No. 18-6161

UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

EMW WOMEN'S SURGICAL CENTER, P.S.C., on behalf of itself, its staff, and its patients; ERNEST MARSHALL, M.D., on behalf of himself and his patients,
Plaintiffs-Appellees,

PLANNED PARENTHOOD OF INDIANA AND KENTUCKY, INC.,
Intervenor Plaintiff-Appellee,

v.

ADAM MEIER, in his official capacity as Secretary of Kentucky's Cabinet for Health and Family Services; MATTHEW G. BEVIN, Governor of Kentucky, in his official capacity,
Defendants-Appellants.

On Appeal from the United States District Court
for the Western District of Kentucky, No.3:17-cv-00189
Before the Honorable Gregory N. Stivers

BRIEF OF AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS AND SOCIETY FOR MATERNAL-FETAL MEDICINE AS AMICI CURIAE IN SUPPORT OF APPELLEES AND AFFIRMANCE

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April 5, 2019

DISCLOSURE OF CORPORATE AFFILIATIONS AND FINANCIAL INTEREST

Pursuant to Sixth Cir. R. 26.1, the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine make the following disclosure:

1. Is said party a subsidiary or affiliate of a publicly owned corporation? If Yes, list below the identity of the parent corporation or affiliate and the relationship between it and the named party:

No. The American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine are non-profit organizations, with no parent corporations or publicly traded stock.

2. Is there a publicly owned corporation, not a party to the appeal, that has a financial interest in the outcome? If yes, list the identity of such corporation and the nature of the financial interest:

None.

Dated: April 5, 2019

/s/ Kimberly A. Parker
KIMBERLY A. PARKER

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INTEREST OF AMICI CURIAE

The American College of Obstetricians and Gynecologists (the "College" or "ACOG") and the Society for Maternal-Fetal Medicine ("SMFM") submit this amici curiae brief in support of Appellees.[1]

ACOG is the nation's leading group of physicians providing health care for women. With more than 58,000 members—representing more than 90% of all obstetricians-gynecologists in the United States—ACOG advocates for quality health care for women, maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness among its members and the public of the changing issues facing women's health care. ACOG is committed to ensuring access to the full spectrum of evidence-based quality reproductive health care, including abortion care, for all women. ACOG opposes medically unnecessary laws or restrictions that serve to delay or prevent care.

ACOG has previously appeared as amicus curiae in various courts throughout the country. ACOG's brief and guidelines have been cited by

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[1] The parties have consented to the filing of this brief. No counsel for a party authored this brief in whole or in part and no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of the brief. No person or entity other than amici or their counsel made a monetary contribution to the preparation or submission of this brief.

numerous courts, including the Supreme Court and this Court, seeking authoritative medical data regarding childbirth and abortion.[2]

SMFM supports the clinical practice of maternal-fetal medicine ("MFM") by providing education, promoting research, and engaging in advocacy to optimize the health of high-risk pregnant women and their babies. Founded in 1977, SMFM is the medical professional society for obstetricians who have additional training in the area of high-risk, complicated pregnancies. Representing over 4,000 members who care for high-risk pregnant women, with 22 in Kentucky, SMFM works to

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[2] *See, e.g.*, *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2312, 2315 (2016) (citing amici brief submitted by ACOG and other medical associations in assessing disputed admitting privileges and surgical center requirements); *Stenberg v. Carhart*, 530 U.S. 914, 928, 932-936 (2000) (quoting ACOG's amicus brief extensively and referring to ACOG as among the "significant medical authority" supporting the comparative safety of the abortion procedure at issue); *Hodgson v. Minnesota*, 497 U.S. 417, 454 n.38 (1990) (citing ACOG's amicus brief in assessing disputed parental notification requirement); *Simopoulos v. Virginia*, 462 U.S. 506, 517 (1983) (citing ACOG publication in discussing "accepted medical standards" for the provision of obstetric-gynecologic services, including abortions); *Planned Parenthood Cincinnati Region v. Taft*, 444 F.3d 502, 506 n.2 (6th Cir. 2006) (citing an ACOG practice bulletin regarding updated recommendations for the administration of medication abortions); *Isaacson v. Horne*, 716 F.3d 1213, 1225-1226, 1228 n.13 (9th Cir. 2013) (citing ACOG amicus brief in discussing fetal viability); *see also Gonzales v. Carhart*, 550 U.S. 124, 170-171, 175-178, 180 (2007) (Ginsburg, J., dissenting) (referring to ACOG as "experts" and repeatedly citing ACOG's amicus brief and congressional submissions regarding abortion procedure); *Greenville Women's Clinic v. Bryant*, 222 F.3d 157, 168 (4th Cir. 2000) (ACOG's guidelines are "commonly used and relied upon by obstetricians and gynecologists nationwide to determine the standard and the appropriate level of care for their patients").

increase promotion of high-quality MFM research and expand access to MFM services to reduce healthcare disparities for high-risk pregnant women.

