medical Abortion</i> , 353 New Eng. J. Med. 2352 (2005) .....	17
M.F. Greene, <i>Fatal Infections Associated with Mifepristone Induced Abortion</i> , 353 New Eng. J. Med. 353 2317 (2005).....	17
M. Niinimäki, et al., <i>Immediate Complications after Med. Compared with Surgical Termination of Pregnancy</i> , 114 Obstet. Gynecol. 795 (Oct. 2009) .....	16
Merck Manuals, available at <a href="http://www.merckmanuals.com/home/womens_health_issues/complications_of_pregnancy/miscarriage.html">http://www.merckmanuals.com/home/womens_health_issues/complications_of_pregnancy/miscarriage.html</a> .....	6
<i>Mifeprix FPL</i> at 11, available at <a href="http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020687s015lbl.pdf">http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020687s015lbl.pdf</a> .....	12

R. Jones and J. Jerman, <i>Abortion Incidence and Service Availability in the United States</i> , 2011 (Alan Guttmacher Institute 2013), <a href="http://www.guttmacher.org%2Fpubs%2Fjournals%2Fpsrh.46e0414.pdf&amp;usg=AFQjCNHA0QeuMcSHPbtDE_5y8a1QmYOow&amp;sig2=i7a96rPvN79UYCJvLKevfQ">www.guttmacher.org%2Fpubs%2Fjournals%2Fpsrh.46e0414.pdf&amp;usg=AFQjCNHA0QeuMcSHPbtDE_5y8a1QmYOow&amp;sig2=i7a96rPvN79UYCJvLKevfQ</a> .....	27-28
S. Kaali, et al., <i>The Frequency and Management of Uterine Performations During First-Trimester Abortions</i> , 6 Am. J. Obstet. Gynecol. 406 (1989) .....	7
S.K. Henshaw & L.B. Finer, <i>The Accessibility of Abortion Servs. in the U.S., 2001</i> , 35 Perspectives on Sexual and Reproductive Health 16 (2003) .....	8
S. Su, et al., <i>Delayed Presentation of Uterine Perforation with Ovary Migration After Dilatation and Curretage</i> , 8 In. J. Exp. Med. 6311 (2015).....	7, 8
Te Linde's Operative Gynecology 9th ed. 499-504 (Philadelphia: Lippincot Williams & Wilkins 2003) .....	7, 27, 31
Dale W. Stovall et al., <i>Dilation &amp; Curettage: Complications</i> , UpToDate, Jan. 14, 2014, available at <a href="http://www.uptodate.com/contents/dilation-and-curettage">http://www.uptodate.com/contents/dilation-and-curettage</a> .....	31

Tex. Dep't of Health & Human Servs., <i>Statements of Deficiencies and Plans of Correction with Various Dates from 2011-2013</i> , available at <a href="http://www.texasallianceforlife.org/wpcontent/uploads/imported/issues/hb2/DSHS_inspection_WWH_Beaumont_11_17_2011.pdf">http://www.texasallianceforlife.org /wpcontent/uploads/imported/issues/hb2/DSHS_i nspection_WWH_Beaumont_11_17_2011.pdf</a> . .....	19
Tex. Dep't of Health & Human Servs., <i>Statement of Deficiencies and Plan of Correction</i> , October 3, 2013, available at <a href="http://www.texasallianceforlife.org/issues/hb2/DSHS_inspection_WWH_Beaumont_11_17_2011.pdf">http://www. texasallianceforlife.org/issues/hb2/DSHS_inspect ion_WWH_Beaumont_11_17_2011.pdf</a> . .....	20
United States Government Accountability Office, GAO-08-751, <i>Food and Drug Administration: Approval and Oversight of the Drug Mifeprex 2</i> (2008) .....	12
U. Upadhyay, et al., <i>Incidence of Emergency Department Visits and Complications After Abortion</i> , 125 <i>Obstetrics &amp; Gynecology</i> 175 (2015) .....	9

## INTEREST OF *AMICI CURIAE*<sup>1</sup>

*Amici curiae* are national medical organizations and their combined membership of thousands of physicians, nurses, physician assistants, pharmacists and other healthcare professionals who share a profound interest in protecting maternal health and the sanctity of human life. *Amici*'s members include obstetrician/gynecologists whose patients see abortion providers and then return to their care, emergency physicians and other staff who treat emergent complications caused by abortion, and clinical staff who counsel women regarding abortion and treat its damaging physical and psychological consequences.

**American Association of Pro-Life Obstetricians & Gynecologists** ("AAPLOG") is a non-profit professional medical organization that consists of 3,000 obstetrician-gynecologist members and associates. AAPLOG held the title of "special interest group" within the American College/Congress of Obstetricians and Gynecologists (ACOG) from 1973 to 2013 until this designation was discontinued by ACOG. AAPLOG is concerned about the quality of care provided to pregnant women and the potential long-term adverse consequences of abortion on women's future health, and explores data from around the world regarding abortion-

---

<sup>1</sup> The parties to this case have consented to the filing of this brief and letters indicating their consent are on file with the Clerk. *Amici* state that no counsel for a party authored this brief in whole or in part, and no person other than *Amici* and their counsel made any monetary contribution intended to fund the preparation or submission of this brief.

associated complications (such as depression, substance abuse, suicide, other pregnancy-associated mortality, subsequent preterm birth, and *placenta previa*) in order to provide the general public and others with a realistic appreciation and understanding of abortion-related health risks.

**American College of Pediatricians** is a national not-for-profit organization of pediatricians and other healthcare professionals formed in 2002 dedicated to the health and well-being of children. The mission of the College is to enable all children to reach their optimal physical and emotional health and well-being. To this end, the College has written a number of position statements on matters unique to children, and continues to produce sound policy based upon the best available research to assist parents and society in the care of children. Membership is open to qualifying healthcare professionals who share the College's Mission, Vision and Values. The College currently has members in forty-seven states and several countries outside of the United States.

**Christian Medical and Dental Association** ("CMDA"), founded in 1931, is a non-profit national membership organization primarily for physicians and dentists. With more than 16,000 members, CMDA provides a public voice on bioethics and healthcare policy. CMDA provides missionary doctors and medical education to the developing world, provides continuing medical and dental education, and sponsors student chapters at most U.S. medical and dental schools.

**Catholic Medical Association** (“CMA”) consists of over 1,000 physician members and hundreds of allied health members nationwide. CMA members seek to uphold the principles of the Catholic faith in the science and practice of medicine – including the belief that human life begins at conception.

**Physicians for Life** is a national membership organization whose purpose is to inform and educate the public about stem cell research, cloning, fetal development, abortion, infanticide, euthanasia, “safe sex”, sexually transmitted diseases, and risk elimination through sexual abstinence.

