19-5516

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; ASHLEE BERGIN, M.D., M.P.H., on behalf of herself and her patients; TANYA FRANKLIN, MD, M.S.P.H., on behalf of herself and her patients,

Plaintiffs-Appellees,

v.

ADAM MEIER, in his official capacity as Secretary of Kentucky's Cabinet for Health and Family Services,

Defendant-Appellant,

and

THOMAS B. WINE, et al.,

Defendants.

On Appeal from the United States District Court for the Western District of Kentucky (Louisville)

BRIEF FOR STATES OF NEW YORK, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, HAWAI'I, ILLINOIS, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, NEVADA, NEW MEXICO, OREGON, PENNSYLVANIA, VERMONT, VIRGINIA, and WASHINGTON, and the DISTRICT OF COLUMBIA AS AMICI CURIAE IN SUPPORT OF APPELLEES

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INTEREST OF *AMICI CURIAE*

Amici are the States of New York, California, Colorado, Connecticut, Delaware, Hawai'i, Illinois, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Mexico, Oregon, Pennsylvania, Vermont, Virginia, and Washington, and the District of Columbia. Amici agree that "[t]he ability of women to participate equally in the economic and social life of the Nation has been facilitated by their ability to control their reproductive lives." *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 856 (1992). Amici are therefore committed to advancing their interest in promoting the health and safety of all women seeking abortion services without creating unwarranted obstacles to a woman's right to terminate a pregnancy. Amici also have an interest in ensuring that all physicians are permitted to provide services that are consistent with professional standards of care.

Both interests are threatened by the Kentucky statute at issue in this case, because that law prohibits physicians from providing second-trimester abortion services using the most common and safest procedure available for women after 15 weeks of pregnancy. Residents of amici States may need medical care while present as students, workers, or

visitors in Kentucky or other States with similar statutes; and physicians licensed in amici States may also practice medicine in Kentucky or other States with similar statutes.[1] Amici's interest in the provision of abortion services in a safe manner thus extends to both patients and physicians who may be residents of amici States but present in Kentucky and affected by the law at issue here. Moreover, a substantial reduction in the availability of abortion services in one State—here in the form of a de facto ban on abortions after 15 weeks—is likely to cause some women to seek services in neighboring States. Such consequences may limit the regulatory choices available to these States and could burden their health-care systems.

[1] More than 20% of all American doctors—over 200,000 physicians—maintain active licenses to practice medicine in more than one State. *See* Aaron Young et al., *FSMB Census of Licensed Physicians in the United States 2018*, 105 J. Med. Reg. 7, 11 (July 2019).

STATEMENT OF THE CASE

This case involves the constitutionality of House Bill 454 (the "Act"), an abortion restriction enacted by the Commonwealth of Kentucky in March 2018. *See* Ky. Rev. Stat. §§ 311.787, 311.990 (H.B. 454, Ky. Acts ch. 142 (2018 Reg. Sess.)). The Act imposes civil and criminal sanctions on any physician who performs an abortion after 13 weeks of pregnancy[2] that "dismember[s]" a "living unborn child" with the purpose of causing that unborn child's death.[3] Ky. Rev. Stat. § 311.787(1)-(2). The Act's prohibition on "dismemberment" abortion applies to "the use of clamps, grasping forceps, tongs, scissors, or a similar instrument." *Id.* § 311.787(1)(a). The parties agree that the Act requires a physician to

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[2] Medical literature refers to the gestational age of a fetus as the number of weeks after a woman's last menstrual period (LMP). The Act applies starting at 11 weeks measured from fertilization, Ky. Rev. Stat. § 311.787(2)(b), which is 13 weeks LMP. Unless otherwise noted, amici will refer to the LMP measure of gestational age.

[3] The Act includes a narrow "medical emergency" exception that applies only when an "immediate abortion" is necessary to "avert [the woman's] death" or for which a "delay will create a serious risk of substantial and irreversible impairment of a major bodily function." Ky. Rev. Stat. §§ 311.720(9), 311.787(1)(b).

cause fetal demise by terminating the fetal heartbeat before undertaking an abortion procedure that involves any of the prohibited instruments.

The purpose and effect of the Act is to prohibit the standard dilation and evacuation (D&E) procedure, which is widely regarded as the safest and most common method of second-trimester abortion after 15 weeks of pregnancy. (Mem. Op., R.126, PageID#5726.) Although at least 11 other States have enacted similar bans,[4] every court that has examined a D&E ban, including the district court below, has enjoined it upon application of the Supreme Court's controlling undue-burden standard.[5]

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[4] *See* Ala. Code §§ 26-23G-1 to -9; Ark. Code. Ann. §§ 2O-16-1801 to -1807; Ind. Code §§ 16-18-2-96.4, 16-34-2-1(c), 16-34-2-7(a); Kan. Stat. Ann. §§ 65-6741 to -6750; La. Rev. Stat. Ann. § 40:1061.1.1; Miss. Code Ann. §§ 41-41-151 to -169; N.D. Century Code § 14-02.1-04.2; Ohio Rev. Code § 2919.15; Okla. Stat. tit. 63, §§ 1-737.7 to .16; Tex. Health & Safety Code §§ 171.151 to .154; W. Va. Code § 16-2O-1.

