In The Supreme Court of the United States

TERRY CLINE, ET AL.,

Petitioners,

v.

OKLAHOMA COALITION FOR REPRODUCTIVE JUSTICE, ET AL.,

Respondents.

On Petition For A Writ Of Certiorari To The Oklahoma Supreme Court

REPLY BRIEF FOR PETITIONERS

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REPLY BRIEF FOR PETITIONERS

Respondents' Brief in Opposition is strikingly candid in two respects: it makes no attempt to defend the Oklahoma Supreme Court's failure to conduct the thoughtful analysis required by this Court's abortion precedents, and it acknowledges that a host of assumptions about the state court's decision must be made as a predicate to their arguments against certiorari.

On the other hand, Respondents' two arguments against certiorari – that (1) there is "an unsettled, predicate question of state law," and (2) that the lower court split is "illusory" – are impossible to reconcile with the record, this Court's prior abortion cases, and the lower court cases upon which Respondents rely.

I. No "unsettled" question of state law, in fact, exists.

Respondents first argue that the case presents "an unsettled, predicate question of state law" – namely, whether the Oklahoma law is an outright ban on medication abortions, or simply a regulation of how those abortions may be performed.

1. The record proves exactly the opposite. The trial court below made alarmingly few factual findings in support of its decision, but it did agree that, as

a matter of fact, the Oklahoma law was not a complete ban on medication abortions:

The Act provides a ban on medication abortion in the State of Oklahoma except as provided and in the manner and regimen set forth in the RU-486 FPL and it explicitly prohibits the "off label" use of RU-486 or any abortion drug or medication.

Pet. App. 5.1 This conclusion was compelled by the text of the Oklahoma law, which could not be plausibly read as a complete ban on medication abortions.

To understand why this is so, you have to first understand Respondents' reading of the law, as convoluted as it may be: they claim that because the

¹ Respondents claim that this complete ban encompasses the use of methotrexate as a treatment for an ectopic pregnancy. But as was explained below, the Oklahoma law categorically excludes treatment of an ectopic pregnancy from its definition of "abortion." 63 O.S. § 1-730(A)(1). As a result, a doctor can, consistent with the Oklahoma law, prescribe methotrexate to treat an ectopic pregnancy because such a prescription would not be "specifically with the intent of causing an abortion." See Oklahoma House Bill 1970, 2011 Okla. Sess. Laws ch. 216 § 1(A)(1) (amending 63 O.S. § 1-729a) ("'Abortion-inducing drug' . . . includes off-label use of drugs known to have abortion-inducing properties, which are prescribed specifically with the intent of causing an abortion, such as misoprostol (Cytotec), and methotrexate.") (emphasis added). And even if Respondents' interpretation were not directly at odds with the text of the Oklahoma law, the record reflects that the state courts below made no finding agreeing with Respondents' strained reading of the law.

Oklahoma law requires the on-label use of abortion-inducing drugs, and because the FDA-approved protocol for Mifeprex calls for the use of a second drug called misoprostol, whose FDA-approved label does not describe abortion as an approved use, the Oklahoma law must necessarily prevent the use of misoprostol as part of the FDA-approved protocol for Mifeprex, which means that it is impossible for a physician to use the FDA-approved protocol for Mifeprex.

As Petitioners explained below, there were multiple reasons why that interpretation of the Oklahoma law was wrong. First, in approving the protocol for Mifeprex, the FDA has approved the use of misoprostol as part of that protocol. The clear thrust of the Oklahoma law is to require that medication abortions be performed according to the FDA-approved protocol. Since the approved protocol for Mifeprex – the *only* protocol the FDA has approved for terminating a pregnancy with medication – requires the use of misoprostol, the Oklahoma law does not ban the use of misoprostol as part of that protocol – a position that Petitioners maintained below, and maintain here.

