No. 12-1094

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

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the Oklahoma Supreme Court correctly invalidated a state statute that at a minimum bans a safe and prevalent first-trimester abortion procedure, and in fact effectively prohibits all abortions induced using prescription medication, even during the earliest stages of pregnancy.

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INTRODUCTION

In recent years, the Oklahoma legislature has repeatedly restricted when and in what fashion a woman may have an abortion. The Oklahoma Supreme Court has approved some such restrictions. *See Davis v. Fieker*, 952 P.2d 505 (Okla. 1997) (upholding an Oklahoma law restricting the facilities where abortions may be performed). But it has correctly held that others—including this one—simply go too far. The statute at issue here effectively bans all abortions performed using medication (rather than by surgery), no matter how early in the pregnancy. Accordingly, the statute's only practical consequence is to force a woman who wishes to terminate a pregnancy to undergo a surgical procedure even though a safe, effective, non-invasive, and widely used alternative is available. The statute is plainly invalid under settled precedents.

More important for present purposes, this case presents an unsuitable vehicle for resolving a question that does not merit this Court's attention in any event. It is an unsuitable vehicle because it requires resolution of an unsettled, predicate question of state law that Petitioners Terry Cline et al.[1] do not acknowledge or address. It is unworthy of this Court's attention because even the shallow, 1-1 conflict of authority that Cline asserts is illusory and unripe. Cline argues that there is a split between the decision below and a lone Sixth Circuit case, *Planned Parenthood Southwest Ohio Region v.*

[1] Referred to hereafter as "Cline" (or occasionally "Petitioners") in the interest of brevity.

DeWine, 696 F.3d 490 (6th Cir. 2012). But the Ohio statute at issue there differs significantly from the Oklahoma statute. So, too, do the legal issues. Most significant, the Sixth Circuit indicated that it would have struck down the statute had facts been present in the Ohio record that are present here.

Few states have sought to limit—indeed, effectively to ban—medication abortions in the fashion the Oklahoma statute did here. But if, despite this, Cline is correct that the status of such statutes is sufficiently important to merit this Court's attention, then there surely will be another opportunity for review once these issues have percolated in the lower courts. The decision of the Oklahoma Supreme Court, however, provides no basis for review at this time.

COUNTERSTATEMENT OF THE CASE

1. For a woman who wishes to terminate a pregnancy early in the first trimester, the use of prescription medications is often preferable to undergoing surgery. The medications used for this purpose include mifepristone (also known as Mifeprex or RU-486), misoprostol, and methotrexate. The United States Food & Drug Administration (FDA) has approved all three drugs for domestic marketing, and doctors routinely prescribe all three for use in inducing abortion.

a. The FDA approved mifepristone as a non-invasive alternative to surgical abortion in 2000, including a Final Printed Label (FPL) that the sponsor had proposed. An FPL provides guidance to physi-

cians about indications, dosage, and protocol. The FPL for mifepristone described a protocol, developed by the drug's sponsor, for terminating a pregnancy up to 49 days after a woman's last menstrual period. Under that FPL protocol, the patient takes 600 mg of mifepristone orally at a health-care facility. Two days later, the patient must return to the facility, where she will receive a dose of misoprostol. Two weeks later, the patient again must visit the facility to allow the physician to verify that the procedure was successful.

Medical advances with regard to a drug do not stop upon approval of a sponsor's FPL. Research institutions continue performing clinical trials, and doctors continue gaining experience and collecting data about side effects, alternative doses, and more. Doctors develop alternative protocols, which the medical literature properly terms "evidence-based" regimens.[2]

Mifepristone is no exception. As often occurs, the protocol that the sponsor initially put forth in the FPL became obsolete. Medical researchers and clinical trials amassed evidence that alternative regimens of mifepristone in combination with misoprostol were safer, more effective, and less expensive than the initial regimen. *See, e.g.*, R. on Appeal: Tab 14 at App. 4, ¶¶ 21-24. The new protocols vary from the FPL protocol in three ways. First, they allow women to take only one-third the dosage

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[2] *See, e.g.*, R. on Appeal: Tab 14 at App. 4, ¶ 21; *id.* Ex. B, at 5 (*ACOG Practice Bulletin*, "Medical Management of Abortion," Oct. 2005).