SUMMARY OF ARGUMENT

Reproductive healthcare is essential to a woman's overall health, and access to abortion is an important component of reproductive healthcare. Accordingly, laws that regulate abortion should be evidence-based and designed to improve women's health.[3] At issue here are two provisions of Kentucky law that provide no medical benefit and are not supported by accepted medical practice or scientific evidence:

- The "transfer agreement requirement," which requires abortion facilities[4] to have a written agreement with an acute-care hospital "capable of treating patients with unforeseen complications related to an abortion facility procedure by which agreement the hospital agrees to accept and treat these patients" and to which patients will be

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[3] *See, e.g.*, ACOG, Comm. on Health Care for Underserved Women, *Committee Opinion Number 613, Increasing Access to Abortion*, 124 Obstetrics & Gynecology 1060, 1062-1063 (2014); ACOG, *College Statement of Policy, Abortion Policy* 1-2 (2014), https://www.acog.org/-/media/Statements-of-Policy/Public/sop069.pdf?dmc=1&ts=20190404T1136144909; *see also* ACOG, *Statement of Policy, Legislative Interference with Patient Care, Medical Decisions, and the Patient-Physician Relationship* (2013, reaffirmed 2016), https://www.acog.org/-/media/Statements-of-Policy/Public/89LegislativeInterferenceAug2016.pdf?dmc=1&ts=20190404T1138103818.

[4] "Abortion facility" is defined as "any place in which an abortion is performed." Ky. Rev. Stat. § 216B.015(1). We use the term "clinic" interchangeably with "abortion facility" throughout this brief.

transferred "[i]f unforeseen complications arise prior to or during an abortion facility procedure."[5]

- The "transport agreement requirement," which requires abortion facilities to "enter into a written agreement with a licensed local ambulance service for the transport of any emergency patient … to the licensed acute-care hospital."[6]

Neither of Kentucky's provisions is necessary to protect patient safety. Abortion is a safe medical procedure that almost never requires transfer from a clinic to a hospital. In the exceedingly rare instances in which such a transfer is required, having in place an emergency protocol, or plan, is the recommended best practice. Written transfer and transport agreements are unnecessary and create needless administrative burdens. Emergency services providers, both hospitals and ambulances, will care for women who are experiencing complications from an abortion regardless of the existence of transfer and transport agreements.

Enforcement of Kentucky's transfer and transport agreement requirements would result in the closure of Kentucky's one remaining abortion clinic and

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5 *Id.* § 216B.0435(1)-(2).

6 *Id.* § 216B.0435(3). Administrative regulations implemented in 2017 (902 Ky. Admin. Reg. 20:360 § 10) imposed additional restrictive conditions, including that the hospital be in the same county or no further than a 20-minute drive from the abortion facility (*id.* § 10(3)(a)) and that the ambulance service be located in the same county or no further than a 5-mile or 10-minute drive from the abortion facility (*id.* § 10(4)(a)). The 2017 regulations also contain 14 explicit conditions that must be included in the transfer and transport agreements (*id.* § 10(3)(e)-(f), 4(c)).

prevent another clinic that plans to provide abortions from doing so. This will delay or prevent women from accessing safe, legal abortion care. Both outcomes have serious, negative health consequences that are felt most intensely by women living at or below the poverty line, women of color, and young women or minors.

Beyond the harm they cause to women's health, Kentucky's provisions violate clear Supreme Court precedent. The Supreme Court recently reaffirmed the importance of evaluating "the existence or nonexistence of medical benefits" when evaluating a regulation's impact on women's access to abortion.[7] States should not be permitted to enforce laws that restrict access to abortion when those laws are not medically necessary to protect patient safety. Because Kentucky's enforcement of its transfer and transport agreement requirements restricts access to abortion care but offers no medical benefit to patients, amici urge this Court to affirm the district court's decision.

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[7] *Whole Woman's Health*, 136 S. Ct. at 2309 ("The Court of Appeals' articulation of the relevant standard is incorrect. The first part of the Court of Appeals' test may be read to imply that a district court should not consider the existence or nonexistence of medical benefits when considering whether a regulation of abortion constitutes an undue burden. The rule announced in *Casey*, however, requires that courts consider the burdens a law imposes on abortion access together with the benefits those laws confer.").

ARGUMENT

I. ABORTION IS A SAFE MEDICAL PROCEDURE THAT RARELY REQUIRES TRANSPORT TO A HOSPITAL

Abortion is a common and safe medical procedure.[8] In the United States, approximately one-quarter to one-third of women will seek an abortion by 45 years of age.[9] In 2015, the last year for which data is available from the Centers for Disease Control and Prevention, 638,169 abortions were performed in the United States and 3,188 were performed in Kentucky.[10] The vast majority of abortions are performed—safely—in a clinic or office-based setting,[11] without any need for hospitalization.