[5] *See West Ala. Women's Ctr. v. Williamson*, 900 F.3d 1310 (11th Cir. 2018) (permanently enjoining Alabama statute), *cert. denied* 139 S. Ct. 2606 (2019); *Bernard v. Individual Members of Ind. Med. Licensing Bd.*, No. 18-cv-1660, 2019 WL 2717620 (S.D. Ind. June 28, 2019) (preliminarily enjoining Indiana statute); *Planned Parenthood Sw. Ohio Region v. Yost*, 375 F. Supp. 3d 848 (S.D. Ohio 2019) (preliminarily enjoining Ohio statute in part); *Whole Woman's Health v. Paxton,* 280 F. Supp. 3d 938 (W.D. Tex. 2017) (permanently enjoining Texas statute), *appeal filed*, No. 17-51060 (5th Cir. Nov. 22, 2017); *Hopkins v. Jegley*, No. 17-cv-00404, 2017 WL 3220445 (E.D. Ark. July 28, 2017) (preliminarily enjoining Arkansas statute), *appeal filed*, No. 17-2879 (8th Cir. 2017);

Plaintiffs are a medical clinic and two individual physicians who provide second-trimester abortion services in Kentucky.[6] (Franklin, R.107, PageID#4630.) Plaintiffs sued to enjoin implementation of the Act immediately after it was enacted, arguing that it imposed an undue burden on the constitutional rights of their patients to obtain pre-viability abortions. (Compl., R.1, PageID##1-12.) In April 2018, Kentucky agreed not to enforce the Act while the district court was adjudicating the merits of plaintiffs' challenge. (Joint Consent Order, R.24, PageID#163-65; *see also* Order, R.56, PageID#791.)

Hodes & Nauser, MDs, P.A. v. Schmidt, 440 P.3d 461 (Kan. 2019) (preliminarily enjoining Kansas statute); *Nova Health Sys. v. Pruitt*, No. 2015-cv-1838, 2015 Okla. Dist. Lexis 1045 (Okla. County Dist. Ct. Oct. 28, 2015) (preliminarily enjoining Oklahoma statute). In addition, a federal district court denied Louisiana's motion to dismiss a challenge to that State's D&E ban, which has not taken effect pursuant to stipulation. *See June Med. Servs. LLC v. Gee*, 280 F. Supp. 3d 849 (M.D. La. 2017). To date, the D&E bans in Mississippi and West Virginia have not been challenged. By its terms, North Dakota's D&E ban will not take effect until the United States Court of Appeals for the Eighth Circuit or the United States Supreme Court upholds such a statute as constitutional.

[6] Plaintiff EMW Women's Surgical Center is Kentucky's sole licensed abortion facility, and plaintiffs Tanya Franklin and Ashlee Bergin are the only physicians who currently perform surgical abortions in Kentucky. (Franklin, R. 107, PageID#4630.)

Following a five-day bench trial, the district court entered judgment in favor of plaintiffs and issued a permanent injunction against enforcement of the law. (Mem. Op., R.126, PageID##5724-5750.) With a fully developed record before it, the district court found that the Act imposes an undue burden by banning the principal method of post-15-week pre-viability abortions without preserving a safe and medically accepted alternative. Specifically, the district court determined that the three procedures that Kentucky identified as measures to stop the fetal heartbeat in utero—digoxin injections, potassium chloride injections, and umbilical cord transections—are experimental, risky to women, often ineffective, and result in delays and increased costs to women seeking second-trimester abortions. (*Id.* at PageID##5734-5742, 5744-5745.) The district court further held that the Act imposes an undue burden on all women seeking a second-trimester abortion after 15 weeks, because it subjects them to dangerous, invasive, and medically unnecessary fetal demise procedures. (*Id.* at PageID##5747-5748.)

SUMMARY OF ARGUMENT

Under controlling Supreme Court precedent, a statute or regulation imposes an unconstitutional undue burden if its purpose or effect is to "plac[e] a substantial obstacle in the path of a woman seeking an abortion." *Casey*, 505 U.S. at 877 (plurality op.); *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2309 (2016). That standard bars any abortion restriction whose benefits are not "sufficient to justify the burdens upon access." *Whole Woman's Health*, 136 S. Ct. at 2300.