Second, Respondents' interpretation violated a basic tenet of statutory interpretation by rendering a large portion of the Oklahoma law superfluous. It is a "cardinal rule of statutory interpretation that no provision should be construed to be entirely redundant" *Kungys v. United States*, 485 U.S. 759, 778 (1988) (Scalia, J., plurality opinion), but if the Oklahoma

law were interpreted as banning all medication abortions, even those performed according to the FDAapproved protocol for Mifeprex, numerous provisions of the Oklahoma law make little sense. For instance, as amended by the new Oklahoma law, 63 O.S. § 1-729a: (1) sets forth detailed qualifications for physicians who perform medication abortions, § 1-729a(B)1-5; (2) describes disclosures that physicians who perform medication abortions must make to their patients, § 1-729a(D)1-5; (3) describes procedures with which physicians who perform medication abortions must adhere while performing a medication abortion, § 1-729a(E)-(F); and (4) describes post-procedure reporting requirements with which physicians who perform medication abortions must comply, § 1-729a(G)1-2. If the Oklahoma Legislature intended to effectuate a complete ban of medication abortions, it certainly made some odd drafting choices in doing so, as each of these provisions plainly assumes that medication abortions can and will be performed.

And lastly, even if Respondents' interpretation of the Oklahoma law were the best and fairest reading of that law (it is not), that interpretation violates the canon of constitutional avoidance, by creating a potential constitutional infirmity where none need exist. See Clark v. Martinez, 543 U.S. 371, 381 (2005) (the canon is a "tool for choosing between competing plausible interpretations of a statutory text, resting on the reasonable presumption that [the legislature]

did not intend the alternative which raises serious constitutional doubts.").2

- 2. Ironically, Respondents' primary argument against certiorari is one that if correct, would actually counsel in *favor* of certiorari, in that the court's conclusion that the Oklahoma law violated "the mandate of *Casey*" would have been made in the absence of any threshold understanding of the reach and effect of the challenged regulation (i.e., whether it is a complete ban or a more limited regulation). *See Gonzales v. Carhart*, 550 U.S. 124, 126 (2006) (noting that an understanding of the "purpose and effect" of an abortion regulation is critical to the "undue burden" analysis). Such an error would warrant this Court granting the Petition, summarily vacating the state court's decision, and remanding the case for additional proceedings to decide the issue.
- 3. Not surprisingly, Respondents quickly reverse course and attempt to defend the Oklahoma court's decision by arguing that the court in fact settled this question in their favor. *Compare* Opp. 1 (advancing their "unsettled, predicate question of state" law argument as their primary argument

² Respondents suggest that Petitioners first raised the avoidance canon at the Oklahoma Supreme Court, Opp. 9, but that is not true. As the briefing below plainly shows, Respondents raised this argument in their summary judgment briefing to the trial court. Petitioners responded accordingly, and that response has not wavered.

against certiorari); with Opp. 10, 12 (arguing that the "Oklahoma Supreme Court appears to have rejected" Petitioners' interpretation of the law and that "[t]he decision of the Oklahoma Supreme Court is sensibly read as having rejected [Petitioners'] implausible reading of the statute").

While Petitioners agree that the decision below is wholly indefensible unless the Oklahoma court in fact adopted *in toto* Respondents' strained interpretation of the Oklahoma law, the record establishes that the Oklahoma court did not adopt that interpretation. And in any event, Respondents' interpretation renders most of the statute superfluous, raises constitutional doubts when those doubts can easily be avoided, and ignores the binding admissions Petitioners, as enforcers of the law, made below regarding their understanding of the limited effect of the law.

II. The Oklahoma Supreme Court and the Sixth Circuit reached exactly opposite results when analyzing similar claims to similar abortion regulations.

1. Respondents next argue that the lower court split identified in the petition is "illusory," but Respondents' attempt to distinguish the Ohio law at issue in *Planned Parenthood Southwest Ohio Region v. DeWine*, 696 F.3d 490, 496 (6th Cir. 2012) is predicated entirely on their mistaken characterization of the Oklahoma law as a complete ban on medication abortions. With that point disproven, it becomes clear

that the Oklahoma and Ohio laws have the same effect: to require that abortion-inducing drugs be administered according to the protocol described on their FDA-approved label.

Indeed, as explained by the Ohio district court, the Ohio law requires compliance with the "medical regimen described in the FPL," i.e., compliance with the FDA-approved label. See Planned Parenthood Southwest Ohio Region v. DeWine, 2011 WL 9158009, *5 (S.D. Ohio May 23, 2011) (hereinafter *DeWine I*). The Sixth Circuit agreed, noting that the law requires that the FDA-approved protocol be followed. See Planned Parenthood Southwest Ohio Region v. DeWine, 696 F.3d 490, 504 (6th Cir. 2012) (hereinafter DeWine II) ("[A] physician may provide mifepristone for the purpose of inducing an abortion only through the patient's 49th day of pregnancy and only by using the dosage indications and treatment protocols expressly approved by the FDA in the drug's final printed labeling as incorporated by the drug approval letter.").