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[8] *See generally* National Academies of Sciences, Engineering, Medicine, *The Safety and Quality of Abortion Care in the United States* ("*Safety and Quality of Abortion Care*") (2018); *see also id.* at 10 ("The clinical evidence clearly shows that legal abortions in the United States—whether by medication, aspiration, D&E, or induction—are safe and effective. Serious complications are rare."); *id.* at 36 ("In this report, 'rare' is used to describe outcomes that affect fewer than 1 percent of patients."); *id.* at 51-68 (summarizing methods for performing abortions and their associated complication rates).

[9] ACOG, Comm. on Health Care for Underserved Women, *Committee Opinion Number 613*, 124 Obstetrics & Gynecology at 1060; Guttmacher Inst., *Induced Abortion in the United States* (Jan. 2018).

[10] Jatlaoui et al., *Abortion Surveillance – United States 2015*, 67 Morbidity & Mortality Weekly Rep. 1, 5, 21 tbl. 2 (2018).

[11] Roberts et al., *Association of Facility Type with Procedural-Related Morbidities and Adverse Events Among Patients Undergoing Induced Abortions*, 319 J. Am. Med. Ass'n 2497, 2502 & tbl. 1 (2018) (approximately 90% of abortions performed in office-based setting); *Safety and Quality of Abortion Care* 31 (majority of abortions performed in non-hospital settings); Silverthorn Dep. Ex.

In the rare instances where a complication arises in connection with an abortion (in one study, approximately 2.1%[12]), most are minor and can be managed on an outpatient basis, i.e., without going to a hospital.[13] For example, the most common complications following an abortion—incomplete abortion or

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26, RE 100-13, PageID # 3226, *Number of Induced Termination of Pregnancy (ITOP) Cases in KY, by Facility and State of Residency 2015-2017* (all but a handful of abortions in Kentucky in 2015-2017 performed in clinics).

[12] Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175, 181 (2015).

Additionally, in the United States, the rate of death resulting from an abortion is exceptionally low—0.6 per 100,000 (or 0.0006%). *See* Raymond & Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215, 215-216 (2012) (also concluding that the risk of death associated with childbirth was approximately fourteen times higher than that with abortion); *see also* ACOG, *Guidelines for Women's Health Care: A Resource Manual* 719 (4th ed. 2014); *Safety and Quality of Abortion Care*, at 75 (observing that there is a higher mortality rate associated with colonoscopies, plastic surgery, dental procedures, adult tonsillectomies).

[13] *Safety and Quality of Abortion Care*, at 116 ("In addition to disrupting continuity of care and increasing medical costs, emergency department visits are not the ideal avenue for follow-up abortion care. Evidence suggests that abortion providers are better prepared than emergency department staff to evaluate women post-abortion, avoiding unnecessary use of such interventions as repeat aspiration or antibiotics." (citations omitted)).

infection[14]—can typically be treated by follow-up procedures at the clinic and/or antibiotics.[15]

Women visit an emergency department after abortion procedures only in extremely rare cases. One multistate study found that only 0.01% of emergency department visits by women aged 15-49 were abortion-related.[16] Even when these visits occur, they do not necessarily indicate a serious medical issue. That same study found that only 0.11% of abortions were followed by an emergency department visit for a major incident[17] and that approximately half of abortion-related emergency department visits resulted in only observational care and no other treatment.[18]

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14 Upadhyay et al., 125 Obstetrics & Gynecology at 180 tbl. 4.

15 ACOG, *Induced Abortion: What Complications Can Occur with an Abortion?* (May 2015), https://www.acog.org/Patients/FAQs/Induced-Abortion?IsMobileSet=false.

16 Upadhyay et al., *Abortion-Related Emergency Department Visits in the United States: An Analysis of a National Emergency Department Sample*, 16 BMC Med. 1, 5 (2018).

17 *Id.* (major incident is defined as requiring blood transfusion, surgery, or overnight inpatient stay); *see also Safety and Quality of Abortion Care*, at 57 (in study of medication abortions in Iowa, rate of clinically significant adverse events (hospital admission, surgery, blood transfusion, emergency department treatment, or death) was less than 0.3%).

18 Upadhyay et al., 16 BMC Med. at 6-7 (2018).

Even when women seek emergency care after an abortion, they typically do so after returning home from the facility at which the abortion was performed. One study found that only 1 in 5,491 (0.03%) abortions led to transfer by ambulance to an emergency department for immediate care.[19] By contrast, approximately 343 in 5,491 abortions were followed by an emergency department visit in the six weeks following an abortion,[20] i.e., the vast majority of emergency department visits following an abortion did not require immediate transportation from a clinic to an emergency department. Often, these visits did not indicate a serious complication caused by abortion—only approximately 40% of emergency department visits following an abortion were found to be abortion-related; of that 40%, two-thirds did not require a diagnosis or treatment.[21]

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[19] Upadhyay et al., 125 Obstetrics & Gynecology at 180.