Kentucky and its amici agree that the undue-burden standard applies to this case. They nonetheless contend that when an abortion restriction is enacted to promote respect for fetal life and to protect medical ethics, rather than to advance women's health, a balancing test is an inappropriate way to assess whether a burden is undue. Br. for Appellant (Br.) at 28-30; Br. for Amici Curiae State of Ohio et al. (Ohio Amici Br.) at 7-18. But they are mistaken; the Supreme Court has made clear that the test set forth in *Casey* and *Whole Woman's Health* applies to all abortion restrictions, regardless of the State's asserted interest in that law.

Moreover, the Supreme Court has specifically addressed how to evaluate the conflicting interests implicated by an abortion-method restriction that purportedly advances a State's interests in promoting respect for fetal life and protecting medical ethics. Such a restriction imposes an undue burden if it "subject[s] women to significant health risks." *Gonzales v. Carhart*, 550 U.S. 124, 161 (2007) (alteration and quotation marks omitted). The district court correctly held here that the Act imposes an undue burden because it criminalizes the safest and most common form of second-trimester abortion after 15 weeks without ensuring that safe and medically accepted alternatives remain available to women who exercise their constitutional right to choose to terminate a pregnancy.

There is no merit to Kentucky's argument (Br. at 33-54) that a physician can safely perform a second-trimester abortion while avoiding liability under the Act by ensuring fetal demise prior to a D&E procedure using digoxin injections, potassium chloride injections, or umbilical cord transections. Ample record evidence supports the district court's factual findings that each of these options is either unavailable, experimental, or ineffective, and each unnecessarily increases the medical risks of an

otherwise routine procedure. The district court thus reasonably rejected each option, separately and collectively, as a feasible alternative to standard D&E, particularly after 15 weeks of pregnancy. The burden imposed by the Act is therefore undue, amounting to essentially a prohibition on legal second-trimester abortions after 15 weeks. No benefit proffered (or even hypothesized) could justify such a burden.

Kentucky and its amici are also incorrect to argue (Br. at 27, 29; Ohio Amici Br. at 16) that the purported existence of "medical uncertainty" about the safety and efficacy of Kentucky's proposed alternative procedures establishes the need for deference to the legislative decision to prohibit standard D&E. To the contrary, medical uncertainty about the safety and efficacy of the State's proffered alternative procedures signals the presence of impermissible risks and requires courts to evaluate whether the challenged statute imposes an undue burden by imposing such risks on women.

Finally, the district court properly sustained the challenge to the Act on its face. Such relief is appropriate when an abortion restriction creates a substantial obstacle for a large fraction of "those women for whom the provision is an actual rather than an irrelevant restriction."

Whole Woman's Health, 136 S. Ct. at 2320 (quotation and alteration marks omitted). Contrary to Kentucky's argument (Br. at 58-63), the appropriate denominator in this case is not all women in Kentucky who consider obtaining an abortion, but rather, all women in Kentucky who seek an abortion after 15 weeks using the standard D&E procedure. The district court reasonably found that the Act imposes a substantial obstacle for all such women.

ARGUMENT

POINT I

THE CONSTITUTION FORBIDS A STATE FROM REGULATING ABORTION IN A MANNER THAT IMPOSES AN UNDUE BURDEN ON A WOMAN'S RIGHT TO CHOOSE TO TERMINATE A PREGNANCY

The Supreme Court has long recognized a woman's substantive due process right to "choose to have an abortion before viability and to obtain it without undue interference from the State." *Casey*, 505 U.S. at 846; *see also Roe v. Wade*, 410 U.S. 113, 153-54 (1973). Preservation of this right "is a rule of law and a component of liberty." *Casey*, 505 U.S. at 871 (plurality op.). At the same time, the Supreme Court has recognized that there are legitimate governmental interests in regulating abortion, including some of the interests that Kentucky identifies in this case, such

as promoting respect for potential life and protecting the integrity of the medical profession. *See Gonzales*, 550 U.S. at 157-58. In *Casey* and the numerous cases that followed, the Court struck a balance between these concerns with a legal standard that accommodates legitimate governmental interests while at the same time ensuring "real substance to the woman's liberty to determine whether to carry her pregnancy to full term." *Casey*, 505 U.S. at 869 (plurality op.); *see also Whole Woman's Health*, 136 S. Ct at 2309; *Gonzales*, 550 U.S. at 158; *Stenberg v. Carhart*, 530 U.S. 914, 930-31 (2000).

An abortion restriction is unconstitutional if it imposes an "undue burden" on a woman's constitutional right to choose an abortion. *Casey*, 505 U.S. at 877 (plurality op.). Under this standard, "'a statute which, while furthering a valid state interest, has the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends.'" *Whole Woman's Health*, 136 S. Ct. at 2309 (alteration marks omitted) (quoting *Casey*, 505 U.S. at 877 (plurality op.)). Further, a court reviewing the constitutionality of an abortion regulation must "consider the burdens a law imposes on abortion access together with the benefits those laws confer,"

id., and invalidate any statute whose benefits are not "sufficient to justify the burdens upon access," *id.* at 2300.