of mifepristone. Second, they allow a woman to self-administer the second drug, misoprostol, in the privacy of her own home, rather than at a medical facility. Third, they extend the effective use of the medications for two additional weeks into the pregnancy (from 49 days to 63 days). *Id.* ¶¶ 26-28. Leading medical organizations, including the American College of Obstetricians and Gynecologists (ACOG) and the World Health Organization have formally recommended these evidence-based regimens over the FPL protocol. *See, e.g.*, *id.* ¶¶ 24-25. Nationwide, at least 96% of all medication abortions now involve an evidence-based regimen that departs from the FPL. *Id.* ¶¶ 31, 37.

b. Such "off-label" use of a drug is perfectly legal, and indeed common. It is "an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (so explaining in the analogous context of medical devices). Accordingly, while FDA approval limits how a drug can be *marketed*, the FDA approval process does not regulate how a physician prescribes a drug. *See, e.g.*, R. on Appeal: Tab 14 at App. 2, ¶¶ 4-7. To the contrary, the FDA understands that a drug's sponsor may choose to seek marketing authorization for only one of multiple medically appropriate uses for a drug and that medical knowledge continues to advance post-approval.

In keeping with this regulatory regime, physicians routinely prescribe off-label uses. Indeed, in numerous circumstances, good medical practice re-

quires such uses. *See, e.g.*, *id*. ¶¶ 10-12; R. on Appeal: Tab 14 at App. 4, ¶¶ 6-9; R. on Appeal: Tab 14 at App. 5, ¶ 9. For instance, as noted above, mifepristone is approved for abortion, and the mifepristone FPL and evidence-based regimen both require mifepristone to be used in conjunction with misoprostol. But this is an off-label use of misoprostol; its FPL is silent on abortion-related uses. The same is true of methotrexate, which physicians frequently prescribe to terminate early ectopic pregnancies without surgery, even though its FPL does not describe that use. Ectopic pregnancies pose grave health risks, and surgical intervention can result in serious complications, including future infertility, organ damage, and death. *See* R. on Appeal: Tab 14 at App. 4, ¶¶ 10-13.

c. For years, Oklahoma physicians have relied on evidence-based regimens to provide safe access to mifepristone, misoprostol, and methotrexate. *See* R. on Appeal: Tab 14 at App. 5; R. on Appeal: Tab 14 at App. 7, ¶ 14. At the clinic operated by Respondent Reproductive Services, an evidence-based regimen of mifepristone and misoprostol is by far the most prevalent method for terminating early pregnancies—it accounts for some two-thirds of all abortions performed by the clinic. R. on Appeal: Tab 14 at App. 7, ¶ 9.

2. Oklahoma law elsewhere recognizes the importance of allowing physicians to prescribe medications off label. *See, e.g.*, Okla. Rev. Stat. § 63-1-2604 (prohibiting health insurers from excluding coverage of off-label cancer treatments). In 2011, however, the Oklahoma legislature enacted Oklahoma House

Bill 1970 (H.B. 1970 or the Act). That statute severely restricts, and as a practical matter prohibits, abortions performed using medication. Relevant here, the Act provides that physicians may only prescribe

> RU-486 (mifepristone) or any abortion-inducing drug according to the protocol tested and authorized by the U.S. Food and Drug Administration *and as authorized in the drug label for the RU-486 (mifepristone) or any abortion-inducing drug*.

Pet. App. 13 (Okla. Rev. Stat. § 63-1-729a(C)) (emphasis added). The Act defines "abortion-inducing drug" to "mean[] a medicine, drug, or any other substance prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman, with knowledge that the termination shall with reasonable likelihood cause the death of the unborn child." Pet. App. 11 (Okla. Rev. Stat. § 63-1-729a(A)). The definition specifically names misoprostol and methotrexate. *Id*. The Act's regulation of off-label use is targeted exclusively at abortion; it does not limit the off-label use of mifepristone, misoprostol, or methotrexate (or any other drug) for any non-abortion-related purpose. The Act makes no exception for any off-label use that is necessary to protect the life or health of the pregnant woman. Nor does it include any legislative findings that identify the State's rationale for this abortion-specific restriction.