### SUMMARY OF ARGUMENT

*Amici* respectfully wish to address Petitioners’ Question I from their perspective as medical professionals, and particularly whether Texas House Bill 2 (“HB2”)’s provisions are medically reasonable. *Amici* urge that far from expressing views based on “medical uncertainty,” *Gonzales v. Carhart*, 550 U.S. 128, 163 (2007), the surgical center and admitting privileges requirements imposed by the Act reflect the professional standard of practice for outpatient gynecological and similar surgery.

The Fifth Circuit recognized that Texas has a legitimate interest in regulating abortion because it is a surgical or drug-induced procedure that carries significant health risks. Thus, Texas has a proper interest in protecting the health and safety of women who seek abortions. In enacting HB2, Texas sought

to protect women’s health by requiring that abortion facilities meet the same health and safety standards as Texas requires of outpatient surgical centers. Texas also sought to protect women’s health by ensuring that physicians who terminate pregnancies are able to attend to the patient’s health, both during and after an abortion, by having admitting privileges at a hospital within thirty miles of the location of the abortion. *Amici* urge the Court to affirm that the quality of medical care provided to women seeking abortion should not be any lower than the quality of care provided to women undergoing similar invasive procedures. The health and safety of all women should not be compromised.

## ARGUMENT

### I. HB2 APPROPRIATELY EXPRESSES TEXAS’S CONSTITUTIONAL INTEREST IN SAFEGUARDING WOMEN’S HEALTH AND MAINTAINING MEDICAL STANDARDS.

Texas women obtained 68,298 reported abortions in 2012. *See* Tex. Dep’t of State Health Servs., *2012 Induced Terminations of Pregnancy* (2014), available at <http://www.dshs.state.tx.us/chs/vstat/vs12/t38.shtm> (last visited February 1, 2016). The vast majority of these abortions – 78.6 percent – were performed in outpatient abortion facilities or locations other than hospitals or licensed ambulatory surgical centers (“ASC”s). *Id.* Because abortion involves risks to patient health and safety, Texas has a legitimate interest in regulating abortions, abortion providers, and abortion facilities.



In passing HB2, Texas relied upon long-standing Supreme Court precedent that recognizes the states' constitutional authority to regulate abortion and their strong interests in doing so. In *Roe v. Wade*, 410 U.S. 113, 162-64 (1973), this Court recognized an "important interest" in protecting a pregnant woman's health, and a "legitimate interest in seeing to it that abortion, like any other procedure, is performed under circumstances that ensure maximum safety for the patient." *Id.* at 150. In replacing *Roe*'s trimester framework with a bifurcated pre-viability/post-viability framework and applying a new "undue burden" standard to gauge the constitutionality of pre-viability abortion restrictions, this Court in *Casey* acknowledged that "the State has legitimate interests *from the outset of the pregnancy* in protecting the health of the woman." *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 846 (1992) (plurality op.). The *Casey* plurality held that an abortion regulation could be declared unconstitutional if "*in a large fraction of cases* in which [the challenged requirement] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion." *Id.* at 895 (emphasis added). More recently, in *Gonzales v. Carhart*, this Court acknowledged that government "undoubtedly 'has an interest in protecting the integrity and ethics of the medical profession.'" 550 U.S. at 128 (quoting *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997)). *Gonzalez* affirmed the well-accepted rule that states have "wide discretion" in passing health and safety legislation, even if "medical and scientific uncertainty" exists – a threshold of authority that outpatient and admitting

privileges standards easily surmount. *Id.* at 163. The safeguards HB2 inaugurated are an appropriate expression of the states' duty and authority to maximize patient safety.

A. Abortion, Like Many Outpatient  
Procedures, Carries Inherent Serious  
Risks.

The performance of abortion, whether by means of surgery or medication, is associated with risks, including risks of major complications and even death. *See, e.g., E. Hakim-Elahi, et al., Complications of First Trimester Abortion: A Report of 170,000 Cases*, 76 *Obstet. Gynecol.* 129 (1990). Surgical abortion is directly comparable to dilatation and curettage ("D&C") a procedure done usually in an ambulatory surgical facility. There are no substantive technical differences between a D&C procedure performed for the purpose of abortion and one to manage a natural miscarriage.<sup>2</sup> Even the most experienced physician performing a D&C procedure (whether for induced abortion or natural miscarriage) faces known complications, including perforation of the uterus (meaning that the tip of an instrument can pass through the wall of the uterus), damage to the cervix, retention of fetal parts,

---

<sup>2</sup> Treatment for a suspected miscarriage involves an examination of the cervix and the use of ultrasonography to confirm fetal death. If any remnants of the pregnancy remain in the uterus after a miscarriage, D&C is often used to remove the remaining uterine contents. *Merck Manuals*, available at [\(http://www.merckmanuals.com/home/womens\\_health\\_issues/complications\\_of\\_pregnancy/miscarriage.html\(miscarriage/spontaneous-abortion\)\)](http://www.merckmanuals.com/home/womens_health_issues/complications_of_pregnancy/miscarriage.html(miscarriage/spontaneous-abortion)) (last visited Feb. 1, 2016).

infection and hemorrhage. Am. Coll. of Obstetricians and Gynecologists (“ACOG”), *Dilation and Curettage* (May 2012), available at <https://www.acog.org/-/media/Forpatients/faq062.pdf?dmc=I&ts=20141102T1627592544> (last visited Feb. 1, 2016); Mayo Clinic Staff, *Dilation and Curettage (D&C): Risks* (2014), available at <http://www.mayoclinic.org/tests-procedures/dilation-andcurettage/basics/risks/prc20013836> (last visited Feb. 1, 2016).<sup>3</sup>

The frequency of perforating the uterus at the time of first trimester surgical abortion has been estimated to vary between .08% to 3% of first trimester abortions. S. Kaali, et al., *The Frequency and Management of Uterine Perforations During First-Trimester Abortions*, 6 Am. J. Obstet. Gynecol. 406 (1989). These complications usually go undetected until after the abortion procedure has been completed and the patient has left the clinic,<sup>4</sup>

---

<sup>3</sup> Besides these immediate complications, a more comprehensive list of potential complications includes: Rh sensitization (endangering future children), missed diagnosis of ectopic pregnancy, missed diagnosis of twin pregnancy with surviving or retained twin demise, inability to complete the procedure, embolization of gestational trophoblastic disease (GTD) tissue, convulsive seizure due to administration of local anesthetic, bowel injury following uterine perforation, bladder injury following uterine perforation, large vessel injury following uterine perforation, nerve injury following uterine perforation, and uterine synechia formation (Asherman's syndrome), sepsis (bacterial infection of the blood), and maternal death. Te Linde's Operative Gynecology 9th ed. 499-504 (Philadelphia: Lippincott Williams & Wilkins 2003).