Kentucky and its amici contend that the balancing test used in *Casey* and *Whole Woman's Health* applies only "in the context of a law that a state claimed protected women's health," and does not apply to the interests Kentucky asserts here—respect for potential life and the integrity of the medical profession.[7] Br. at 28; Ohio Amici Br. at 8-13. This argument misunderstands the Supreme Court's case law. The Court did not invent a balancing test in *Whole Woman's Health* but rather applied "[t]he rule announced in *Casey*" to the facts of the case presented. 136 S. Ct. at 2309. And neither *Casey* nor *Whole Woman's Health* purported to limit the application of this test to health-related abortion regulations. Indeed, *Whole Woman's Health* expressly noted that *Casey*

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[7] Although Kentucky does not expressly assert an interest in avoiding fetal pain perception, it suggests (Br. at 32) that the elimination of any hypothetical fetal pain perception could support the State's "interests regarding unborn life." But the medical consensus is that fetal pain perception is not possible before at least 24 weeks LMP. (Ralston, R.103, PageID##4140-4155; *see id.* at 4100-4102.) *See also* Br. for Appellees at 57. And Kentucky law independently prohibits abortion at that stage of the second trimester. *See* Ky. Rev. Stat. § 311.782(1) (prohibiting abortion after 22 weeks LMP).

"performed this balancing" when evaluating a spousal notification provision and a parental notification provision, neither of which implicates the State's interest in women's health. *Id.*; *see also Casey*, 505 U.S. at 887-901.

The test set forth in *Casey* and *Whole Woman's Health* is a linchpin of the undue-burden analysis because a court cannot evaluate whether a burden on abortion access is undue without evaluating the extent to which a statute advances legitimate state interests. *See Casey*, 505 U.S. at 878 (plurality op.); *Planned Parenthood of Wisc., Inc. v. Schimel*, 806 F.3d 908, 919-20 (7th Cir. 2015); *Planned Parenthood Ariz., Inc. v. Humble*, 753 F.3d 905, 911-15 (9th Cir. 2014). Contrary to Ohio Amici's suggestion (Ohio Amici Br. at 8-11), the Supreme Court has performed a balancing analysis in every abortion case it has considered, including *Gonzales*. *See* 550 U.S. at 161 (analyzing benefits of ban on "intact" D&E), *id.* at 164 (concluding that burdens are minimal because the prohibited procedure is rarely used and standard D&E remained available).

Ohio Amici also erroneously suggest (Ohio Amici Br. at 5, 12-13) that the balancing test cannot apply to statutes like the D&E ban because the State's interest in promoting respect for potential life and medical

ethics is "immeasurable." The benefits analysis does not require a court to evaluate the weight of an asserted state interest. Rather, the review focuses on the extent to which an abortion restriction actually advances a legitimate state interest rather than serving the impermissible purpose of making abortion more difficult to access. *See Whole Woman's Health*, 136 S. Ct. at 2312, 2316.

Even when an abortion restriction furthers legitimate government interests, a court must consider whether the statute also "has the effect of imposing an unconstitutional burden on the abortion right." *Gonzales*, 550 U.S. at 161. As explained *infra* (at 17-18), the statute at issue in this case functions as a ban on legal abortions after 15 weeks. It is well settled that a ban on pre-viability abortions is unconstitutional. *See Whole Woman's* Health, 136 S. Ct. at 2299; *Gonzales*, 550 U.S. at 146; *Casey*, 505 U.S. at 846; *see also* Br. for Appellees at 31. "[T]he means chosen by the State to further [its] interest . . . must be calculated to inform the woman's free choice, not hinder it." *Casey*, 505 U.S. at 877 (plurality op.). And even if the Act did not function as an outright ban, it would nevertheless impose substantial burdens on women in Kentucky seeking

to exercise their constitutional right to choose an abortion—burdens that could not be justified by whatever benefits the Act purportedly provides.

Finally, Kentucky is wrong to rely on dictum from the Eighth Circuit's decision in *Planned Parenthood of Arkansas & Eastern Oklahoma v. Jegley*, 864 F.3d 953, 960 n.9 (8th Cir. 2017), and the Fifth Circuit's decision in *June Medical Services L.L.C. v. Gee*, 905 F.3d 787, 803 n.50 (5th Cir. 2018), in support of its argument that the undue-burden standard requires proof that a statute's burdens "substantially outweigh" its benefits.[8] *See* Br. at 56. Neither *Jegley* nor *June Medical Services* could have endorsed the distorted legal standard proposed by Kentucky because that standard departs from controlling Supreme Court precedent. *See Whole Woman's Health*, 136 S. Ct. at 2309; *Casey*, 505 U.S.