3. Shortly after the enactment of H.B. 1970, Respondents Reproductive Services (a medical clinic in

Tulsa that provides health services including contraception counseling, adoption counseling, and surgical and medication abortions) and Oklahoma Coalition for Reproductive Justice (a membership organization comprised of Oklahoma taxpayers) brought this challenge in Oklahoma state court. The lawsuit raised a variety of state constitutional claims, including that the Act violated women's state constitutional rights to privacy and bodily integrity, which Respondents asserted were at least as robust as the equivalent due process rights under the Federal Constitution. In support of their challenge, Respondents showed, among other things, that

- medication abortion is an extremely safe, non-invasive alternative to surgery for women seeking abortions early in pregnancy[3];

- the medical community regards the prevailing off-label mifepristone-misoprostol regimens as superior to the mifepristone FPL protocol, with improved safety and effectiveness, fewer side effects, and lower costs[4];

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[3] *See, e.g.*, R. on Appeal: Tab 14 at App. 4, ¶¶ 14, 32-33 (the risk of death following medication abortion is only a fraction of the risk following penicillin use).

[4] *See, e.g.*, *id.* ¶¶ 24-30, 37 (ACOG has accorded off-label regimens "a Level A rating, which is the highest possible rating based on high quality scientific studies").

- the Act's ban on the off-label use of "all abortion-inducing drugs" would have grave consequences for women's health[5];

- and even a ban solely on the off-label use of mifepristone could cause clinics to stop providing medication abortions, and at a minimum would create significant barriers to obtaining them.[6]

Most of this evidence went uncontested.

On the parties' cross-motions for summary judgment, the trial court found certain critical facts to be undisputed, including that

- "[g]ood medical practice and the best interests of the patient often includes drug use that is not displayed in the FPL of that drug";

- "a regimen different from that set forth in the [mifepristone] FPL has been used in a great majority of cases of medication abortions in the United States"; and

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[5] *See, e.g.*, *id.* ¶¶ 10-14 (medication restrictions could be life-threatening); R. on Appeal: Tab 14 at App. 5, ¶¶ 10-12 (same).

[6] *See, e.g. id*. ¶¶ 26-29; R. on Appeal: Tab 14 at App. 7, ¶ 21 (the Act likely would prompt Respondent Reproductive Services to stop offering medication abortions entirely "because our physicians think that the Mifeprex FPL protocol … does not meet the standard of care").

- the evidence-based regimen has been "demonstrated by scientific research to be safer and more effective than the regimen provided in the [mifepristone] FPL."

Pet. App. 6. Based on these determinations, the court concluded that the Act's ban on off-label use "is so completely at odds with the standard that governs the practice of medicine that it can serve no purpose other than to prevent women from obtaining abortions and to punish and discriminate against those who do." Pet. App. 7. Describing the Oklahoma Constitution as protecting the rights to privacy and bodily integrity "at least [to] the same extent" as its federal counterpart, Pet. App. 6, the court declared the Act invalid and enjoined its enforcement, Pet. App. 8.

The Oklahoma Supreme Court summarily affirmed. Before that Court, Cline urged a saving construction that would permit off-label uses of misoprostol and methotrexate, notwithstanding the Act's plain regulation of "any abortion-inducing drug." The court was unswayed. "Upon review of the record and the briefs of the parties," the court concluded that the case was controlled by *Planned Parenthood of Southeast Pennsylvania v. Casey*, 505 U.S. 833 (1992).

REASONS FOR DENYING THE PETITION

I. THE PETITION SHOULD BE DENIED BECAUSE A PREDICATE DISPUTE OVER THE MEANING OF OKLAHOMA STATE LAW RENDERS THIS CASE AN UNSUITABLE VEHICLE FOR REVIEW.

The Petition rests on a reading of Oklahoma law that the Oklahoma courts never have endorsed and that the Oklahoma Supreme Court appears to have rejected. To the extent there is any uncertainty over this question of state law, that uncertainty is itself sufficient basis to deny the Petition.