<sup>4</sup> See, e.g., S. Su, et al., *Delayed Presentation of Uterine Perforation with Ovary Migration After Dilatation and Curettage*, 8 In. J. Exp. Med. 6311 (2015).

and can require the patient to be hospitalized and undergo surgical correction. Such complications can be life threatening and likely occur in hundreds of cases in Texas per year. See *Planned Parenthood of Greater Tex. Surgical Health Services v. Abbott*, 748 F.3d 583, 595 (5th Cir. 2014) (“*Abbott II*”) (citing figure of 210 hospitalizations annually). Texas counsels women about these risks and complications in a booklet entitled “A Woman’s Right to Know,” which must be provided to all women seeking abortions. See Tex. Dep’t of Health, *A Woman’s Right to Know*, available at <http://www.dshs.state.tx.us/wrtk/> (2003) (last visited Feb. 1, 2016).

The overall hospitalization rate following elective abortion (one in three hundred patients) is similar to rates for other invasive outpatient procedures such as liposuction, gastrointestinal endoscopy such as colonoscopy and upper endoscopy. Ctrs. for Disease Control, *National Health Statistics Reports: Ambulatory Surgery in the United States*, No. 11 (Jan. 28, 2009, revised Sept. 4, 2009). S.K. Henshaw & L.B. Finer, *The Accessibility of Abortion Services in the United States, 2001*, 35 *Perspectives on Sexual and Reproductive Health* 16 (2003) (stating hospitalization rate for abortion is 0.3%). Thus, for a year such as 2012 in which Texas reported 68,298 abortions, the state should expect to see approximately 204 abortion patients hospitalized for complications, a figure that is consistent with the number of 210 annual hospitalizations acknowledged

by one of the plaintiffs in *Abbott II*. 748 F.3d at 595.<sup>5</sup>

B. Drug-Induced Abortion Carries Greater Risks than Surgical Abortion.<sup>6</sup>

While the term “abortion” is most often associated with surgical abortion, the practice of drug-induced abortion has become prevalent in Texas and other states. Drug-induced abortion is accomplished by administering drugs such as mifepristone (“RU-486”) and misoprostol to terminate a pregnancy. HB2 requires that drug-induced abortion providers adhere to the only dosage and treatment protocol for the practice that has been approved by the federal Food and Drug

---

<sup>5</sup> This figure may be conservative. Compare U. Upadhyay, et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 *Obst. & Gyn.* 175 (2015) (stating that one in 115 abortions resulted in an abortion related complication treated in an emergency room; for 2012, this would equate to 593 hospitalizations in the state of Texas).

<sup>6</sup> The Fifth Circuit held that Petitioners failed to defend their claim that the ASC requirement was unconstitutional as applied to medication abortion. *Whole Woman’s Health v. Cole*, 790 F.3d 563, 590-91 (5th Cir. 2015). Petitioners mention the legal practice of medication abortion only twice in their brief, and then in passing. Pet. Br. at 18, 20. Their brief makes no argument that HB2, as applied to their practice of medication abortion in Texas, violates the *Casey* standard, nor do they cite any authority in support of such an argument. Petitioners have therefore waived this argument. *Hill v. Colorado*, 530 U.S. 703, 720 (2000).

Administration (FDA). Texas Health & Safety Code § 171.063(a).<sup>7</sup>

The district court concluded that “[t]he imposition of [ASC] requirements [on abortion facilities] is even weaker in the context of medication abortions, where no surgery is involved.” *Whole Woman’s Health v. Lakey*, 46 F. Supp. 3d 673, 684-85 (W.D. Tex. 2014). But approximately 1 out of 20 women require post-abortion surgery to complete a failed drug-induced abortion, and that number increases for gestational ages over 49 days. M. Chen & M. Creinin, *Mifepristone with Buccal Misoprostol for Medical Abortion*, 126 Obst. & Gyn. 12 (2015). Drug-induced abortion involves substantial risks to patient health and safety and Texas has a legitimate interest in regulating such abortions and the facilities in which they occur, just as it has in regulating surgical abortions.

The health risks associated with drug-induced abortion were acknowledged by both the United States FDA and the manufacturer of Mifeprex, the principal drug used for the procedure. When the FDA approved the new drug application for Mifeprex (mifepristone), the approval was made subject to “Subpart H” restrictions. Subpart H is the only FDA approval process that allows for post-marketing restrictions, *i.e.*, restricting the way in which a drug is used after it has been approved and released into

---

<sup>7</sup> The Fifth Circuit upheld this provision in *Planned Parenthood v. Abbott*, *supra*, 748 F.3d at 604-605, and it is not at issue here.

the market.<sup>8</sup> To put this restricted distribution Subpart H approval in perspective, out of almost 1,800 New Drug Applications (NDAs) approved between 1992 and 2015, only eight were approved under the restricted distribution section Subpart H.<sup>9</sup> Subpart H restrictions apply only when the drug product presents safety concerns. 21 C.F.R. § 314.520(b) (2007). The “FDA concluded that Mifeprex could only be used safely if distribution was limited to physicians who could assess the duration of a pregnancy, diagnose an ectopic pregnancy, *and provide patients with access to surgical intervention if necessary.*” U.S. Gov’t

---

<sup>8</sup> See 21 C.F.R. 314.520, Approval with restrictions to assure safe use.

- (a) If FDA concludes that a drug product shown to be effective can be safely used only if distribution or use is restricted, FDA will require such postmarketing restrictions as are needed to assure safe use of the drug product, such as:
  - (1) Distribution restricted to certain facilities or physicians with special training or experience; or
  - (2) Distribution conditioned on the performance of specified medical procedures.
- (b) The limitations imposed will be commensurate with the specific safety concerns presented by the drug product.

<sup>9</sup> These include one drug for prostate cancer (Plenaxis), two drugs for severe pulmonary hypertension (Letairis, Tracleer), one drug for severe anemia (Revlimid), one drug for narcolepsy (Xyrem), one drug for leprosy (thalidomide), one drug for severe cancer pain in patients that cannot take narcotics (Actiq) and one drug for abortion (Mifeprex). See <http://www.fda.gov/downloads/Drugs/Development/ApprovalProcess/HowDrugsareDevelopedandApproved/DrugsandBiologicApprovalReports/NDAandBLAApprovalReports/UCM404466.pdf> (last visited 01/23/16).

Accountability Office, GAO-08-751, *Food and Drug Administration: Approval and Oversight of the Drug Mifeprex 2* (2008) (emphasis added).