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[8] Kentucky also relies on the Seventh Circuit's decision in *Schimel*, but that case does not stand for the proposition that the undue-burden standard requires that an abortion regulation's burdens "substantially outweigh" its benefits. Instead, the Seventh Circuit correctly held that the State must show that challenged "restrictions are not disproportionate, in their effect on the right to an abortion," when compared to the "benefits that the restrictions are believed to confer." 806 F.3d at 919. As the court explained, "[t]he feebler" the benefits asserted by the State, "the likelier is the burden on the right to abortion to be disproportionate to the benefits and therefore excessive." *Id.* at 920. *Schimel* therefore represents a straightforward balancing of benefits and burdens in accordance with *Casey* and *Whole Woman's Health*.

at 877 (plurality op.). In any event, the Act would constitute an undue burden even under Kentucky's erroneous standard because the statute's burdens—a de facto prohibition on post-15-week pre-viability abortions—substantially outweigh its purported benefits.

POINT II

THE ACT IMPOSES AN UNDUE BURDEN BECAUSE IT SUBJECTS WOMEN TO SIGNIFICANT HEALTH RISKS

The Supreme Court has explained how to balance the benefits and burdens of a statute that, like the Act, is purportedly aimed at advancing a State's interests in promoting respect for fetal life and protecting medical ethics. Such a regulation imposes an "undue burden" on a woman's right to terminate a pregnancy if it "subject[s] women to significant health risks." *Gonzales*, 550 U.S. at 161 (quotation and alteration marks omitted). Accordingly, a State may not prohibit a method of abortion without ensuring that "a commonly used and generally accepted method" remains available. *Id.* at 165; *see id.* at 167. The Supreme Court has "repeatedly invalidated statutes that in the process of regulating the methods of abortion, imposed significant health risks" by compelling "women to use riskier methods of abortion."

Stenberg, 530 U.S. at 931 (emphasis omitted); *see also Thornburg v. American Coll. of Obstetricians & Gynecologists*, 476 U.S. 747, 768-69 (1986) (invalidating on its face a statute compelling abortion providers to use a procedure that "require[s] a 'trade-off' between the woman's health and fetal survival"); *Colautti v. Franklin*, 439 U.S. 379, 400 (1979) (same); *Planned Parenthood of Cent. Mo. v. Danforth*, 428 U.S. 52, 76-79 (1976) (invalidating ban on safest and most common method of second-trimester abortion at the time); *Doe v. Bolton*, 410 U.S. 179, 197 (1973) (invalidating statute that interfered with a "woman's right to receive medical care in accordance with her licensed physician's best judgment").

These precedents recognize the obvious: by forcing women to choose between a risky and experimental abortion and no abortion at all, the Act in effect bans abortions for those women. *See Danforth*, 428 U.S. at 79. And that is precisely what the Act does for women in Kentucky who seek legal second-trimester abortions after 15 weeks. A State may not advance its legitimate interests by expressly or implicitly "prohibit[ing] any woman from making the ultimate decision to terminate her pregnancy before viability." *Casey*, 505 U.S. at 879 (plurality op.). Nor can a State advance such interests by "endanger[ing] a woman's health." *Stenberg*, 530 U.S.

at 931; *see also Casey*, 505 U.S. at 893 (rejecting spousal-notification requirement because it could subject women to physical and psychological abuse). Thus, a statute is unconstitutional if it forces a woman and her physician "to terminate her pregnancy by methods more dangerous to her health than the method outlawed." *Danforth*, 428 U.S. at 79.

Although the Act does not use medical terminology, the statute describes and prohibits the standard D&E procedure. *See* Ky. Rev. Stat. § 311.787. Standard D&E has long been recognized as the safest and most common method of second-trimester abortion after 15 weeks. *See, e.g.*, *Gonzales*, 550 U.S. at 164; *Stenberg*, 530 U.S. at 924. The procedure is currently used for approximately 95% of all second-trimester abortions performed in the United States,[9] and 99% of post-15-week abortions in Kentucky (Mem. Op., R.126, PageID#5746). Given the widespread use and medical acceptance of standard D&E, States and the federal government have conceded that a prohibition on the method would impose an undue burden. *See, e.g.*, *Stenberg*, 530 U.S. at 938 (Nebraska); *Gonzales*, 550 U.S. at 147 (United States).

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[9] *See* Am. Coll. of Obstetricians & Gynecologists, *Second-Trimester Abortion*, 121 Obstetrics & Gynecology 1394 (2013).