[20] *Id.* at 180-181; *see also* Upadhyay et al., *Distance Traveled for an Abortion and Source of Care After Abortion*, 130 Obstetrics & Gynecology 616, 619 (2017) (of participants in this study who sought care at an emergency department following an abortion, 88% sought care the day after the abortion or later); Upadhyay et al., *Admitting Privileges and Hospital-Based Care After Presenting for Abortion: A Retrospective Case Series*, 54 Health Servs. Research 425, 434 (2019) ("Most who receive hospital-based care after presenting for an abortion are not directly transferred from an abortion facility. Instead, most of the patients in our study were referred to a hospital either at the initial visit (because of a suspected ectopic pregnancy or, more rarely, a need for hospital-based abortion care) or self-referred to a hospital after the initial visit.").

[21] Upadhyay et al., 125 Obstetrics & Gynecology at 180-181. Diagnosis and treatment may not have been required at many of these post-abortion emergency department visits because women—particularly those who live far from a clinic—

The approximately 30% of abortions that are medication abortions[22] are even less likely to result in a need to be transported directly from a clinic to an emergency department. Medication abortions use two doses of medicines to end a pregnancy. The second medication, which completes the abortion, is taken outside the clinic.[23] Accordingly, if a patient requires emergency medical assistance in connection with a medication abortion, she will most likely be outside the clinic and, in many cases, hundreds of miles away at her home, where a clinic's written transfer or transport agreements would have no effect.[24]

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may seek follow-up care at emergency departments that could be provided in a clinic or by phone. *See* Upadhyay et al., 130 Obstetrics & Gynecology at 622; *see also* Upadhyay et al., 54 Health Servs. Research at 428-429 & tbl. 2 (most patients referred by direct phone call or referral form from the abortion facility to the emergency department were cases of suspected ectopic pregnancy (i.e., not abortion-related)).

[22] Jones & Jerman, *Abortion Incidence and Service Availability in the United States, 2014*, 49 Perspectives on Sexual & Reprod. Health 17, 24 tbl. 5 (Mar. 2017); Jatlaoui et al., 67 Morbidity & Mortality Weekly Rep. at 33 tbl. 11.

[23] *See Safety and Quality of Abortion Care*, at 56 ("Indeed, most women in the United States return home after taking mifepristone and take the misoprostol 28 to 48 hours later. As a result, medication abortions occur largely in nonclinical settings.").

[24] *See id.* at 10 ("No special equipment or emergency arrangements are required for medication abortions."); *id.* at 79 (explaining that the effects of the medication occur after women leave the clinic and that the risks of medication abortion are similar in magnitude to the risks of taking commonly prescribed and over-the-counter medications such as antibiotics and NSAIDs).

The above discussion demonstrates that abortion is a very safe procedure with a very low rate of complications that might require a woman to visit a hospital on an emergency basis. Further, even when such a visit is required, the need will typically arise after a woman has returned home from the clinic at which her abortion was performed or from which she received a prescription, in which case she will likely seek medical attention locally.[25] In such situations, a clinic's transfer and/or transport agreements do not benefit women's health and safety.

II. IN THE INFREQUENT INSTANCES THAT REQUIRE TRANSFER TO A HOSPITAL FROM A FACILITY AT WHICH ABORTIONS ARE PERFORMED, TRANSFER AND TRANSPORT AGREEMENTS ARE MEDICALLY UNNECESSARY

Even in the exceedingly rare cases where a woman needs to be transferred from a clinic where she received an abortion to an emergency department, written transfer and transport agreements are unnecessary. Appellants have posed to this Court that transfer and transport agreements protect patient safety and health by "ensur[ing] that healthcare facilities will implement measures to help emergency transfers from one to another go as smoothly and safely as possible" and "that the

[25] *See id.* at 116 ("Women traveling longer distances (25-49 miles, 50-99 miles, or 100 miles or more) were significantly more likely than those traveling 25 miles or less to seek follow-up care in a local emergency department instead of returning to their original provider." (citation omitted)).

necessary medical records are transferred with a patient."[26] However, written transfer and transport agreements—especially those with provisions as restrictive as those found in Kentucky's administrative regulations[27]—are unnecessary for achieving these goals. These goals can be equally accomplished through maintenance of an emergency transfer *protocol*, i.e., internal plan or processes for transferring a patient to a hospital in the rare instance such a need arises. Ambulance services and emergency departments are required to provide services regardless of the existence of written transfer and transport agreements. Further, the appellants' argument that the abortion facility transfer or transport agreements improve patient safety is undermined by the facts that (i) not all facilities that perform medical procedures that are similarly safe or have higher complication rates than abortion are required to have equivalent agreements or the requirements are less stringent, (ii) abortions can be legally performed at private physicians' offices that do not have such agreements (although none have been in recent years), and (iii) such agreements may be impossible to obtain for arbitrary or abusive reasons unrelated to the clinic's competency.

