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2016 Jun 13 PM 4:24 CLERK OF THE APPELLATE COURT CASE NUMBER: 114153

No. 15-114153-A

IN THE SUPREME COURT OF THE STATE OF KANSAS

HODES & NAUSER, MDS, P.A.; HERBERT C. HODES, M.D.; and TRACI LYNN NAUSER, M.D., Plaintiffs-Appellees,

v.

DEREK SCHMIDT, in his official capacity as Attorney General of the State of Kansas; and STEPHEN M. HOWE, in his official capacity as District Attorney for Johnson County, *Defendants-Appellants*.

On Petition from the Court of Appeals, there heard on appeal from the District Court of Shawnee County, Kansas Honorable Larry D. Hendricks, Judge District Court Case No. 2015-CV-490

BRIEF FOR AMICUS CURIAE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS IN SUPPORT OF PLAINTIFFS-APPELLEES

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INTEREST OF AMICUS CURIAE

The American College of Obstetricians and Gynecologists (the "College" or "ACOG") is a national 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 national professional organization dedicated to the advancement of women's health and the professional interests of its members. Sharing more than 57,000 members, the College and the Congress are the leading professional associations of physicians who specialize in the health care of women, representing approximately 90% of all board-certified obstetricians and gynecologists practicing in the United States.

ACOG opposes legislation that interferes in patient care without a substantial public health justification. ACOG, Statement of Policy: Legislative Interference with Patient Care, Medical Decisions, and the Patient-Physician Relationship (May 2013) ("ACOG Policy Statement"), available at http://www.acog.org/~/media/Statements%20 of%20Policy/Public/2013LegislativeInterference.pdf (last accessed May 23, 2016). Though their views on abortion may vary, ACOG's members share an interest in opposing laws that interfere with a physician's ability to exercise his or her best medical judgment to determine the safest and most appropriate care for each patient.

ACOG has previously appeared as *amicus curiae* in various courts, including the Supreme Court of the United States. In addition, ACOG's work has been cited by numerous courts seeking authoritative medical data regarding reproductive health. *See*,

e.g., Hodgson v. Minnesota, 497 U.S. 417, 454 n.38 (1990) (citing ACOG's amicus brief in assessing disputed parental notification requirement); Simopoulos v. Virginia, 462 U.S. 506, 517 (1983) (citing ACOG publication in discussing "accepted medical standards" for the provision of obstetric-gynecologic services, including abortions); Planned Parenthood Ariz., Inc. v. Humble, 753 F.3d 905, 916-917 (9th Cir. 2014) (citing ACOG and the American Medical Association's ("AMA") amicus brief as further support for a particular medical regimen), cert. denied, 135 S. Ct. 870 (2014); Stuart v. Camnitz, 774 F.3d 238, 251-252, 254, 255 (4th Cir. 2014) (citing ACOG's and the AMA's amicus brief in assessing how an ultrasound requirement exceeded the bounds of traditional informed consent and interfered with physicians' medical judgment), cert. denied, 135 S. Ct. 2838 (2015); Greenville Women's Clinic v. Bryant, 222 F.3d 157, 168 (4th Cir. 2000) (extensively discussing ACOG's guidelines and describing those guidelines as "commonly used and relied upon by obstetricians and gynecologists nationwide to determine the standard and the appropriate level of care for their patients"). On May 12, 2016, this Court granted ACOG's application to file an amicus brief in this appeal.

INTRODUCTION

The patient-physician relationship is essential to the provision of safe and quality medical care and should be protected from unnecessary governmental intrusion. *See* ACOG Policy Statement. Kansas Senate Bill 95 (the "Act") unduly interferes with the patient-physician relationship by seeking to criminally sanction physicians for exercising their best medical judgment in treating their patients. This Court should uphold the District Court's temporary injunction; and, ultimately, the Act should be permanently enjoined.