Because of these unusual risks, the FDA conditioned its approval on the manufacturer's compliance with Subpart H restrictions, which mandated that physicians prescribing Mifeprex "fully explain the procedure to each patient," provide her with a copy of a "Medication Guide" and "Patient Agreement" and obtain her signature on the agreement. Both the Medication Guide and the Patient Agreement specify the exact regimen which the FDA approved. FDA, *Mifeprex Approval Letter to Population Council* dated Sep. 28, 2000 at 3, available at [http://www.accessdata.fda.gov/drugsatfda\\_docs/appltr/2000/20687appltr.htm](http://www.accessdata.fda.gov/drugsatfda_docs/appltr/2000/20687appltr.htm) (last visited Feb. 1, 2016). FDA, *Mifeprex Medication Guide* at 3, available at [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2011/020687s014lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020687s014lbl.pdf) (last visited Feb. 1, 2016). Likewise, the FDA-approved Mifeprex final printed labeling (FPL) warns that "[n]early all [90%] of the women who receive Mifeprex and misoprostol will report adverse reactions, and many can be expected to report more than one such reaction." FDA, *Mifeprex FPL* at 11 (2009), available at [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/020687s015lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020687s015lbl.pdf) (last visited Feb. 1, 2016). These risks include, but are not limited to, abdominal pain, cramping, vomiting, headache, fatigue, uterine hemorrhage, viral infections, anemia, and pelvic inflammatory disease. *Id.* at 12 (Table 3). In part because of these risks, the Subpart H restrictions included the mandate that physicians prescribing Mifeprex have "[the]



[a]bility to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through other qualified physicians, and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.” *Mifeprex Approval Letter, supra.*

While FDA would be fully empowered to lift its restrictions, the FDA has never concluded that any other regimen is safe for use. The FDA continues to identify the FPL regimen as the only regimen approved for use:

While some of the modified regimens have been well described in the literature, the safety and effectiveness of Mifeprex dosing regimens, other than the one approved by FDA, including use of oral misoprostol intravaginally, has not been established by the FDA.<sup>10</sup>

That the FDA has not changed its opinion about the need to adhere to the FDA-approved label is also evidenced by the 2011 enrollment of Mifeprex on the list of medications which require a Risk Evaluation and Management Strategy (REMS). The FDA enrolls drugs into a REMS when the drug is identified as being at high risk of post-marketing complications:

---

<sup>10</sup> See FDA, Mifeprex Questions and Answers, Feb. 24, 2010, available at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111328.htm> (last visited Feb. 1, 2016).

The Food and Drug Administration Amendments Act of 2007 gave FDA the authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks.<sup>11</sup>

The Mifeprex REMS includes a clear directive that providers and patients must adhere to the postmarketing restrictions as reflected in the Patient Agreement and Provider Agreement discussed above.<sup>12</sup> The FDA also continues to identify the FPL regimen as the only approved regimen in the context of the FDA Drug Safety information.<sup>13</sup>

According to ACOG, the risks of drug-induced abortion are similar to surgical abortion, and include infection, heavy bleeding/hemorrhage, and failed medical abortion/retained products of conception, in addition to other risks. ACOG warns of these risks in Practice bulletins published in 2005 (and reaffirmed in 2011). *See ACOG Practice Bulletin 67: Med. Management of Abortion 4-6* (Oct. 2005, reaffirmed 2011). Approximately two to three

---

<sup>11</sup> See FDA, Approved Risk Evaluation and Mitigation Strategies (REMS), available at <http://www.accessdata.fda.gov/scripts/cder/remis/index.cfm> (last visited Feb. 1, 2016)

<sup>12</sup> See Danco Laboratories, LLC, Risk Evaluation and Mitigation Strategy (REMS), available at [http://www.accessdata.fda.gov/drugsatfda\\_docs/remis/Mifeprex\\_2011-06-08\\_REMS%20DOCUMENT.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/remis/Mifeprex_2011-06-08_REMS%20DOCUMENT.pdf) (last visited Feb. 1, 2016).

<sup>13</sup> See FDA, Mifeprex (mifepristone) Information May, 17, 2015, available at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111323.htm> (last visited Feb. 1, 2016).

percent of drug-induced abortion patients will require a D&C procedure to aspirate retained products of conception, and the rate is higher for later gestational ages. *See* Chen and Creinin, *supra*. The complication logs from petitioner Whole Woman's Health reflect dozens of patients who required surgical follow-up after an incomplete drug-induced abortion. J.A. 865.

Since treatment of drug-induced abortion complications can require surgical intervention, the same rationale for admitting privileges applies to the provision of drug-induced abortion as to surgical abortion. According to ACOG's current guidance, "Clinicians who wish to provide medical abortion services either should be trained in surgical abortion or should work in conjunction with a clinician who is trained in surgical abortions." ACOG Practice Bulletin 143, *Medical Management of First-Trimester Abortion* (2014), available at <http://www.acog.org/Resources-And-Publications/PracticeBulletins/Committee-on-Practice-BulletinsGynecology/Medical-Management-of-First-Trimester-Abortion> (last visited Jan. 29, 2016).

Another Subpart H condition of Mifeprex approval mandated that physicians prescribing Mifeprex report adverse events to the FDA, *Mifeprex Approval Letter*, *supra* at 2. In July 2011, the FDA reported 2,207 cases of adverse events after mifepristone abortions. FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/2011* (July 2011). Among these were 14 deaths, 612 hospitalizations, 339 blood transfusions,

and 256 infections (including 48 “severe infections”).  
*Id.*

The largest and most accurate study of drug-induced abortion was published in 2009 and consists of a review of medical records of 22,368 women who underwent drug-induced abortions, compared with 20,251 women who underwent surgical abortions. According to this study, the “overall incidence of adverse events was fourfold higher in” drug-induced abortions than in surgical abortions. See M. Niinimäki, et al., *Immediate Complications after Medical Compared with Surgical Termination of Pregnancy*, 114 *Obstet. Gynecol.* 795 (Oct. 2009). Likewise, a 2015 review of women receiving buccal administration of misoprostol for the abortion regimen at 50-56 days gestation reported that 3.3% of women required surgery to complete the abortion. M. Chen and M. Creinin, *supra*. However the number of women requiring surgery to complete the abortion increased to 6.9% as the gestational age of the pregnancy increased. *Id.*

Drug-induced abortion presents a much greater risk of life-threatening infections than does surgical abortion. For example, drug-induced abortion is associated with a greater risks of death from dangerous *Clostridium sordelli* bacterial sepsis than surgical abortion. Mark Fischer of the Centers for Disease Control and Prevention (CDC) reports the risk of death from *C. sordelli* infection during a mifepristone abortion is at least ten times the risk of death from all types of infection after surgical abortion. See M. Fischer et al., *Fatal Toxic Shock*

*Syndrome Associated with Clostridium Sordelli after Medical Abortion*, 353 New Eng. J. Med. 2352 (2005); see also M.F. Greene, *Fatal Infections Associated with Mifepristone Induced Abortion*, 353 New Eng. J. Med. 353 2317 (2005). Other serious complications from using misoprostol for drug-induced abortion have been reported anecdotally, including acute hemolytic anemia, see A. Filippini, et al., *Acute Hemolytic Anemia with Acanthocytosis Associated with High-dose Misoprostol for Medical Abortion*, 50 Ann. Emerg. Med. 289 (2006), and fatal septic shock. See F. Cittadini et al., *A Case of Toxic Shock Due to Clandestine Abortion by Misoprostol Self-administration*, 59 J. Forensic Sci. 1662 (2014).

C. Recognizing these Risks, Texas has Taken Appropriate Steps to Safeguard Women's Health and Safety by Regulating Abortion in a Manner Consistent With Other Outpatient Procedures.