That interpretation of the Ohio law mirrors the finding made by the trial court below, that "[the Oklahoma law] provides a ban on medication abortion in the State of Oklahoma **except as provided and in the manner and regimen set forth in the RU-486 FPL**." Pet. App. 5 (emphasis added). Thus, in "purpose and effect," the Ohio and Oklahoma laws are analogous for purposes of application of this Court's abortion precedents.

2. Respondents further attempt to distinguish the Ohio case by claiming that the claims there were different than those here, and that no final judgment has been reached in the Ohio case. Opp. 17-18. Respondents' claims are (again) demonstrably false.

In the Ohio case, Planned Parenthood alleged that (1) the law is unconstitutionally vague; (2) the law violates a woman's right to bodily integrity; (3) the law imposes an undue burden on a woman's right to choose an abortion because the law acts as a "ban" on medication abortion and increases the dosage required; and (4) the law lacks a necessary health and life exception. *Id.* at 498, 514-17. Final judgment has been rendered in all but the health exception claim. *Id.* at 500-03.

Respondents' federal law-based challenges to the Oklahoma law mirror those claims, with the exception of the health exception claim, which Respondents did not raise below. Respondents claim that the law is (1) unconstitutionally vague, (2) violates a woman's right to bodily integrity, and (3) imposes an undue burden on a woman's right to choose an abortion because the law acts as a "ban" on medication abortion, increases the dosage amount, and limits from 63 to 49 days the amount of time in which a medication abortion is available. See, e.g., Memorandum of Law in Support of Plaintiffs' Motion for Summary Judgment. Because there is no health exception claim in this case, ongoing litigation in Ohio over the health exception claim has no relevance to the ripeness of the lower court split identified here.

3. The record similarly disproves Respondents' attempt to distinguish the evidentiary records in the two cases. Respondents make the bald assertion that their evidence "went uncontested" below, Opp. 8, but the record demonstrates that Petitioners disputed each and every of Respondents' material facts, presenting the trial court with hundreds of pages of evidence spread out over dozens of exhibits, including peer-reviewed studies and medical expert testimony. See, e.g., Defendants' Response to Plaintiffs' Motion for Summary Judgment; Defendants' Motion for Summary Judgment; and Defendants' Reply in Support of its Motion for Summary Judgment.

As did the defendants in Ohio, Petitioners offered evidence that medical abortions using the FDAapproved protocol are safer than those that use offlabel protocols, specifically pointing to the fact that eight women have died from bacterial infection following off-label use - seven of which whom used vaginal administration of misoprostol – while no deaths from bacterial infection have been reported following the FDA-approved protocol. See GAO Report, at 7, Appendix 3 to Plaintiffs' Motion for Summary Judgment; FDA, Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/2011 (July 2011), Exhibit P to Defendants' Response to Plaintiffs' Motion for Summary Judgment. DeWine II, 696 F.3d at 498. So in both cases the parties "dispute whether the medical community accepts that the alternative protocols cause fewer side effects or have a higher success rate than the FDA-approved regimes." *Id.* at 497.

As did the defendants in Ohio, Petitioners offered evidence that there is a correlation between off-label use of Mifeprex and deaths from bacterial infections. See FDA, Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/2011 (July 2011), Exhibit P to Defendants' Response to Plaintiffs' Motion for Summary Judgment; FDA, Mifeprex Questions and Answers, Exhibit O to Defendants' Response to Plaintiffs' Motion for Summary Judgment; Dewine II, 696 F.3d at 498. So as it did in the Ohio case, the record here reflects that women sometimes die when an off-label protocol is used, but there are no reported deaths when the FDA-approved protocol is used, and that there is medical and scientific uncertainty as to why this is so.

³ Respondents claim that they introduced "uncontested evidence that the FDA and leading experts carefully studied the issue and found no causal relationship" between off-label use and death from bacterial infection. Opp. 20, but this is a flat mischaracterization of the record. Petitioners contested Respondent's claims and informed the trial court that the FDA has stated it "[d]oes not know whether using Mifeprex and misoprostol caused" the deaths associated with bacterial infection. As the Sixth Circuit noted, "[t]he FDA could not state whether the use of mifepristone was the cause of these deaths." *DeWine II*, 696 F.3d at 498. Not being able to conclusively state a cause of death and definitively concluding that there is "no causal relationship" are worlds apart scientifically.