H.B. 1970 prohibits doctors from prescribing for off-label use any drug "dispensed with the intent of terminating the clinically diagnosable pregnancy." Pet. App. 11 (Okla. Rev. Stat. § 63-1-729a(A)). This blanket prohibition has two plain implications, as Respondents consistently argued below. *First*, this provision amounts to an outright ban on all medication abortions. That is because virtually all medication abortions involve the use of misoprostol in conjunction with mifepristone and, as noted above (at 5), the use of misoprostol for abortions is an off-label use. *Second*, the Act also has the effect of prohibiting the use of medication to treat life-threatening ectopic pregnancies. As an alternative to invasive and risky surgery, physicians frequently end ectopic pregnancies with an injection of methotrexate. Because this use of methotrexate is off-label, it is outlawed by the Act, which expressly names methotrexate as an "abortion-inducing drug." Pet. App. 11 (Okla. Rev. Stat. § 63-1-729a(A)).

In the Oklahoma courts, Petitioners advanced a contrary, atextual reading of the statute: They maintained that the Act does not bar physicians from using misoprostol as part of a two-drug abortion protocol, or using methotrexate to end ectopic pregnancies. As to misoprostol, they argued that because the drug approval for *mifepristone* mentions misoprostol, the off-label use of misoprostol is not prohibited, even though misoprostol's own drug label does not authorize such usage.[7] Oklahoma law, however, already regulated mifepristone, and H.B. 1970 specifically modified that law to ban the off-label use of "any abortion-inducing drug," including misoprostol. With respect to methotrexate, Petitioners argued that physicians may still use it to end ectopic pregnancies because the termination of an ectopic pregnancy is not an "abortion" as Oklahoma law elsewhere defines that term. *See* Okla. Rev. Stat. § 63-1-730(A)(1). But the relevant term is not "abortion"; it is "abortion-inducing drug," which H.B. 1970 inserts after every reference to mifepristone in existing law and defines to mean any "medicine, drug, or any other substance prescribed or dispensed with the intent of terminating the clinically diagnosed pregnancy of a woman, with knowledge that the termination shall with reasonable likelihood cause the death of the unborn child." Pet. App. 11 (Okla. Rev. Stat. § 63-1-729a(A)). That definition encompasses methotrexate when used to terminate an ectopic pregnancy.

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[7] *See, e.g.*, Appellants' Reply Br. at 2, *Okla. Coal. for Reprod. Justice v. Cline*, 292 P.3d 27 (Okla. 2012).

The Petition does not so much as acknowledge this critical dispute. It simply proceeds as if the Oklahoma Supreme Court adopted Petitioners' strained interpretation of the Act. *See, e.g.,* Pet. 12 (describing H.B. 1970 as "virtually indistinguishable" from an Ohio law that applies only to mifepristone). The decision of the Oklahoma Supreme Court, however, is sensibly read as having rejected Cline's implausible reading of the statute. The court did not resolve this issue expressly, but as the highest court of a sovereign state, it is entitled to a presumption of regularity, and its summary determination is consistent with the Oklahoma Supreme Court Rule providing that opinions should be issued in memorandum form when they break no new legal ground. *See* Okla. Sup. Ct. R. 1.200(a). Upon adopting the plain, broad meaning of the Oklahoma restriction, no new ground could be broken because even Petitioners did not seriously contest that the court would have to invalidate the Act if it rejected their atextual saving construction.[8] For the same reason, there likewise would be little for this Court to review. *Cf. Johnson v. Fankell*, 520 U.S. 911, 916 (1997) ("Neither this Court nor any other federal tribunal has any authority to place a construction on a state statute different from the one rendered by the highest court of the State.").

If instead the Oklahoma Supreme Court left these questions of Oklahoma state law unre-

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[8] *See, e.g.*, Appellants' Reply Br. at 3 (describing "a complete ban on medication abortions" as "considerably more burdensome" than a restriction on mifepristone alone, thus "creating a potential constitutional infirmity").