Kentucky acknowledges (Br. at 17) that the Act can pass constitutional muster only if "safe and effective" alternatives to standard D&E are available. According to Kentucky, the Act satisfies this requirement because it allows physicians to perform second-trimester abortions by D&E after first causing fetal demise using one of three methods: digoxin injection, potassium chloride injection, or umbilical cord transection. *Id.* at 33-54. But ample record evidence supports the district court's factual findings that each of these proposed alternatives is either unavailable after 15 weeks or is an experimental procedure whose safety and efficacy are unknown. Accordingly, none of Kentucky's alternative procedures qualifies as the kind of "standard medical option[]" required by the Supreme Court. *See Gonzales*, 550 U.S. at 166.

Kentucky's arguments on appeal largely boil down to a disagreement with the district court's weighing of the record evidence, specifically the parties' expert testimony. But the district court was not obligated to credit the testimony of the State's experts over plaintiffs' more qualified and experienced experts; indeed, district courts conducting bench trials have wide latitude to decide how much weight to afford to any given expert opinion. *See Deal v. Hamilton County Bd. of*

Educ., 392 F.3d 840, 852 (6th Cir. 2004). Here, the district court properly reviewed the record evidence and made detailed factual findings based on the weight of the credible evidence.

First, the district court found that, although digoxin injections are less technically challenging than other fetal demise measures, they are not sufficiently safe, reliable, or effective to warrant upholding the Act. As the court explained, the use of digoxin injection before 18 weeks is "essentially experimental" because there are no medical studies of the safety or efficacy of the procedure at that stage of pregnancy. (Mem. Op., R.126, PageID## 5735-5736.) Moreover, the record established that the procedure would be more difficult to perform, and thus riskier to women and less likely to be effective, at that stage. (*See, e.g.*, Brady, R.106, PageID##4394-4395.) Digoxin injection before 18 weeks would also create additional burdens that are medically unwarranted, including a full day of delay beyond the one-day standard D&E procedure, and a substantial increase in the cost of the procedure. (Mem. Op., R.126, PageID#5736.)

Kentucky also failed to demonstrate that a digoxin injection used after 18 weeks is a standard medical option. While the record showed that some physicians (although none who practice in Kentucky) perform

digoxin injections after 18 weeks, such injections have a significant failure rate—between 5% and 20%—a rate that is even higher for women who are obese, have anatomical variations of the uterus or vagina, or have certain types of fetal positioning. (*Id.* at PageID#5735.) Moreover, the Act would prohibit physicians who perform digoxin injections from continuing with the standard D&E procedure if the injection fails. However, there are no studies of the safety or efficacy of using a second digoxin injection to induce fetal demise where the first does not work. (*Id.*) Even if successful, the digoxin injection adds significant delay and cost, and imposes a greater risk of known medical complications to women compared to standard D&E without the use of digoxin, including infection, extra mural delivery, vomiting, and hospitalization. (*Id.* at PageID#5736.)

Second, the district court reasonably concluded that abortion providers in Kentucky do not have the specialized training and high-grade equipment necessary to perform the extraordinarily difficult potassium chloride injection procedure, which can result in cardiac arrest and death if performed improperly. (*Id.* at PageID##5737-5739.) In addition, potassium chloride injections are not medically appropriate for

many women, and impose various other medical risks, including uterine or other internal organ perforation, and infection. (*Id.* at PageID##5738-5739.)

Finally, the district court had ample reason to conclude that umbilical cord transection is not a safe and effective alternative procedure. As with digoxin and potassium chloride injections, record evidence showed that the procedure would likely be more difficult and riskier to perform during the early stages of the second trimester. (*Id.* at PageID##5740-5741.) The district court was entitled to disregard the single study of cord transection cited by the State, given that study's substantial methodological flaws. (*Id.* at PageID#5741.) In any event, the district court correctly found on the basis of the record before it that cord transection is a difficult procedure with the potential for serious harm, including increased risk of uterine damage, infection, and bleeding. (*Id.* at PageID##5741-5742.)

Contrary to Kentucky and its amici's representations, the risks associated with these procedures are not "marginal" or "insignificant." (Br. at 55; Ohio Amici Br. at 15.) At a minimum, the record evidence establishes substantial medical uncertainty about the safety and efficacy

of Kentucky's proposed alternative methods. Kentucky and its amici are also wrong to argue (Br. at 27-29, 56; Ohio Amici Br. at 10, 16) that, under *Gonzales*, a court must automatically defer to the legislature where any amount of medical uncertainty exists. To the contrary, "the division of medical opinion about the matter at most means uncertainty, a factor that signals the presence of risk, not its absence." *Stenberg*, 530 U.S. at 937. The presence of risk, in turn, demonstrates that the State's proposed substitutes to the standard D&E procedure are not the commonly used or generally accepted alternatives required by controlling precedent. The Supreme Court has made clear that, where the constitutional right to obtain an abortion is at stake, courts "retain[] an independent constitutional duty to review" the legislation and determine whether it imposes an undue burden. *Gonzales*, 550 U.S. at 165. A State cannot shield its abortion regulations from all judicial review merely by identifying medical or scientific disputes, especially where, as here, the very existence of such disputes is directly relevant to the application of the controlling legal standard.