Texas, like many other states, recognized the risks associated with both surgical and drug-induced abortion and took steps to regulate abortion procedures to minimize these risks and protect women's health and safety. The steps Texas has taken, from its prior regulation of abortion to HB2, are consistent with the standard of care for outpatient medical practice.

1. Texas's Prior Regulation of Abortion Facilities.

Due to the significant health and safety risks to women, well before HB2, Texas regulated abortions

and abortion facilities consistent with *Roe* and its progeny. It did so in a regime that was, until HB2, separate from the regulation of ASCs. *See* 25 Tex. Admin. Code § 139.1 *et seq.* Texas defined abortion facilities as facilities that perform abortions, excluding licensed hospitals, ASCs, and physician offices that perform 50 or fewer abortions per year. Notably, since 2009, well before the Legislature enacted HB2, Texas required licensed abortion facilities either to have a physician with admitting privileges at a local hospital or to have a working arrangement with an outside physician who had those privileges so as to ensure that abortion facilities could provide appropriate follow-up patient care when necessary. *See id.* at § 139.56. Texas also required abortion facilities to maintain a quality assurance program, *see id.* at § 139.8, and to submit to a full on-site inspection at least once per year. *See id.* at § 139.31. And several years earlier, in 2003, the Texas Legislature required that abortions after fifteen weeks' gestation generally must be performed in an ambulatory surgical center or hospital. *See* Tex. Health & Safety Code § 171.004.

These provisions were insufficient to ensure patient safety in outpatient abortion practice, *see generally* I.C.2 *infra*, and so Texas took further steps to protect its citizens. Among other provisions, HB2 required (1) that licensed abortion facilities operating after September 1, 2014 meet ASC standards; and (2) that abortion practitioners must possess admitting privileges at a hospital within thirty miles of where an abortion is performed. *See* Tex. Health & Safety Code §§ 245.010(a), 171.0031(a). The rules for licensing general ASCs

pre-date HB2 and include “Operating Requirements,” “Fire Prevention and Safety Requirements,” and “Physical Plant and Construction Requirements.” *See* 25 Tex. Admin. Code §§ 135.1-56. HB2 left in place existing laws allowing abortions to be performed at hospitals and general ASCs, even where the latter are not licensed as abortion facilities. Tex. Health & Safety Code § 245.004; 25 Tex. Admin. Code § 139.1(b); *see also* Tex. Health & Safety Code chs. 241, 243.

## 2. Texas Addressed Reasonable Concerns Over Substandard Outpatient Abortion Practice.

Documented experiences in Texas illustrate the legitimacy of Texas’s concern over the adequacy of abortion facilities’ care for women. Inspections of Texas abortion facilities over the past few years have documented many deficiencies that reflect substandard patient care, including lack of staff training; lack of sterilization; lack of medical personnel; lack of emergency medication and procedures; expired credentials, equipment, and medication; failure to follow emergency procedures; and performing abortions beyond the legal gestational limit. *See* Tex. Dep’t of Health & Human Servs., *Statements of Deficiencies and Plans of Correction with Various Dates from 2011-2013*, available at [http://www.texasallianceforlife.org/wp-content/uploads/imported/issues/hb2/DSHS\\_inspecti on\\_WWH\\_Beaumont\\_11\\_17\\_2011.pdf](http://www.texasallianceforlife.org/wp-content/uploads/imported/issues/hb2/DSHS_inspecti on_WWH_Beaumont_11_17_2011.pdf) (last visited Feb. 1, 2016). When questioned, one employee said it was too expensive to maintain a sanitary

environment: “The functional check is more expensive and the facilities do not want to pay for the functional check.” *Id.* In short, the facilities “failed to provide a safe environment for patients and staff.” *Id.* At another facility, there was no one in charge of medical decisions, and employees were observed handling tissue and body fluids and drawing up medications and sterilizing instruments at the same time, without washing hands or wearing gloves. *See* Tex. Dep’t of Health & Human Servs., *Statement of Deficiencies and Plan of Correction* (5/23/2013), available at <http://prolifeaction.org/docs/2013/2013-05-23AlamoWomens.pdf> (last visited Feb. 1, 2016).

At Whole Woman’s Health Beaumont (a facility run by one of the Petitioners), state health inspectors reported in October 2013 that “[b]ased on observation and interview, the facility failed to provide a safe environment for patients and staff.” Inspectors documented numerous deficiencies at the abortion facility. *See* Tex. Dep’t of Health & Human Servs., *Statement of Deficiencies and Plan of Correction*, October 3, 2013, available at [http://www.texasallianceforlife.org/issues/hb2/DSHS\\_inspection\\_WWH\\_Beaumont\\_11\\_17\\_2011.pdf](http://www.texasallianceforlife.org/issues/hb2/DSHS_inspection_WWH_Beaumont_11_17_2011.pdf) (last visited Feb. 1 2016). Given this unfortunate track record for unhealthy and dangerous conditions at multiple abortion facilities in the state, Texas’s concerns over substandard outpatient abortion practice were more than reasonable.

3. HB2 Was Intended to Strengthen Protections for the Health and Safety of Women Seeking Abortions.



Because of this poor safety record in Texas and reports of abominable dangerous practices at abortion facilities elsewhere in the country, the legislature passed HB2 with the overarching purpose of “increase[ing] the health and safety” of abortion patients and providing them with “the highest standard of health care.” *See* Senate Comm. on Health & Human Servs., *Bill Analysis, Tex. H.B. 2*, 83d Leg., 2d C.S. (2013). HB2 required that “the minimum standards for an abortion facility must be equivalent to minimum standards adopted under [Texas Health & Safety Code] Section 243.010 for ambulatory surgical centers.” *See* Tex. Health & Safety Code § 245.010(a); 25 Tex. Admin. Code § 139.40 (incorporating existing ASC standards). HB2 also added Tex. Health & Safety Code § 171.0031, which requires that an abortionist must, on the date the abortion is performed or induced, “have active admitting privileges at a hospital that: (A) is located not further than 30 miles from the location at which the abortion is performed or induced; and (B) provides obstetrical or gynecological health care services.” HB2 further required that the abortionist provide the pregnant woman with 24-hour contact information for the physician or another medical employee of the facility with access to the woman’s relevant medical records, as well as the name and telephone number of the hospital nearest to the woman’s home at which an emergency would be treated. *Id.* These provisions of HB2 were clearly designed to protect women’s health and safety by ensuring that every abortion patient in Texas has access to a doctor familiar with her particular case at

every step of the procedure and recovery and that all abortions are performed in facilities that meet the same minimum health and safety standards as other ASCs.