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[26] Appellants' Br. 34-35.

[27] *See supra* note 6.

A. Current Best Practices For Handling Clinic Emergencies Require Emergency Protocols, Not Written Transfer And Transport Agreements

Amici recommend that clinics that provide abortion care—like outpatient facilities that perform other types of obstetric and gynecologic procedures—have a protocol in place for handling emergencies,[28] and all clinics do. For example, depending on the practice's needs, such protocols typically include information about: (i) how to identify particular emergency situations (e.g., hemorrhage, uterine preformation) and specific treatment steps for those emergencies; (ii) staff roles during the course of an emergency; (iii) location of emergency supplies; and (iv) evaluating patients for hospital transfer. These protocols typically also include guidelines for arranging emergency transport and coordinating with a hospital once the determination is made that a patient needs such care,[29] such as plans for calling

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[28] *See, e.g.*, ACOG, Comm. on Patient Safety and Quality Improvement, *Committee Opinion Number 590, Preparing for Clinical Emergencies in Obstetrics and Gynecology*, 123 Obstetrics & Gynecology 722, 722 (2014, reaffirmed 2018).

[29] *See, e.g.*, *id.* ("A plan for the transportation of unstable patients or transfer of care should be established."); *Safety and Quality of Abortion Care*, at 162 ("Most abortions can be provided safely in office-based settings. No special equipment or emergency arrangements are required for medication abortions. For other abortion methods, the minimum facility characteristics depend on the level of sedation that is used. Aspiration abortions are performed safely in office and clinic settings. If moderate sedation is used, the facility should have emergency resuscitation equipment and an emergency transfer plan, as well as equipment to monitor oxygen saturation, heart rate, and blood pressure.").

an ambulance, providing relevant medical records to the hospital, and communication between the clinic physician(s) and hospital physician(s). A clinic's appropriately designed emergency protocols sufficiently ensure patient safety.[30]

Written transfer and transport agreements are also unnecessary because ambulance services providers and hospitals must assist patients regardless of the existence of transfer and transport agreements. As the district court stated, under Kentucky law at the time the relevant regulations were promulgated, ambulances were required to accept requests for emergency service if a unit was available in

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[30] *Safety and Quality of Abortion Care*, at 166 ("The key safeguards—for abortions and all outpatient procedures—are whether the facility has the appropriate equipment, personnel, and emergency transfer plan to address any complications that might occur."); Levy et al., *Report From the Project on Facility Guidelines for the Safe Performance of Primary Care and Gynecology Procedures in Offices and Clinics* 7-8 (July 11, 2018), http://www.nationalpartnership.org/our-work/resources/project-on-facility-guidelines-report.pdf ("Facilities should establish written policies and procedures for managing facility emergencies (e.g., natural disaster, fire) and patient emergencies (e.g., vasovagal reaction, hemorrhage) and should conduct periodic drills and staff trainings on those policies and procedures. A formal transfer agreement with a hospital is not required as transfers are rare and hospitals are required to accept patients with emergent needs. Good communications in the event of a transfer, and working relationships with facilities that may receive or refer patients are encouraged."); *see* Upadhyay et al., 54 Health Servs. Research at 435 ("For both transfers and referrals, continuity of care was evident when abortion providers took an active role in calling hospitals before the patient arrived, in order to provide clinical information and advocate for the best course of action for their patient.").

the service area regardless of the absence of any transport agreement.[31] And under federal law, hospital emergency departments must treat and stabilize all emergency patients.[32] Accordingly, the lack of either a transfer or transport agreement does not impact whether the patient is actually transported and transferred to an emergency department. Moreover, the mere existence of a transfer or transport agreement does not ensure better emergency care for the patient by ambulance providers or hospitals, because, like clinics, they also as a matter of course have protocols for receiving and/or transporting patients that help ensure a smooth transition.[33]

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[31] D. Ct. Op., RE 168, PageID # 6844.

[32] D. Ct. Op., RE 168, PageID # 6842 (citing 42 U.S.C. § 1395dd).

[33] Appellants incorrectly suggest that the National Abortion Federation's ("NAF") guidelines support the transfer agreement requirement. This is not the case. NAF's guidelines include a recommendation that "[c]linics should consider developing a transfer agreement with a hospital outlining the means of communication and transport and the protocol for emergent transfer of care." National Abortion Federation, *2018 Clinical Policy Guidelines for Abortion Care* (2018). The recommendation for a provider to *consider* whether such an agreement would be helpful is not and should not be construed as a recommendation that such an agreement be mandated by law. The decision should be left up to the medical provider, based on its assessment of the needs of its patients, not forced on clinics by state regulation where it is medically unnecessary. Similarly, the American Medical Association ("AMA") study referenced by the expert witness for defendants-appellants, D. Ct. Trial Tr. Vol. 3A, RE 126, PageID # 4561 (testimony of Dr. Richard Hamilton), does not support the transfer agreement requirement. It was a survey of recommendations by other professional medical organizations related to the safety of office-based surgery, and one recommendation was emergency transfer *protocols* (not the types of