The arguments to the contrary advanced by Kentucky and its amici rely on a fundamental misunderstanding of *Gonzales*. *Gonzales* involved

a challenge to a federal statute banning a rarely used procedure, the "intact" D&E. The plaintiffs in *Gonzales* challenged the statute on several grounds, including its lack of an exception allowing intact D&E when necessary to preserve a woman's health. *See* 550 U.S. at 161. The Supreme Court noted that there was "documented medical disagreement" about whether intact D&E was "medically necessary" for a "discrete and well-defined" class of women, and thus, whether prohibiting the procedure subjected those women to a significant health risk. *Id*. at 162-63, 166-67. But it was undisputed that the alternative procedure available—standard D&E—was a "safe," "commonly used and generally accepted method" of abortion for nearly all women. *Id*. at 164-65, 167. Accordingly, the Court held that uncertainty about whether the prohibited procedure was "medically necessary" in discrete circumstances was insufficient to invalidate the statute on its face. *Id*. at 163. And the Court suggested that those women for whom intact D&E was arguably medically necessary could challenge the statute's lack of a health exception in an as-applied challenge. *Id*. at 167.

Gonzales did not, as Kentucky and its amici suggest (Br. at 28; Ohio Amici Br. at 16), hold that state legislatures may resolve all medical

uncertainty against women seeking abortions. In *Gonzales,* the uncertain question was whether the prohibited procedure was medically necessary for a small group of women; the Court concluded it could resolve the question against the challengers without subjecting anyone to harm so long as it left open the possibility of an as-applied challenge. By contrast, the uncertain question in this case is whether the methods permitted under Kentucky's statute are safe and effective alternative procedures for the overwhelming majority of women who will be required to use them as a result of the prohibition on standard D&E. Here, resolving the question against plaintiffs would impermissibly subject large numbers of women to an unjustifiable risk of harm. *Gonzales* did not address that situation: it did not discuss medical uncertainty about alternatives to intact D&E, because there was, and is, no dispute about the safety and efficacy of the main available alternative, standard D&E. In fact, *Gonzales*'s outcome was predicated on the availability of standard D&E as a safe alternative procedure for women seeking second-trimester abortions. *Gonzales*, 550 U.S. at 166-67.

It is simply impossible to determine whether a statute subjects women to "significant" health risks—and thus imposes an undue

burden—without assessing the extent and nature of medical uncertainty about the procedures to which women would necessarily be relegated in the absence of the prohibited procedure. *Gonzales* does not hold otherwise.

POINT III

AN ABORTION RESTRICTION IS FACIALLY UNCONSTITUTIONAL WHEN, AS HERE, IT IMPOSES AN UNDUE BURDEN ON A LARGE FRACTION OF AFFECTED WOMEN

In *Casey* and *Whole Woman's Health*, the Supreme Court explained that a statute is facially unconstitutional if "it will operate as a substantial obstacle to a woman's choice to undergo an abortion" in "a large fraction of the cases in which" the law is relevant. *Casey*, 505 U.S. at 894-95; *Whole Woman's Health*, 136 S. Ct. at 2320. "The proper focus of constitutional inquiry is the group for whom the law is a restriction, not the group for whom the law is irrelevant." *Casey*, 505 U.S. at 894. Here, the district court correctly concluded that the Act creates a substantial obstacle for 100% of women who seek a second-trimester abortion after 15 weeks and would otherwise obtain a standard D&E, because the Act compels them "to endure a medically unnecessary and

invasive procedure" in exchange for exercising their constitutional right to obtain a pre-viability abortion. (Mem. Op., R.126, PageID#5747.)

Kentucky ignores the applicable case law (and record evidence) and asserts that the Act "will not create a substantial obstacle for '100%' of women seeking a D&E abortion," because some women might not experience the risks and side effects associated with the proposed fetal demise measures. Br. at 58-59. Even if some women ultimately experience no complications associated with fetal demise measures, all women forced to undergo these procedures are subjected to a medically unnecessary risk of potentially life-threatening harm. Compelling women to face medically unnecessary risks is a burden in and of itself, even if some women are able to undergo a particular procedure without experiencing side effects.[10] Moreover, the only physicians currently performing surgical abortions in Kentucky categorically refuse to subject their patients to the medically unnecessary risks associated with fetal demise measures and will therefore cease to perform abortions

[10] Kentucky also ignores the district court's findings that the Act imposes other burdens on abortion access, including delay, increased costs, and emotional burdens associated with fetal demise measures. (Mem. Op., R.126, PageID#5736-5737.)

after 15 weeks if the Act is allowed to take effect. (Mem. Op., R.126, PageID#5747.) While Kentucky contends (Br. at 60; *see id.* at 57-58) that a physician's refusal "to offer a reasonable medical procedure" is insufficient to constitute an undue burden, the fetal demise procedures proposed here are not "reasonable."[11] See *supra* at 20-22.