There is no medical justification for the Act. While the Act uses politically charged terminology not recognized by the medical community, it is without dispute that the Act would, with very limited exceptions, bar a medical procedure known as dilation and evacuation ("D&E"), which is the safest and most common method of second-trimester abortion and is performed on approximately 600 women in Kansas each year, or require physicians to perform additional procedures that are not necessary to safely perform a D&E. *See* Kansas Dep't Health & Env't, *Amnual Summary of Vital Statistics*, 2014 (Oct. 2015), at tbl. 38, available at http://www.kdheks.gov/hci/annsumm.html (containing annual statistics for 2000-2014). As a result of the ban, the remaining alternatives that physicians will be able to offer their patients are procedures that may be less safe for women seeking second-trimester abortions.

The Act also imposes grave consequences for physicians who do not comply, setting a dangerous precedent for legislative interference into the patient-physician relationship. Under the Act, a physician who performs a D&E procedure could face felony charges, as well as civil penalties. These penalties may apply even in cases where a physician determines, in his or her best medical judgment, that a D&E procedure alone is the safest and best procedure for a particular patient. The Act's draconian measures create a conflict between a physician's interest in avoiding criminal and civil liability, on the one hand, and a physician's duties to his or her patient, on the other.

The Act's attempt to criminalize physicians for performing a common and accepted medical procedure that is in the best interest of their patients could have broad sweeping consequences for public health more generally. If legislatures are permitted to criminalize accepted, safe, and recommended medical procedures, such interference will

erode the very nature of the patient-physician relationship. In short, the Act would prevent a physician from performing procedures that may be necessary for the safety of particular patients in contravention of his or her medical licensure and ethical obligations.

For these reasons and others discussed below, ACOG urges the Court to uphold the Court of Appeals' affirmance of the District Court's injunction.

ARGUMENT

While ACOG acknowledges the valuable role of government in protecting public health and safety, laws that "mandate which tests, procedures, treatment alternatives, or medicines physicians can perform, prescribe, or administer are ill-advised" and detrimental to the patient-physician relationship. *See* ACOG Policy Statement. The Act, the first of its kind in the United States, does not serve to protect public health and safety. Instead, it criminalizes performance of a safe and common medical procedure that could, under a variety of circumstances, serve a patient's best medical interests.

By preventing physicians from performing a D&E procedure—the most common and safest form of second-trimester abortion—the Act seeks to substitute the legislature's political judgment for the medical judgment of physicians to the detriment of patient safety. Indeed, the Act subjects women in need of a second-trimester abortion to other procedures that may be less safe and/or less effective for them and seeks to criminalize physicians who, in their medical judgment, offer D&E procedures as the best and most appropriate care for their patients. Permanently enjoining this law is, accordingly, crucial to ensuring the health and safety of women who seek a second-trimester abortion and to preserving the patient-physician relationship in Kansas.

I. THE ACT IS A MEDICALLY UNNECESSARY INTRUSION INTO THE EXAMINATION ROOM AND THREATENS PATIENT SAFETY.

While the vast majority—nearly 90%—of induced abortions are performed in the first trimester of pregnancy, some women, in consultation with their physicians, find it necessary to obtain an abortion in the second trimester for various reasons. ACOG, Practice Bulletin No. 135: Second Trimester Abortion, 121 Obstetrics & Gynecology 1394, 1394 (2013) ("ACOG Bulletin") ("Circumstances that can lead to second-trimester abortion include delays in suspecting and testing for pregnancy, delay in obtaining insurance or other funding, and delay in obtaining referral, as well as difficulties in locating and traveling to a provider . . . [Further,] [t]he identification of major anatomic or genetic anomalies in the fetus through screening and diagnostic testing most commonly occurs in the second trimester," and "[s]ome obstetric and medical indications for second-trimester termination include preeclampsia and preterm premature rupture of membranes"). In the second trimester, the vast majority of abortions are performed by D&E. See id. (stating that 95% of second trimester abortions are performed by D&E). In Kansas, approximately 600 women undergo D&E procedures annually. See, e.g., Kansas Dep't Health & Env't, Annual Summary of Vital Statistics, 2014 (Oct. 2015), at tbl. 38; Kansas Dep't Health & Env't, Annual Summary of Vital Statistics, 2013 (Oct. 2014), at tbl. 38; Kansas Dep't Health & Env't, Annual Summary of Vital Statistics, 2012 (Sept. 2013), at tbl. 38, available at http://www.kdheks.gov/hci/annsumm.html (containing annual statistics for 2000-2014).