The District Court dismissed, *inter alia*, petitioners' equal protection and "arbitrary and unreasonable state action" claims, and recognized HB2's rational relation to patient health and safety. *Lakey, supra*, 46 F. Supp. 3d at 680 (citing Order on Motion to Dismiss dated Aug. 1, 2014). Petitioners did not dispute on appeal, nor before this Court, that HB2's admitting privileges and ASC requirements are rationally related to a legitimate state interest. Petitioners instead focus their attack on whether HB2 has the purpose or effect of erecting a "substantial obstacle" to abortion access in Texas. *See* Pet. Br. at 35-53. For the reasons set forth below, *Amici* maintain that even if the Court determines to re-weigh the reasonableness of HB2 twice under separate prongs of *Casey* (an analysis that would be both unnecessarily redundant and contrary to *Casey's* intent), the sound medical purposes for HB2's protections more than meet the *Casey* standard. It is eminently reasonable to require providers of outpatient procedures such as abortion to comply with basic outpatient clinic safety and health regulations and to have the capacity to admit patients to a nearby hospital and treat them should emergent complications arise.

## II. THE FIFTH CIRCUIT CORRECTLY APPLIED THE CASEY STANDARD TO UPHOLD HB2'S

OUTPATIENT SURGERY AND ADMITTING  
PRIVILEGES REQUIREMENTS.<sup>14</sup>

When the Court first held that the Constitution includes the right to obtain a previability abortion, it also recognized that states could regulate doctors and medical facilities to “insure maximum safety for the patient.” *Roe*, 410 U.S. at 150. More recently, it rejected the notion that federal courts should serve as “the country’s ex officio medical board with powers to approve or disapprove medical and operative practices and standards throughout the United States.” *Gonzales*, 550 U.S. at 162-64 (internal quotation marks and citation omitted). Under the *Casey* standard, the Court has declined to perform the legislative role that would be the essence of such judicial oversight – balancing the medical justifications of regulations against their putative burdens. *Casey* itself upheld a requirement that a physician provide the patient with informed consent information, “even if an objective assessment might suggest that those same tasks could be performed by others.” 505 U.S. at 885; see also *Mazurek v. Armstrong*, 520 U.S. 968, 973 (1997) (upholding a requirement that abortions be performed by physicians, even though “the only extant study comparing the complication rates for first-trimester abortions performed by [physician assistants] with those for first-trimester abortions performed by physicians found no significant

---

<sup>14</sup> The Fifth Circuit’s application of the undue burden standard to require that the McAllen, Texas clinic stay open is not challenged by Texas in this Court, and *Amici* likewise do not take up this point.

difference”) (internal quotation marks and citation omitted); *Gonzales*, 550 U.S. at 158 (upholding a ban on partial-birth abortion without conducting a balancing analysis, requiring only that the state have “a rational basis to act” and that it not “impose an undue burden”).

Rational basis is satisfied if the law at issue is rationally related to a legitimate state interest. 748 F.3d at 594-596; *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 440 (1985). The district court concluded that the admitting privileges requirement “surmount[s] the low bar of rational-basis review.” *Lakey*, 46 F. Supp. 3d at 680. *Casey*’s holding that a state interest in health and safety exists throughout pregnancy necessarily rejects application of a strict standard to reasonable first trimester or pre-viability procedures.<sup>15</sup>

Petitioners contend that the undue burden test requires that the reasonableness of abortion

---

<sup>15</sup> Petitioners also note *Casey*’s statement that “[u]nnecessary health regulations that have the purpose or effect of presenting a substantial obstacle” are unconstitutional. Pet. Br. at I (Questions Presented). But this Court has not used the term “unnecessary” literally to mean “not required,” but simply as a proxy for “unreasonable.” Indeed, this Court has never used the phrase “unnecessary health regulations” in another abortion case and there is no reason to believe that it adds an additional layer of scrutiny beyond the established undue-burden test articulated in *Casey*, as well as *Gonzales*, 550 U.S. at 158, and *Mazurek*, 520 U.S. at 971. To the contrary, “State legislation which has some effect on individual liberty or privacy may not be held unconstitutional simply because a court finds it unnecessary, in whole or in part.” *Whalen v. Roe*, 429 U.S. 589, 597 (1977).

regulations essentially be assessed by the court twice, first under *Casey*'s rational basis prong and then again under the "purpose" prong. But this approach is not warranted by *Casey*'s text and is inconsistent with the manner in which medical regulations have been assessed by this Court.<sup>16</sup> One need look no further than Justice O'Connor's concurrence in *Simopoulos* and her dissent in its companion cases, in which she stated that the rational basis of the ASC mandates in those cases, coupled with the fact that they would not unduly restrict access in the relevant jurisdictions, was enough to uphold them. *Simopoulos v. Virginia*, 462 U.S. 506 at 520 (1983) (O'Connor, J., concurring in part and in the judgment); *City of Akron v. Akron Ctr. for Repro. Health*, 462 U.S. 416, 467 (1983) (O'Connor, J., dissenting) (citing *Williamson v. Lee Optical*, 348 U.S. 483 (1955)); *Planned Parenthood Ass'n of Kansas City, Mo., Inc. v. Ashcroft*, 462 U.S. 476, 504 (1983) (O'Connor, J., dissenting) ("Assuming arguendo that the [second trimester hospitalization requirement] was an undue burden, it would nevertheless 'reasonably relate to the preservation and protection of maternal health.'") (quoting *Roe*, 410 U.S. at 163). In hewing to this rational basis/undue burden interpretation of *Casey*, the Fifth Circuit also reflected the prevailing view among the courts of appeals. *Greenville Women's*

---

<sup>16</sup> In essence, *Gonzales* "simplified *Casey*'s description of an undue burden by collapsing the purpose inquiry into the effects test." *Planned Parenthood v. Wisc., Inc. v. Schimel*, 806 F.3d 908, 930 (7th Cir. 2015) (Manion, J., dissenting); *accord Jackson Women's Health Org. v. Currier*, 760 F.3d 448, 460 n.4 (Garza, J., dissenting).

*Clinic v. Bryant*, 222 F.3d 157, 170-72 (4th Cir. 2000); *Women’s Med. Profl Corp. v. Baird*, 438 F.3d 595, 604-09 (6th Cir. 2006); *Women’s Health Ctr. of W. Cnty., Inc. v. Webster*, 871 F.2d 1377, 1380-81 (8th Cir. 1989)); *Planned Parenthood Minn., N.D., S.D. v. Rounds*, 686 F.3d 889, 904 (8th Cir. 2012) (*en banc*).<sup>17</sup>

As in *Mazurek*, “[o]ne searches the Court of Appeals’ opinion in vain for any mention of any evidence suggesting an unlawful motive on the part of the [Texas] Legislature.” 520 U.S. at 972. Where a legislature has “legitimate reasons” for acting, courts will not infer an impermissible purpose. *McCleskey v. Kemp*, 481 U.S. 279, 298-99 (1987); see *Smith v. Doe*, 538 U.S. 84, 92 (2003) (“only the clearest proof will suffice to override” the “legislature’s stated intent”) (internal citation omitted). Lacking direct evidence of a purpose to