Kentucky is likewise mistaken in arguing (Br. at 61-62) that, under *Gonzales*, the Act should not be invalidated on its face because the State's alternative procedures will affect different women in different ways. In *Gonzales*, the Supreme Court suggested that a member of the "discrete and well-defined" group of women for whom intact D&E was arguably medically necessary could challenge the statute's lack of a health exception in an as-applied challenge. 550 U.S. at 167. Here, by contrast, the safety and efficacy concerns associated with Kentucky's proposed

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[11] Equally unavailing is Kentucky's contention (Br. at 19-25) that plaintiffs' refusal to perform, or hire physicians that will perform, these unnecessary and dangerous fetal demise measures demonstrates that plaintiffs, rather than the State, are imposing a burden on abortion access. *Whole Woman's Health* made clear that a statute which forces an abortion provider to choose between shutting down a clinic and undertaking medically unnecessary compliance measures at great cost imposes an undue burden on women who rely on that provider for abortion access. *See* 136 S. Ct. at 2317.

alternative procedures are widespread and varied, and also difficult to predict in an individual case before initiating a medical procedure. The pregnant women subjected to an undue burden by the Act are thus not the "discrete and well-defined" group contemplated in *Gonzales*, but rather the much larger number of women who seek legal abortions after 15 weeks using the standard D&E procedure.

Next, Kentucky erroneously contends (Br. at 62-63) that the appropriate denominator in the "large fraction" analysis is the entire class of women considering an abortion in Kentucky. Specifically, Kentucky contends that the Act is relevant to such women because it might eventually affect their decision regarding when to obtain an abortion. *Id.* at 63. But the Supreme Court has made clear that the appropriate denominator in the "large fraction" analysis is "a class narrower than 'all women,' 'pregnant women,' or even 'the class of women seeking abortions identified by the State.'" *Whole Woman's Health*, 136 S. Ct at 2319 (quoting *Casey*, 505 U.S. at 894-95). Rather, the correct denominator is the class of women "for whom the law is a *restriction*," rather than a hypothetical future limitation. *Casey*, 505 U.S. at 894 (emphasis added). In this case, that class consists of women seeking a

second-trimester abortion after 15 weeks using the standard D&E procedure. Even if that class is a small percentage of the women who seek an abortion in Kentucky, "[t]he analysis does not end with the one percent of women upon whom the statute operates; it begins there." *Id.*

Finally, Kentucky and amici are wrong to suggest that the district court should have ordered "limited injunctive relief" akin to the partial preliminary injunction entered in a recent challenge to Ohio's D&E ban. *See* Br. at 62; Ohio Amici Br. at 22-23 (citing *Yost*, 375 F. Supp. 3d at 857). As plaintiffs correctly note (Br. for Appellees at 64), this contention is not properly preserved for appellate review because Kentucky failed to make the argument in district court. Plaintiffs are also correct in arguing that the type of "limited injunctive relief" that Kentucky seeks here would require this Court to rewrite the plain terms of a state statute—an action that is beyond judicial authority and would not cure the statute's constitutional infirmities in any event. *Id.* at 64-66. Ohio Amici's reliance on *Yost* is likewise meritless. The district court in that case found—based on the preliminary injunction record before it—that some Ohio physicians performed digoxin injections after 18 weeks in some cases. The court proceeded to enjoin Ohio's D&E ban statewide except in

cases where a doctor determined that a fetal demise procedure could safely be performed on a patient after 18 weeks.[12] *Yost*, 375 F. Supp. 3d at 867-68, 872. In contrast to *Yost*, the evidence presented at trial in this case established that Kentucky physicians do not utilize fetal demise measures at any stage of the pregnancy. (*See, e.g.*, Franklin, R.107, PageID#4658.) The district court had no basis to consider ordering "limited" injunctive relief in this case.

[12] Plaintiffs' motion for reconsideration of this decision has been pending for more than three months.

CONCLUSION

The judgment of the district court should be affirmed.

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September 16, 2019

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a) of the Federal Rules of Appellate Procedure, Ester Murdukhayeva, an employee in the Office of the Attorney General of the State of New York, hereby certifies that according to the word count feature of the word processing program used to prepare this brief, the brief contains 6,236 words and complies with the typeface requirements and length limits of Rules 29(a)(5) and 32(a)(5)-(6).

/s/ Ester Murdukhayeva

CERTIFICATE OF SERVICE

I hereby certify that on September 16, 2019, I caused the foregoing to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Sixth Circuit using the CM/ECF system. I further certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ Ester Murdukhayeva