solved, that too would render this case an unsuitable vehicle. It would be highly unusual for this Court to grant plenary review of a case that would require it first to decide whether a state's highest court resolved a question of state statutory construction, and if not, to undertake its own analysis of the state statute. As this Court has noted, "premature adjudication of constitutional questions" is particularly inadvisable when a federal court is called upon to review a state law, "for the federal tribunal risks friction-generating error when it endeavors to construe a novel state Act not yet reviewed by the State's highest court." *Arizonans for Official English v. Arizona*, 520 U.S. 43, 79 (1997). It would be far wiser to wait for a case in which the Court can be certain whether and how the state's high court has construed the challenged statute. *See, e.g.*, *Virginia v. Am. Booksellers Ass'n, Inc.*, 484 U.S. 383, 395 (1988) ("[W]here the nature and substance of plaintiffs' constitutional challenge is drastically altered if the statute is read another way, it is essential that we have the benefit of the law's authoritative construction from the [state high court]."); *Bellotti v. Baird*, 428 U.S. 132, 146-47 (1976) ("As we have held on numerous occasions, abstention is appropriate where an unconstrued state statute is susceptible of a construction by the state judiciary 'which might avoid in whole or in part the necessity for federal constitutional adjudication, or at least materially change the nature of the problem.'") (quoting *Harrison v. NAACP*, 360 U.S. 167, 177 (1959)).

II. THE PETITION SHOULD BE DENIED BECAUSE EVEN THE SHALLOW CONFLICT ALLEGED BY PETITIONERS IS NO CONFLICT AT ALL.

A. Cline asserts (at 11-15) that the decision below conflicts with the Sixth Circuit's decision in *Planned Parenthood Southwest Ohio Region v. DeWine*, 696 F.3d 490 (6th Cir. 2012). But conflicts of authority typically do not merit review until they become important and recurring, *see* Robert L. Stern et al., *Supreme Court Practice* ("Stern & Gressman") 245 (9th ed. 2007), and this is neither. Restrictions on medication abortion have been the subject of little legislation and little litigation. No state other than Oklahoma has imposed a wholesale ban, and only a handful of states have even taken the more modest step of imposing limitations on the off-label use of mifepristone.[9] This case and *DeWine* therefore are the only ones in which any state supreme court or federal court of appeals has confronted a regulation of medication abortion. A purported conflict this shallow would ordinarily not merit this Court's attention, *see* Stern & Gressman, *supra*, at 246, even if the conflict were stark—which presumably is why Cline gives so little prominence to what normally is the most important criterion for this Court's review.

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[9] Other than Ohio, only Arizona and North Dakota have restricted the off-label use of mifepristone. North Dakota's law has been temporarily enjoined, *see MKB Mgmt. Corp. v. Burdick*, No. 09-2011-2205 (N.D. Dist. Ct. Feb. 16, 2012), and litigation is ongoing in state court.

B. Restraint is especially warranted here because in fact there is no conflict at all. The statute, the record, and the legal theories at issue in *DeWine* all differ markedly from this case.

First, the Ohio law at issue in *DeWine* is far less sweeping than the Oklahoma statute. The Ohio law applies only to mifepristone, and it does not restrict the off-label use of misoprostol, methotrexate, or any other abortion-inducing drug.[10] As a result, Ohio physicians, unlike their Oklahoma counterparts, can continue to prescribe medication for abortions using a mifepristone-misoprostol protocol (at least for the first seven weeks of pregnancy) and can continue to use methotrexate to end ectopic pregnancies.

Second, the cases reflect the sort of fact-bound application of legal principles that does not merit this Court's review. Cline argues that this Court's precedents require statutes restricting abortion to be judged on "the specific facts of the case." Pet. 7. Proceeding on that same understanding, the Sixth Circuit framed its decision in terms of a failure of proof.[11] In fact, the records in the two cases differ in

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[10] Ohio Rev. Code § 2919.123(A) ("No person shall knowingly … prescribe RU-486 (mifepristone) to another for the purpose of inducing an abortion" except "in accordance with all provisions of federal law that govern the use of RU-486 (mifepristone) for inducing abortions."); *see DeWine*, 696 F.3d at 494 n.2 (the Ohio law "does not explicitly ban or regulate the prescription of misoprostol").

[11] *See, e.g.*, 696 F.3d at 514 ("[T]he record simply does not give rise to a reasonable inference that the Act imposes a substantial obstacle for Ohio women deciding whether to abort a

ways important to their outcomes. The Oklahoma trial court, after examining the parties' evidentiary submissions, found no genuine dispute about the superiority of the evidence-based, off-label mifepristone-misoprostol regimen "used in a great majority of cases of medication abortions in the United States." Pet. App. 6. This regimen has been "demonstrated by scientific research to be safer and more effective than the regimen provided in the RU-486 FPL." *Id.* In *DeWine*, by contrast, the court simply noted that "[t]he parties dispute[d] whether the medical community accepts that the alternative protocols cause fewer side effects or have a higher success rate than the FDA-approved regimens." 696 F.3d at 497.