---

<sup>17</sup> To the extent that cases in the Seventh and Ninth Circuits have interpreted *Casey* differently, those cases are outliers that do not reflect consistent holdings within their own circuits and can be corrected on further review. Compare *Planned Parenthood v. Schimel*, 806 F.3d 908 (adopting balancing test), with *Karlin v. Foust*, 188 F.3d 446, 481 (7th Cir. 1999) (“[A] court’s proper focus [in the undue burden analysis] must be on the practical impact of the challenged regulation and whether it will have the likely effect of preventing a significant number of women for whom the regulation is relevant from obtaining abortions”); and compare *Planned Parenthood v. Humble*, 753 F.3d 905 (9th Cir. 2014) (adopting balancing test), with *Tucson Woman’s Clinic v. Eden*, 379 F.3d 531, 541 (9th Cir. 2004) (holding ASC regulations to be rational; “the undue burden standard is not triggered at all if a purported health regulation fails to rationally promote an interest in maternal health on its face”).

unduly burden abortion access, Petitioners urge that the improper purpose for HB2 is manifest in its real-world effects, but as *Mazurek* also held, effects alone cannot prove unconstitutional motive. 520 U.S. at 972 (“We do not assume unconstitutional legislative intent even when statutes produce harmful results.”) Even a legislator’s awareness of possible consequences is insufficient to demonstrate an unconstitutional intent. *Pers. Adm’r of Mass. v. Feeney*, 442 U.S. 256, 278-79 (1979). Nor can differential treatment of abortion providers demonstrate an unconstitutional motive. If HB2 regulates outpatient abortion differently from other outpatient procedures (an assertion neither Respondents nor *Amici* admit), the Court has recognized that abortion may be regulated differently than other medical procedures. *See, e.g., Harris v. McRae*, 448 U.S. 297, 325 (1980).

A. The Ambulatory Surgical Center Requirements Rationally Relate to Texas’s Legitimate Interest in Upholding Consistent Standards for Outpatient Abortion Providers.

The practice of surgical abortion overwhelmingly occurs in outpatient clinical facilities. *Te Linde’s Operative Gynecology* 448 (reporting that 93% of abortions occur in free-standing clinics and 2% in physicians’ offices); R. Jones & J. Jerman, *Abortion Incidence and Service Availability in the United States, 2011* (Alan Guttmacher Institute 2013), available at <http://www.guttmacher.org/pubs/journals/psrh.46e04>

14.pdf (last visited Jan. 29, 2016). Abortion practice is similar to procedures that are typically performed in ASCs such as cataract surgery, upper gastrointestinal endoscopy, colonoscopy and spinal injection. See C. Pallardy & S. Becker, *50 Things to Know About the Ambulatory Surgery Center Industry*, Becker's ASC Rev. (Jul. 20, 2013), available at <http://www.beckersasc.com/lists/50-things-to-know-about-the-ambulatory-surgery-center-industry.html> (last visited Feb. 1, 2016). In passing the ASC requirements, the Texas legislature relied upon testimony that surgical abortion should be performed in a sterile environment because it involves entry into the sterile uterus (J.A. 846-50); that procedures requiring entry into the uterus, such as dilation and curettage, are traditionally performed in ASC or hospital settings (J.A. 48-50); that performing such procedures in an ASC environment ensures enhanced pain management options for patients (J.A. 807-08);<sup>18</sup> and that ASCs provide accountability and monitoring mechanisms that ensure patient safety (J.A. 852).

The ambulatory surgical centers requirement is rationally related to a legitimate state interest. The District Court below concluded that the ASC requirement “surmount[s] the low bar of rational-basis review.” *Lakey*, 46 F. Supp. 3d at 673. And this Court, in *Simopoulos*, upheld Virginia’s similar ASC requirement for second-trimester abortions

---

<sup>18</sup> The president of petitioner Whole Woman’s Health acknowledged that its ASC offers “more robust pain management options” for abortions than those performed at non-ASC facilities. See J.A. 807-08.



even under this Court's pre-*Casey* strict-scrutiny framework. *Simopoulos*, 462 U.S. at 519.<sup>19</sup>

Petitioners claim they will close if forced to comply with the ASC provisions, but many of the regulations impose no real burden and are consistent with procedures that outpatient clinics should already voluntarily have in place. For example, the regulations establish patient rights, including the right to be “treated with respect, consideration, and dignity,” to be “provided with appropriate privacy,” to be provided with “appropriate information concerning their diagnosis, treatment, and prognosis,” and a host of other commonsense provisions. 25 Tex. Admin. Code § 135.5. Another regulation requires that “[a]dministrative policies, procedures and controls shall be established and implemented to assure the orderly and efficient management of the ambulatory surgical center.” *Id.* § 135.6. Healthcare practitioners are required to have “the necessary and appropriate training and skills to deliver the services provided.” *Id.* § 135.7. While the financial concerns of the district court seemed to be focused on the construction requirements contained in 25 TEX. ADMIN. CODE § 139.40, that is but one small portion of the regulations, and conflicts with the district court's

---

<sup>19</sup> Although Petitioners did not identify which ASC regulations would require them to close, the Fifth Circuit granted as-applied relief to the McAllen facility from two components of the ASC regulations - the physical-plant and fire-prevention requirements. *Cole, supra*, 790 F.3d at 596. But the Court of Appeals agreed with the trial court that the ASC requirement had a rational basis and could be applied to facilities opening after September 2014. *Id.* at 567.

broad injunction finding that the entire “ambulatory-surgical-center requirement is unconstitutional.” *Lahey*, 46 F.Supp.3d at 687.

B. The Admitting Privileges Requirement  
Rationally Relates to Texas’s Legitimate  
Interest in Regulating Outpatient  
Abortion.

Based upon convincing testimony, the Texas legislature concluded that the admitting privileges requirement was “reasonable and medically necessary” to “improve the post-operative management of serious post-abortion complications.” J.A. 865; *see also Cole*, 790 F.3d at 579 n.19 (admitting-privileges requirement “assures peer-review” and “protect[ s] patients”). HB2’s admitting privileges requirement is consistent with the ordinary standard of care for D&C and similar outpatient procedures, and as such is a reasonable and medically necessary measure to promote patient health and safety.<sup>20</sup>

Because of the threat of complications, the success and safety of performing a D&C depend in part on the willingness of the practitioner to admit a

---

<sup>20</sup> See Declaration of Mikeal Love, M.D. filed Oct. 15, 2013 in *Abbott*, Civ. No. 1:13-cv-862-LY (W. Dist. Tex.), Doc. No. 60-1 at 3 (“Requiring hospital admitting privileges for physicians who perform abortions is the general standard of care.”); *id.* at 3 (“This is the standard of care, and it is consistent with the way medicine has been practiced for over 100 years.”); *Stenberg v. Carhart*, 530 U.S. 914, 958 (2000) (Kennedy, J., dissenting) (observing that the respondent was an “abortionist” who “lack[ed] admitting privileges at any hospital”).