B. The State's Proffered Justification For Transfer And Transport Agreements Is Undermined By Arbitrary Application

Any argument that the transfer and transport agreements applicable to abortion facilities are medically necessary for facilities that perform abortions is undermined by the failure to require equivalent agreements (i) for all facilities that perform medical procedures that are similarly safe or have higher complication rates than abortion; and (ii) for all types of facilities that are permitted to perform abortions. Ambulatory surgical centers[34] ("ASCs") and hospitals perform procedures with much higher rates of complication than abortion clinics, such as invasive surgery under general anesthesia. However, to the extent that Kentucky regulations require ASCs to obtain transfer agreements,[35] the agreements do not have to meet the heightened standards of the current regulations applying to abortion facilities.[36] Hospitals in Kentucky are also permitted flexibility not made

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written transport or transfer agreements at issue here). *See* AMA, *Research in Ambulatory Patient Safety, 2000-2010: A 10-Year Review* 56 (2011).

[34] Ky. Rev. Stat. § 216B.015(4) (defining "[a]mbulatory surgical center").

[35] Ky. Attorney General Amicus Br. 19-20; Appellees' Br. (EMW Women's Surgical Center, P.S.C. and Ernest Marshall, M.D.) 12 (addressing differential treatment of ASCs relative to abortion facilities).

[36] The regulations applicable to ASCs require only written policies and procedures regarding "[a]rrangement for transportation of patients who require hospital care." 902 Ky. Admin. Reg. 20:106 § 2(b)(10). The current Certificate of Need Review Standards, which apply to newly established ASCs, Ky. Rev. Stat. § 216B.061(7)-(8), indicate that an ASC would need a transfer agreement with at least one acute care hospital located within a 20-minute drive of the ASC.

available to abortion facilities—although they are required to have transfer agreements with another facility that can provide care not provided by the hospital, the hospital may be exempted from compliance with that requirement if it shows that it made a good faith attempt to enter into a transfer agreement but could not.[37] No such good faith exemption applies to abortion facilities.[38] Not requiring transport or transfer agreements in all circumstances and imposing more lenient requirements around such agreements for hospitals and ASCs,[39] which perform

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Kentucky Cabinet for Health & Family Servs., *2018 Update to the 2017-2019 State Health Plan: Certificate of Need Review Standards* 52 (Nov. 2018), https://chfs.ky.gov/agencies/os/oig/dcn/Pages/cn.aspx. These standards do not contain the detailed requirements found in the abortion facility regulations. *See supra* note 6 (describing such regulations) & 902 Ky. Admin. Reg. 20:360 § 2(2)(c) (excluding ASCs and hospitals from the scope of the regulations).

[37] 902 Ky. Admin. Reg. 20:016 § 3(7)(b). Similarly, "intermediate care facilities" (providing supervision, medical, and other services to patients with physical or mental conditions requiring intermittent nursing services and continuous supervision of the activities of daily living) may be exempted from a regulatory requirement to have a written transfer agreement with another health care facility on a showing of good faith. *Id.* 20:051 § (8)(a).

[38] The strict procedural hurdles, e.g., "a certification under oath that the party seeking the extension of time has exhausted all reasonable efforts to obtain a transfer or transport agreement for a continuous ninety (90) calendar day period prior to the request," to obtaining the extension of time purportedly offered to abortion facilities to comply with the transfer and transport agreement requirements based on a showing of good faith (902 Ky. Admin. Reg. 20:360 § 10(5)(a)) do not appear in the hospital or intermediate care facility regulations (*id.* 20:016 § 3(7)(b); *id.* 20:051 § (8)(a)).

[39] There is no need for abortion facilities to meet the requirements of ASCs because of the stark difference in the types of procedures they perform. Accordingly, the regulations cited in the amicus brief filed by certain states in

procedures with higher complication rates than abortion facilities, indicates that the driver of Kentucky's regulations is not patient safety.

Similarly, not all facilities that are permitted to provide abortions are required to have transfer and transport agreements. Private physicians' offices are exempt from licensing regulations that would require such agreements (although no abortions have been provided in private physicians' offices in recent years).[40] There is no medical reason why facilities that are permitted to perform the same procedures should be subject to different regulatory standards.[41]

Finally, that medical providers are unable to obtain transfer or transport agreements does not indicate that they are incapable of providing safe, quality patient care. Obtaining such agreements can be difficult or impossible for

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support of appellants indicating that it is common practice to require transfer agreements for ASCs are inapposite. Additionally, several of the regulations cited are distinguishable from the Kentucky provisions at issue here because (i) the state also has separate regulations for abortion providers that explicitly do not require such agreements, (ii) they provide for alternative means of complying with the state's regulations (e.g., an emergency protocol), and/or (iii) they were enacted prior to the federal law requiring hospital emergency departments to treat and stabilize all emergency patients (*see supra* note 32 and accompanying text).