As important, the Ohio statute imposed less of a burden than Oklahoma's because of differences in the prevalence of medication abortion. According to the undisputed evidence in this case, roughly two-thirds of eligible women at the clinic of Respondent Reproductive Services chose medication abortion over surgery. That number was only *one*-third in *DeWine*, 696 F.3d at 497, and the Sixth Circuit's undue burden analysis rested heavily on the fact that medication abortion was not the most prevalent form of early abortion in Ohio. Had the facts been different, the Sixth Circuit would have struck down the statute: "[S]tate action is likely to constitute an undue burden where the most common abortion technique available to a particular subset of women is prohibited…. So if this case involved a method ban

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pregnancy."); *id.* at 514 n.1 ("Planned Parenthood has not carried its [evidentiary] burden in this case.").

on … the most common procedure at 50-63 days LMP, … *Gonzales* [*v. Carhart*, 550 U.S. 124, 141 (2007)] would dictate the result." *DeWine*, 696 F.3d at 514.

Third, there is no square conflict between these two decisions because the legal arguments presented and resolved differ, and in fact the litigation in *DeWine* has not yet been finally resolved. The Sixth Circuit in *DeWine* addressed only particular aspects of the claimants' legal challenge because the claims in that case had been bifurcated. Accordingly, the premise of the claimed conflict—that the Oklahoma court ran amok while the Sixth Circuit upheld the Ohio statute—is not remotely consistent with the actual course of the Ohio litigation. Not only is that litigation ongoing; the district court issued a partial preliminary injunction against the statute, denied Ohio's motion for summary judgment on plaintiffs' remaining claim, and signaled that plaintiffs may well ultimately prevail in their effort to make the partial injunction permanent.[12]

In short, plenary review would be grossly premature. Apart from the Oklahoma Supreme Court, not a single state high court or federal appellate court—including the Sixth Circuit—has reached final judgment concerning the validity of a restriction on med-

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[12] *See Planned Parenthood Sw. Ohio Region v. DeWine*, No. 04-cv-493, 2011 WL 9158009, at *15 (S.D. Ohio May 23, 2011) ("[W]hether the Act subjects women to significant health risks remains, at a minimum, a disputed issue of material fact."); *see also DeWine*, 696 F.3d at 494 (acknowledging injunction and pending claim).

ication abortions. Petitioners make no serious argument about the broader implications of the decision below. They do not argue that the type of re-restriction at issue here is common and, indeed, acknowledge that the Oklahoma Supreme Court's ruling affects "only one state." Pet. 10. Absent a final decision upholding a statute like Oklahoma's, there is no cognizable conflict at all, and no basis for review.

III. THE PETITION SHOULD BE DENIED BECAUSE THE DECISION BELOW WAS CORRECT, AND DID NOT CONFLICT WITH THIS COURT'S PRECEDENTS.

The Oklahoma Supreme Court's decision is a straightforward, factbound application of this Court's precedents, and does not merit further review.

Under *Casey*, the Due Process Clause of the Fourteenth Amendment protects the freedom "to choose to have an abortion before viability and to obtain it without undue interference from the State." 505 U.S. at 846; *see also id.* at 875 ("the right recognized by *Roe* is a right 'to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child.'") (quoting *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972)). Of direct relevance here, the *Casey* plurality made clear that "[u]nnecessary health regulations that have the purpose or effect of presenting a substantial obstacle to a woman seeking an abortion impose an undue burden on the right" and therefore are unconstitutional. *Id.* at 878.

The Oklahoma Act's prohibition against the off-label use of "any abortion-inducing drug" imposes substantial obstacles to women seeking abortions. It amounts to a total ban on medication abortion, which requires the off-label use of misoprostol or, in the case of ectopic pregnancies, the off-label use of methotrexate. Notably, Cline has never disputed that the Act is invalid if interpreted—as its text requires—to impose these restrictions. The restrictions are plainly "calculated to … hinder" "the woman's free choice" at the earliest stages of her pregnancy. *Casey*, 505 U.S. at 877 (plurality). The statute also needlessly makes surgical intervention the sole means to terminate certain pregnancies and deprives women of the benefit of scientific progress.