patient for observation should complications occur. Te Linde's Operative Gynecology 473 ("Outpatient Curettage"); Dale W. Stovall et al., *Dilation & Curettage: Complications*, UpToDate, Jan. 14, 2014, available at <http://www.uptodate.com/contents/dilation-and-curettage> (last visited Feb. 1. 2016). While some complications of abortion may be treated on an outpatient basis such as by a return visit to the abortion facility if the physician is still available, it is the expectation any physician who operates on a woman as an outpatient have in place a concrete plan for taking care of known and expected complications which often require inpatient hospitalization and further surgery to correct the complication. For this reason, the National Abortion Federation recommended that women choose a doctor who can admit them to a nearby hospital. *Abbott II*, 748 F.3d at 595.<sup>21</sup> Moreover, the 30-mile

---

<sup>21</sup> Cf. American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAASF) *Surgical Standards* 13.0, available at [http://www.aaaasfsurveyors.org/asf\\_web/PDF%20FILES/ASC%20Standards%20and%20Checklist%20Version%2013.pdf](http://www.aaaasfsurveyors.org/asf_web/PDF%20FILES/ASC%20Standards%20and%20Checklist%20Version%2013.pdf) at 13 (last visited Jan. 28, 2016) ("Every physician, podiatrist, and oral and maxillofacial surgeon operating in an AAAASF accredited facility, must hold, or must demonstrate that they have held, unrestricted hospital privileges in their specialty at an accredited and/or licensed acute care hospital within thirty (30) minutes of the accredited facility for all operations that they perform within the facility. Only surgical procedures included in those hospital privileges may be performed within the AAAASF accredited facility."). AAASF is one of the largest not-for-profit accrediting organizations in the United States, accrediting more than 2000 outpatient facilities. See *About AAAASF*, available at <http://www.aaaasf.org/aboutus.html> (last visited Jan. 28, 2016). Similarly, federal law has long required ASCs participating in Medicare to have written transfer agreements with local

proximity to a hospital required by HB2 is a reasonable provision for the most serious complications such as major hemorrhage or uterine perforation which may occur during or shortly after the abortion procedure, in which case the emergency services best provided by the physician who performed the surgery would need to be nearby.

The ability to admit a patient to a local hospital and follow up to complete her care is essential in emergency circumstances in order to provide outpatients with an acceptable level of care. If an abortion doctor is not involved in the admission of a patient experiencing post-abortion complications, a failure to timely convey information about the woman's medical history and the details of her abortion procedure can result in significant time delays that could compromise her physical and emotional health. Most cases of incomplete abortion with retained tissue are first discovered in the emergency room because they occur outside of normal clinic operating hours.<sup>22</sup> If abortion providers were accessible at this time, the woman would have been able to return to the abortion facility, or the ER staff could call the physician who performed the procedure. Instead, women are

---

hospitals or "[e]nsure that all physicians performing surgery in the [center] have admitting privileges" at the hospital. 42 C.F.R. § 416.41(b). This mandate "ensure[s] that patients have immediate access to needed emergency or medical treatment in a hospital." 47 Fed. Reg. 34082, 34086 (Aug. 5, 1982).

<sup>22</sup> It is frequently the case with abortion practice that a clinic will have doctors on site only a few days a week. Patients cannot be safely treated for emergent complications at an abortion clinic when a physician is not present on site.

usually forced to rely on the much less efficient process of ER triage and subsequent consultation with a different physician — one who presumably has admitting privileges, but may not have access to the patients records or have accurate information about her abortion.

Unfortunately, an emergency physician is not necessarily trained to treat complications of abortion requiring surgical intervention such as uterine perforation, retained products of conception or uterine hemorrhage. The accreditation requirements for board certification in emergency medicine include no requirement for this type of surgical training. Accreditation Council of Graduate Medical Education (ACGME), *Program Requirements for Graduate Medical Education in Emergency Medicine*, eff. Jul. 1, 2013, available at <http://www.abim.org/certification/policies/combinedim/comccm.aspx> (last viewed Feb. 1, 2016). In such cases, the ER department has to contact an on-call specialist to handle the complications. Regrettably, however, many hospitals have inadequate on-call specialist coverage. See, e.g., A.S. O'Malley et al., *Hospital Emergency On-Call Coverage: Is There A Doctor in the House?* 115 Issue Brief Ctr. for Studying Health Sys. Change 1 (2007); Love Dec., *supra* n.20 at 4 (“Not all hospitals have OB/GYNs on emergency department call.”). When one is available, there is usually some delay between the call to a specialist and his or her arrival.

Ambulatory surgery facilities require admitting privileges for physicians who do procedures comparable to surgical and medical abortion. This

requirement ensures that someone knowledgeable about the patient's case, and familiar with the management of complications of abortion be available to help the patient in time of an emergency complication, or at the very least have access to the pertinent details of the patient's history and be able to communicate that professional information with the treating physician at the hospital. This information about abortion history becomes particularly important when evaluating the patient for infection after abortion. As mentioned above, medical abortion patients are at higher risk of fatal infection from *C. sordelli*, and if the patient arrives in the ER without the treating physician being aware of the details of the abortion history, the diagnosis of *C. sordelli* sepsis can be delayed, and delay in diagnosis can be fatal.

Likewise, the standard of practice for more serious complications, such as perforated uterus, hemorrhage and serious infection, is to hospitalize the patient. Perforations are particularly dangerous because the perforation could result in bowel contents being introduced into the uterus. In these cases, laparoscopic surgery is the first step in diagnosis, and more serious surgery may be indicated. Where the patient is seriously hemorrhaging, the situation warrants immediate attention in a facility that offers blood transfusion. The blood transfusion process is not available in an abortion clinic setting because blood has to be stored and refrigerated in a blood bank, which requires a level of resources and equipment which physicians do not have access to in non-hospital clinics. Thus it

is imperative for patient safety that close communication between the facility which is performing the surgery and the hospital be assured to maximize patient safety in the predictable cases of surgical emergencies.

In light of the irreducible risks that inhere in practicing surgical and drug-induced abortion, the fulfillment of the medical principles of timely care and continuity of care can best be accomplished only when the physician who performed the procedure that resulted in the complication can assure rapid treatment of the patient in the facility equipped to care for these types of surgical emergencies. That is exactly why ambulatory surgical facilities require admitting privileges for physicians performing surgery comparable to elective abortion, and exactly why Texas needs this law to ensure the health and safety of women undergoing both medical and surgical abortion.

**CONCLUSION**

For the foregoing reasons, *Amici* urge the Court to affirm the judgment of the court of appeals.

Respectfully submitted,

ALLIANCE DEFENDING  
FREEDOM:

STEVEN H. ADEN  
*Counsel of Record*  
440 1st St., N.W., Suite 600  
Washington, DC 20001  
(202) 393-8690  
saden@adfllegal.org

DAVID A. CORTMAN  
KEVIN H. THERIOT  
1000 Hurricane  
Shoals Road, NE  
Suite D-1100  
Atlanta, GA 30043

February 3, 2016