[40] *See* Ky. Rev. Stat. § 216B.020(2)(a); Silverthorn Dep. Ex 26, RE 100-13, PageID # 3026, *Number of Induced Termination of Pregnancy (ITOP) Cases in KY, by Facility and State of Residency 2015-2017*.

[41] *Cf.* Roberts et al., 319 J. Am. Med. Ass'n at 2505 (concluding that there was no statistically significant difference in safety for patients who obtain abortions at different types of outpatient facilities, specifically ASCs and clinics).

unrelated reasons; for example, hospitals may leverage transfer agreement requirements to try to reduce competition by requiring the physicians seeking the agreements to agree to certain limitations on their practice that benefit the hospital.[42] The ease with which these transfer and transport agreement requirements can be used to economically or politically disadvantage medical providers with no patient-safety-based justification undermines their purported significance.

In sum, Kentucky's transfer and transport agreement requirements are unnecessary to protect patient safety—a clinic's transfer protocol is sufficient to meet patient needs—and do not provide patients with better access to ambulance or

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[42] *See, e.g.*, American Society for Gastrointestinal Endoscopy, Comment Letter on Proposed Rule CMS-3346-P (Nov. 19, 2018), https://www.asge.org/docs/default-source/default-document-library/medicare-and-medicaid-programs-asge-comments_regulatory-provisions-to-promote-program-efficiency-transparency-and-burden-reduction_11-19-2018.pdf?sfvrsn=0; Department of Health & Human Resources, Centers for Medicare & Medicaid Services, *Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction*, 83 Fed. Reg. 47,686 (proposed Sept. 20, 2018) (to be codified at 42 C.F.R. pts. 403, 416, 418, 441, 460, 482-486, 488, 491, 494), (proposing "remov[ing] the [federal] requirements related to transfer agreements" because hospitals withhold or reject transfer agreements to augment a competitive edge rather than improve healthcare); Final Order, *Florida Academy of Cosmetic Surgery v. Department of Health*, No.00-1058RX (Fla. Div. Admin. Hrgs. Sept. 7, 2000) (transfer agreement requirement allowed hospitals to exercise unreasonable control over outside physicians and gave hospitals the potential to enter into transfer agreements on competitive economic grounds rather than on quality of care bases).

emergency services than existing laws and practices do. Further, the arbitrary way in which Kentucky requires written transfer and transport agreements combined with the potential that hospitals will decline to enter into such agreements for non-medical reasons undermine the purported medical benefits.

III. KENTUCKY'S TRANSFER AND TRANSPORT AGREEMENT REQUIREMENTS THREATEN TO UNNECESSARILY IMPEDE WOMEN'S ACCESS TO ABORTION

The district court record indicates that enforcement of Kentucky's transfer and transport agreement requirements would cause Kentucky's one remaining abortion clinic, EMW, to close and would prevent another clinic that plans to provide abortions from doing so.[43] The unavailability of these abortion providers would prevent or delay women's access to safe, legal abortion and could have a significant negative impact on women's health.

Appellants have suggested that Kentucky women could travel out of state for abortions, but these out-of-state providers may not be viable alternatives. Setting aside the constitutional question presented, there is a threshold capacity issue. The overall number of outpatient facilities providing abortions is declining, particularly

[43] D. Ct. Op., RE 168, PageID ## 6852-6853.

in the Midwest and the South.[44] For example, two states adjacent to Kentucky have just one open clinic that provides abortions.[45]

Even assuming out-of-state providers have the capacity to see additional patients, the additional travel required to visit these providers could delay or prevent women's access to abortion. The district court found that many Kentucky women would have to travel hundreds of miles to access abortion care if the regulations at issue here were enforced against the appellees.[46] Surveys of women who delay obtaining abortions have found that the time needed to raise money, including for travel, is one of the principal sources of delay.[47]

Delays in obtaining an abortion or the inability to obtain a safe, legal abortion pose serious threats to women's health. While abortion procedures are among the safest medical procedures, the rate of complications associated with

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44 *Safety and Quality of Abortion Care*, at 32.

45 Ingber, *1 Abortion Clinic Remains Open In Missouri, Following New State Requirements*, NPR, Oct. 3, 2018, https://www.npr.org/2018/10/03/654030995/one-abortion-clinic-remains-open-in-missouri-following-new-state-requirements; Keneally, *In Growing Number of States, Women Seeking Abortions Face the Problem of Where To Go*, ABC News, June 14, 2018, https://abcnews.go.com/US/growing-number-states-women-seeking-abortions-face-problem/story?id=55632730.