Even if the Oklahoma Supreme Court were deemed to have interpreted the statute—contrary to its plain text—as banning the off-label use only of mifepristone, its decision still was correct. The statute itself identifies no "valid state interest" supporting such a restriction, *Casey*, 505 U.S. at 877 (plurality), and the state legislature made no supporting findings. *Compare Gonzales*, 550 U.S. at 141 ("Congress made factual findings" in support of its decision to restrict intact D & E procedures). This is not, contrary to Cline's bare assertion, an area in which "great scientific uncertainty" justifies the state's action. Pet. at 9; *compare Gonzales*, 550 U.S. at 162-63. As the trial court properly found, the clear consensus in the medical community is that the prevailing evidence-based regimens are safer and more effective than earlier protocols. Pet. App. 6.

Cline asserts that eight women "have died from bacterial infections following a medical abortion administered according to one of the off-label protocols." Pet. 4. But such deaths have never been causally linked to the use of mifepristone and misoprostol, much less to their use in a particular protocol. Respondents introduced uncontested evidence that the FDA and leading experts carefully studied the issue and found no causal relationship, *see, e.g.*, R. on Appeal: Tab 14, App. 4, ¶ 31; and the Oklahoma courts plainly did not credit Cline's post hoc attempt to justify the Act's restrictions. The evidence-based regimens have been the near-exclusive method of performing medication abortion for nearly a decade. The Act, even under Cline's implausible reading, compels physicians and their patients to return to an outdated procedure that involves an unnecessarily high dose and unnecessary trip to the doctor. As the trial court properly put it, the Act "is so completely at odds with the standard that governs the practice of medicine that it can serve no purpose other than to prevent women from obtaining abortions and to punish and discriminate against those who do." Pet. App. 7.

For closely related reasons, whether or not the Act's purposes are valid, the burdens it imposes are excessive. It outlaws the single most prevalent method used to terminate pregnancies at Respondent Reproductive Services' clinic. *Cf. Gonzales*, 550 U.S. at 165 (reaffirming *Planned Parenthood of Central Missouri v. Danforth*, 428 U.S. 52, 77-79 (1976), "in which the Court invalidated a ban on saline amniocentesis, the then-dominant second-trimester abortion method"). Even as narrowly construed, the

Act leaves some women with no medication abortion option at all, even when surgical abortion could have debilitating health consequences. *Cf. Casey*, 505 U.S. at 880 ("the essential holding of *Roe* forbids a State to interfere with a woman's choice to undergo an abortion procedure if continuing her pregnancy would constitute a threat to her health"). For women who would remain eligible for a medication abortion, the Act restricts them to the FPL protocol, no matter the health advantages of the evidence-based alternative. This means ingesting triple the necessary dosage of mifepristone, and making an unnecessary return visit to a health-care provider, requirements that significantly increase the cost of a medication abortion and subject women to increased health risks and side effects. R. on Appeal: Tab 14 at App. 7, ¶ 17. These are precisely the sorts of "substantial obstacles" that the state cannot validly place in a woman's path, particularly during the earliest days of her pregnancy. *Casey*, 505 U.S. at 877 (plurality).

Cline is simply mistaken that the decision below "effectively held that *Casey* categorically bars states from enacting any abortion-related regulations." Pet. 7. Terse though the opinion may be, it says nothing of the sort. "Upon review of the record" (which included the substantial evidentiary showings made by the law's challengers, and the district court's more expansive findings) "and the briefs of the parties" (in which Cline did not meaningfully contest the statute's infirmity if given its plain meaning), the Oklahoma Supreme Court properly recognized that the Act has impermissible effects. Pet. App. 2. As noted above (at 1), the Oklahoma

Supreme Court has upheld abortion restrictions in the past, and there is every reason to expect that it will do so in the future. Oklahoma has many pages of abortion regulations on its books that remain fully in force. In this case, however, the Oklahoma Supreme Court examined the record and determined that the state's ban on medication abortion could not stand. That decision is manifestly correct, and presents no issue meriting this Court's attention.

CONCLUSION

For the foregoing reasons, the Petition for a Writ of Certiorari should be denied.

Respectfully submitted,

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