Although induced abortion is one of the safest procedures in contemporary medicine, see David A. Grimes & Mitchell D. Creinin, *Induced Abortion: An Overview for Internists*, 149 Annals Internal Med. 620, 623 (2004), the risks of an abortion

procedure increase as a woman advances through pregnancy, see Linda A. Bartlett, Risk Factors for Legal Induced Abortion-Related Mortality in the United States, 103 Obstetrics & Gynecology 729, 732 (2004). Nationally, the risk of death resulting from an abortion is exceptionally low—0.6 per 100,000 (or 0.0006 percent). Elizabeth G. Raymond & David A. Grimes, The Comparative Safety of Legal Induced Abortion and Childbirth in the United States, 119 Obstetrics & Gynecology 215, 216 (2012); see also ACOG, Guidelines for Women's Health Care: A Resource Manual 719 (4th ed. 2014). It is well-established that a D&E is the safest and most common method of secondtrimester abortion. Maureen Paul et al., Management of Unintended and Abnormal Pregnancy: Comprehensive Abortion Care 157-158 (2009); ACOG Bulletin, 121 Obstetrics & Gynecology at 1394-1395. Indeed, by the late 1970s, researchers had documented the safety of D&E and concluded that it was safer than the medical abortion techniques used at the time, and the procedure continues to be the safest method of second-trimester abortion in modern medical practice. ACOG Bulletin, 121 Obstetrics & Gynecology at 1395; see also David A. Grimes et al., Mid-Trimester Abortion by Dilation and Evacuation: A Safe and Practical Alternative, 296 New Eng. J. Med. 1141 (1977). By restricting women's access to D&E in Kansas, the Act disregards nearly four decades of medical understanding.

By banning D&E procedures in most circumstances, the Act principally limits physicians in Kansas to two treatment options: labor induction and fetal demise. Restricting physicians to these two methods—while banning the most common and safest procedure—is a harmful intrusion into the patient-physician relationship and poses risks to women's health. In order to provide the best evidence-based medical care to their

patients, physicians need the freedom to perform procedures that they, in their medical judgment and with patient consultation, determine are in the best interest of their patients. What is in the best interest of and may be the safest for one patient may not be the same for another patient. While there may be some cases in which a physician determines that either induction or fetal demise is in the best interest of a patient given that patient's circumstances or the nature of that physician's practice, for many women, these procedures could present greater risks than a D&E procedure or could be less effective. The State should not be permitted to restrict a physician's ability to treat his or her patient with demonstrably safe procedures that are the best for the patient, nor should it restrict the ability of the physician and the patient to determine, together, a proper course of treatment. However, this is what the Act does and, in so doing, it raises serious safety and health concerns for women as well as intrudes unnecessarily into the patient-physician relationship.

For example, labor induction, also known as medical abortion, involves the use of one or more medications to induce pre-term labor and delivery of the fetus. Induction is the most common alternative to a D&E procedure and could be performed on women in the second-trimester under the Act. While labor induction is appropriate for some patients, it has a greater risk of complications, is less effective, and is a longer procedure than D&E. ACOG Bulletin, 121 Obstetrics & Gynecology at 1395-1396. Moreover, other surgical abortion procedures may be necessary following a labor induction, thereby compounding the health risks to women. Indeed, 10-33% of women have retained placenta and must undergo a surgical dilation and cutterage ("D&C") procedure after fetal expulsion to have the placenta removed. A. M. Autry et al., A Comparison of