46 D. Ct. Op., RE 168, PageID ## 6846-6847.

47 *See* Upadhyay et al., *Denial of Abortion Because of Provider Gestational Age Limits in the United States*, 104 Am. J. Pub. Health 1687, 1692 (2014).

abortion procedures increases as the pregnancy progresses.[48] At 8 weeks' gestation or less, the mortality rate associated with abortion is 0.3 per 100,000 procedures; after 17 weeks, the rate is 6.7 per 100,000.[49] Further, studies suggest that as access to safe, legal abortion decreases, women may be more likely to attempt to self-induce abortion.[50] Self-induced abortions are significantly associated with post-abortion complications and maternal morbidity and mortality.[51]

Laws that unnecessarily restrict women's access to abortion—like the transfer and transport agreements at issue here—disproportionately impact women with low income, women of color, and young women. Women in these groups are more likely than others to experience unintended pregnancies.[52] They are more

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48 *Safety and Quality of Abortion Care*, at 75.

49 *Id.*; *see also* White et al., *Change in Second-Trimester Abortion After Implementation of a Restrictive State Law*, 133 Obstetrics & Gynecology 771, 777 (2019) (number of abortions occurring at 12 weeks' gestation or more increased after implementation of restrictive abortion regulation in Texas).

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

51 *See* AMA House of Delegates, Women Physician's Section, *Resolution 007, Oppose the Criminalization of Self-Induced Abortion* (May 1, 2018), *available at* https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/wps/a18-wps-resolution-007.pdf.

52 Parks & Peipert, *Eliminating Health Disparities in Unintended Pregnancy with Long-Acting Reversible Contraception (LARC)*, 214 Am. J. Obstetrics & Gynecology 681, 681-682 (2016) (citing Finer & Zolna, *Unintended Pregnancy in the United States: Incidence and Disparities, 2006*, 84 Contraception 478 (2011)); *see also* Morse et al., *Reassessing Unintended Pregnancy: Toward a Patient-*

likely than others to seek abortion care.[53] Women of color and women living at or below the poverty line are also more likely to experience complications or deaths in attempting to carry a pregnancy to term.[54]

Women in these groups may also face unique challenges in obtaining an abortion that could be exacerbated by Kentucky's transfer and transport agreement requirements. For example, one of the primary causes in delaying abortion care is the time it takes to raise money for travel and procedure costs (which continue to

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Centered Approach to Family Planning, 44 Obstetrics & Gynecology Clinics 27, 27 (2017) ("Underserved women, especially those with low incomes and from racial and ethnic minorities, experience a disproportionate share of unintended pregnancies in the United States.").

[53] *Safety and Quality of Abortion Care*, at 29-31.

[54] Centers for Disease Control and Prevention, *Pregnancy Mortality Surveillance System*, https://www.cdc.gov/reproductivehealth/maternal infanthealth/pregnancy-mortality-surveillance-system.htm?CDC_AA_ref Val=https%3A%2F%2Fwww.cdc.gov%2Freproductivehealth%2Fmaternal infanthealth%2Fpmss.html#trends (visited Apr. 5, 2019) (during 2011-2014 period, there were 40.0 deaths per 100,000 live births for black women, compared to 12.4 deaths per 100,000 live births for white women); Singh, U.S. Dep't of Health & Human Servs., *Maternal Mortality in the United States, 1935-2007: Substantial Racial/Ethnic, Socioeconomic, and Geographic Disparities Persist* 2, 3 (2010); ACOG, Comm. on Health Care for Underserved Women, *Committee Opinion No. 649, Racial and Ethnic Disparities in Obstetrics and Gynecology*, 126 Obstetrics & Gynecology e130, e131 & tbl. 1 (2015). Even without the additional challenges faced by women of color and women living at or below the poverty line, the risk of death associated with childbirth is approximately fourteen times higher than that with abortion. Raymond & Grimes, 119 Obstetrics & Gynecology at 215.

increase as the pregnancy progresses),[55] and, in Kentucky, almost a fifth of working-age women are at or below 100% of the Federal Poverty Guidelines.[56] For young women or minors, increased travel distances may exacerbate existing difficulties associated with restrictions like waiting periods because they may not have driver's licenses or sufficient personal funds for longer trips.

Amici believe that all women should have access to safe, legal abortion care. Kentucky's transfer and transport agreement requirements jeopardize access to such care for women in Kentucky and are not medically necessary for patient safety.

CONCLUSION

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

Respectfully submitted.

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55 *See* Upadhyay et al., 104 Am. J. Pub. Health at 1689, 1692.

56 TalkPoverty.Org, Kentucky 2018 Report, https://talkpoverty.org/state-year-report/kentucky-2018-report/ (visited Apr. 5, 2019).

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g), the undersigned hereby certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B).

1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(f)(1), the brief contains 6,062 words.

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/s/ Kimberly A. Parker
KIMBERLY A. PARKER

April 5, 2019

CERTIFICATE OF SERVICE

I hereby certify that on this 5th day of April, 2019, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Sixth Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

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