And as was the case in Ohio, Respondents here failed to establish that the Oklahoma law affects a woman's decision to have an abortion. Dewine II, 696 F.3d at 515-16 ("[T]hese statements give rise to the inference that some women prefer a medical abortion over a surgical abortion, but they do not support the conclusion that the unavailability of a medical abortion would create a substantial obstacle for a large fraction of women in deciding whether to have an abortion."). Petitioners offered ample evidence that surgical abortion is considered "very safe" by abortion providers, is commonly available to women throughout the first trimester (including after 49 days gestation), and has been demonstrated in peer-reviewed studies to be safer and more effective than medical abortion. Planned Parenthood, In-Clinic Abortion Procedures (2012), Exhibit Z to Defendants' Response to Plaintiffs' Motion for Summary Judgment; Declaration of Donna Harrison, M.D., Exhibit Y to Defendants' Response to Plaintiffs' Motion for Summary Judgment; M. Niinimaki et al., Immediate Complications after Medical compared with Surgical Termination of Pregnancy, OBSTET. GYNECOL. 114:795 (Oct. 2009), Exhibit 4 to Declaration of Donna Harrison, M.D., Exhibit Y to Defendants' Response to Plaintiffs' Motion for Summary Judgment; ACOG Practice Bulletin 67 Medical Management of Abortion, at Table 2, Appendix 4, Exhibit B to Plaintiffs' Motion for Summary Judgment; J.T. Jenson et al., Outcomes of Suction Curettage and Mifepristone Abortion in the United States: A Prospective Comparison Study, CONTRA-CEPTION 59:153-59 (1999), Exhibit 5 to Declaration

of Donna Harrison, M.D., Exhibit Y to Defendants' Response to Plaintiffs' Motion for Summary Judgmentl.

So the difference in the cases is not found in the evidentiary records that were before the Oklahoma and Ohio courts. Rather, the difference is in how the courts analyzed and applied this Court's precedents to that evidence. Where the Ohio court thoughtfully considered the evidence and recognized factual disputes where they existed, the Oklahoma trial court improperly weighed and then rejected our evidence in toto, without analysis or discussion, and the Oklahoma Supreme Court went a step further and simply struck down the law on its face, with no discussion of the evidence whatsoever. With the records before the Ohio and Oklahoma courts being so similar, the Oklahoma court's conclusion demonstrates the deep divide between the Oklahoma court and the Sixth Circuit – a divide that should be resolved by this Court.

III. Independent of any split of authority, certiorari is warranted in light of the Oklahoma Supreme Court's repeated failures to adhere to this Court's abortion precedents.

As the petition explains, the Oklahoma Supreme Court's recent practice is to invalidate any abortion regulation passed by the Legislature, and to do so in cursory, per curiam opinions that are devoid of any of the analysis required by this Court's precedents. If for

no other reason, certiorari is warranted to correct what appears to be a fundamental misunderstanding of federal abortion law and to prevent such errors from continuing in the future.

Respondents left this point largely unanswered, mustering only a passing reference to a 1997 decision of the Oklahoma Supreme Court where the Court upheld an abortion regulation. Opp. 1. That case was decided 16 years ago, by an Oklahoma Supreme Court whose membership has almost completely turned over, and has no bearing on the current practice of the state court that warrants this Court's intervention.

The decision below is simply indefensible. By disregarding precisely the type of evidence that this Court has deemed highly relevant in this context, and by completely ignoring Gonzales v. Carhart in this and other cases, the Oklahoma court has strayed far from this Court's precedents and failed to follow the proper analysis for vagueness, bodily integrity, and undue burden claims. Without any explanation and without even referencing the "undue burden" standard, the state court here concluded that the law is facially unconstitutional under an unclear "mandate of Casey," applying what can only be described as a strict scrutiny standard that leaves the Oklahoma legislature without guidance in drafting any future laws related to abortion-inducing drugs or any other abortion regulation.

It would be one thing if this was an isolated occurrence, but it is not, and that is precisely why this Court's intervention is needed.

CONCLUSION

The petition for writ of certiorari should be granted.

Respectfully submitted,

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