Medical Induction and Dilation and Evacuation for Second Trimester Abortion, 187 Am. J. Obstetrics & Gynecology 393-397 (2002). In the event of failed or incomplete induction, a D&E—which would be prohibited in many cases under the Act—then becomes necessary to quell infection or heavy bleeding. Phillip G. Stubblefield et al., Methods for Induced Abortion, 104 Obstetrics & Gynecology 174, 180-181 (2004); see also Maureen Paul et al., A Clinician's Guide to Medical and Surgical Abortion 151 (Churchill Livingstone 1999).

Labor induction also heightens certain risks to women with specific medical conditions; for some, the procedure is contraindicated entirely. By example, for women who have undergone a prior hysterotomy or cesarean section delivery, labor induction can cause uterine rupture, hemorrhage, or even death. See P. Boulout et al., Late Vaginal Induced Abortion After a Previous Cesarean Birth: Potential for Uterine Rupture, 36 Gynecologic & Obstetric Investigation 87, 88 (1993).

In short, to the extent the Act's ban on D&E procedures effectively causes physicians to resort to labor induction, that alternative may pose greater risks to women than the D&E procedure. Further, unlike D&E—an outpatient procedure—labor induction requires hospitalization, and is a longer procedure that is more costly and more emotionally taxing to women. *See* Alisa B. Goldberg, *When Pregnancy Must End in the Second Trimester*, 123 Obstetrics & Gynecology 1153 (2014). Physicians should have the ability to perform safe procedures that are in the best interest of their patients, as opposed to having to opt for methods of treatment that may not be in the patient's best interest because of restrictive legislative interference.

The option of performing a second-trimester abortion through induction of fetal demise either through medication or transection prior to the D&E procedure—which Defendants contend would remain available to physicians under the Act—also is not sufficient to ensure a physician's ability to treat patients in accordance with his or her best medical judgment. See Order Granting Temporary Injunction at 2, Hodes & Nauser, MDs. P.A. et al. v. Schmidt, Case No. 2015-CV-490 (Kan. Shawnee Cty. Ct. June 30, 2015) (restating Defendants' assertions regarding available procedures for performing second-trimester abortions). While some physicians may choose to attempt to induce fetal demise due to certain medical or other considerations specific to their patients, inducing fetal demise is neither required prior to a D&E nor proven to be medically beneficial to the woman. Indeed, "[n]o evidence currently supports the use of induced fetal demise to increase the safety of second-trimester medical or surgical abortion." See ACOG Bulletin, 121 Obstetrics & Gynecology at 1396. Moreover, the effectiveness and risk factors of inducing fetal demise prior to 18 weeks of gestation remain unclear. After 18 weeks, the limited available data are inconclusive regarding whether causing fetal demise increases the safety of the D&E procedure, and inducing fetal demise may create additional risks, such as the risk of vomiting, infection, spontaneous abortion, and hospitalization. Id.; see also R. A. Jackson et al., Digoxin to Facilitate Late Second-Trimester Abortion: a Randomized, Masked, Placebo-Controlled Trial, 97 Obstetrics & Gynecology 471 (2001); Gillian Dean et al., Safety of Digoxin for Fetal Demise Before Second-Trimester Abortion by Dilation and Evacuation, 85 Contraception 144 (2012); Justin Diedrich & Eleanor Drey, Induction of Fetal Demise Before Abortion, Society of Family Planning Guideline 20101, 81 Contraception 462 (2010). The only alternative to

inducing fetal demise via medication is by transecting the umbilical cord in utero. That method, however, is not possible in every case, rendering it unreliable. Further, when transection fails, the physician may be exposed to criminal and civil liability under the Act. For these reasons, the decision regarding inducing fetal demise should be made in the context of the patient-physician relationship—not mandated by the State.

There is no medically sound basis for the State to require abortion providers to induce fetal demise prior to performing a D&E or to offer patients only labor induction for second-trimester abortion. Yet, through banning D&E procedures, this is what the Act effectively requires. While the Act would permit performance of a D&E in those cases where it is necessary to preserve a pregnant woman's life or to prevent substantial, irreversible impairment of her bodily functions, these exceptions offer no safety for women who would face increased significant health risks from induction or fetal demise. Legislation of medical care should promote patient safety, not undermine it.

II. THE ACT'S DRACONIAN SANCTIONS THREATEN THE PATIENT-PHYSICIAN RELATIONSHIP.

ACOG's Code of Professional Ethics states that "the welfare of the patient must form the basis of all medical judgments. . . . The obstetrician-gynecologist should . . . exercise all reasonable means to ensure that the most appropriate care is provided to the patient." ACOG, Code of Professional Ethics of the American College of Obstetricians and Gynecologists (Sept. 2015), at 2 ("ACOG Code of Ethics"), available at http://www.acog.org/About-ACOG/ACOG-Departments/Committees-and-Councils/Volunteer-Agreement/Code-of-Professional-Ethics-of-the-American-College-of-Obstetricians-and-Gynecologists. ACOG's members, like all physicians bound by

medical ethics, must simultaneously "recognize responsibility to patients first and

foremost" and "respect the law." Amer. Med. Ass'n, *Principles of Medical Ethics: Preamble* (June 2001). The Act unconscionably compels physicians to choose between these duties. In so doing, the Act creates a number of ethical conflicts of interest that fundamentally disrupt the patient-physician relationship and the very foundation of ethical medical practice.

The application of sound medical judgment is one of the cornerstones of medical ethics. Consistent with the requirements of a medical license, physicians must use their judgment and provide individualized care based on each patient's needs. Accordingly, they must provide their patients with medical facts and recommendations that comport with good medical practice and conduct their practice in a way that conforms to the accepted standards of care. *See* ACOG Code of Ethics at 2. Under the Act, physicians are denied the ability to treat patients according to their best medical judgment.

Instead, the Act imposes a variety of consequences on physicians if their own medical judgment does not comport with its ban on D&E procedures absent fetal demise. The Act exposes physicians to a class A misdemeanor if they act in the patient's best interest by performing a single D&E procedure. Should they perform a subsequent procedure on another patient, the physician could face severity level 10 felony charges. See Kan. S.B. No. 95 § 6 (2015). Additionally, a physician could be subject to private litigation by patients and their spouses, or the parents of patients under the age of 18, resulting in the imposition of both monetary and statutory damages. *Id.* § 5(a)(1)-(3). The detrimental effect of these penalties is compounded by the fact that the physician's medical license could be suspended or revoked upon conviction of either a felony or class A misdemeanor. K.S.A. 65-2836(c) (stating that physician's "license may be revoked,

suspended or limited" if the physician "has been convicted of a felony or class A

misdemeanor"). The Act, thus, presents a physician with a dilemma: either violate the

Act (and face potential criminal charges and license revocation), on the one hand, or

follow his or her best medical judgment, on the other.

While the Act clearly harms women in need of second-trimester abortions and

physicians who perform such procedures, ACOG respectfully submits that the Act's

broad legislative interference with a physician's medical judgment and the patient-

physician relationship could have broad sweeping implications for the larger medical

community. Permitting a legislature to restrict—and criminalize—a common and safe

medical procedure that is in the best interest of particular patients undermines the very

nature of a physician's duty to his or her patients. The Act sets a dangerous precedent of

government intervention into the practice of medicine that is harmful to the public health

and to modern medical practice.

CONCLUSION

This Court should uphold the District Court's injunction and instruct the District

Court to permanently enjoin Kansas Senate Bill 95 because it impermissibly interferes

with the patient-physician relationship and threatens the health of women in the State of

Kansas by compelling physicians to use riskier and medically unnecessary second-

trimester abortion methods.

Dated: June 13, 2016

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