

No. 12-1094

In the Supreme Court of the United States

TERRY L. CLINE, PH.D., OKLAHOMA COMMISSIONER
FOR HEALTH, *IN HIS OFFICIAL CAPACITY, 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 *AMICUS CURIAE* OF EAGLE FORUM
EDUCATION & LEGAL DEFENSE FUND, INC.,
IN SUPPORT OF PETITIONERS
IN SUPPORT OF REVERSAL**

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QUESTIONS PRESENTED

Oklahoma law requires that abortion-inducing drugs be administered according to the protocol described on the drugs' FDA-approved labels. The question presented is whether the Oklahoma Supreme Court erred in holding – without analysis or discussion – that this regulation is facially unconstitutional under *Planned Parenthood v. Casey*.

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INTEREST OF AMICUS CURIAE

Amicus curiae Eagle Forum Education & Legal Defense Fund (“Eagle Forum”),¹ a nonprofit Illinois corporation founded in 1981, has consistently defended federalism and supported state and local autonomy in areas – such as public health – of traditionally state and local concern. In addition, Eagle Forum has a longstanding interest in

¹ *Amicus* files this brief with consent by all parties, with 10 days’ prior written notice; the petitioners have lodged their blanket consent with the Clerk, and *amicus* has lodged the respondents’ written consent with the Clerk. Pursuant to Rule 37.6, counsel for *amicus* authored this brief in whole, no party’s counsel authored this brief in whole or in part, and no person or entity – other than *amicus* and its counsel – contributed monetarily to preparing or submitting the brief.

protecting unborn life and in adherence to the Constitution as written. For these reasons, Eagle Forum has a direct and vital interest in the issues before this Court.

STATEMENT OF THE CASE

Amicus Eagle Forum adopts the facts as stated by Oklahoma. *See* Pet. at 2-6. In summary, the Oklahoma Coalition for Reproductive Justice and Nova Health Systems (collectively, the “Plaintiffs”) have sued Oklahoma’s Commissioner for Health and other state officers (collectively, “Oklahoma”) to overturn an Oklahoma statute, H.B. No. 1970, §1, ch. 216, O.S.L. 2011 (to be codified at Okla. Stat. tit. 63, §1-729a), which limits the use of abortion-inducing drugs to the label uses approved by the federal Food & Drug Administration (“FDA”). Drug-induced abortions are known as “medical abortions,” in contrast with the more common “surgical abortions.” The only drug actually at issue here is mifepristone, also called “RU-486,” which the record indicates is less safe than surgical abortions when used according to its label uses, Pet. at 3-4, and even less safe in its off-label uses. *Id.* The off-label uses preferred by Plaintiffs involve differing doses and less physician oversight and have resulted in greater instances of adverse effects such as deaths due to bacterial infections. *Id.*

Constitutional Background

As the Oklahoma Supreme Court recognized (Pet. App. 2), valid federal laws and the U.S. Constitution preempt state law whenever they conflict. U.S. CONST. art. VI, cl. 2. The questions presented here involve the contours of federal law

with respect to abortion rights created by this Court in *Roe v. Wade*, 410 U.S. 113 (1973), and its progeny. In particular, the questions presented here turn on criteria promulgated in *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833 (1992), for balancing individual rights to an abortion and states' rights to regulate health and safety of the mother as well as to protect the life of the infant:

(a) To protect the central right recognized by *Roe v. Wade* while at the same time accommodating the State's profound interest in potential life, we will employ the undue burden analysis as explained in this opinion. An undue burden exists, and therefore a provision of law is invalid, if its purpose or effect is to place a substantial obstacle in the path of a woman seeking an abortion before the fetus attains viability.

(b) We reject the rigid trimester framework of *Roe v. Wade*. To promote the State's profound interest in potential life, throughout pregnancy the State may take measures to ensure that the woman's choice is informed, and measures designed to advance this interest will not be invalidated as long as their purpose is to persuade the woman to choose childbirth over abortion. These measures must not be an undue burden on the right.

(c) As with any medical procedure, the State may enact regulations to further the health or safety of a woman seeking an abortion. *Unnecessary 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.

(d) Our adoption of the undue burden analysis does not disturb the central holding of *Roe v. Wade*, and we reaffirm that holding. Regardless of whether exceptions are made for particular circumstances, a State may not prohibit any woman from making the ultimate decision to terminate her pregnancy before viability.

(e) We also reaffirm *Roe*'s holding that "subsequent to viability, the State in promoting its interest in the potentiality of human life may, if it chooses, regulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother."

Casey, 505 U.S. at 878 (citations omitted, emphasis added). Significantly, only the mother-focused clause (c) asks whether the state regulation is "necessary."

As explained in Section IV, *infra*, *amicus* Eagle Forum respectfully submits that only mother-focused abortion regulations include a "necessity" inquiry because only such regulations protect the holders of the *Roe*-based right to an abortion, which justifies placing that inquiry *before* determining whether the regulation presents an undue burden.² Were it

² *Amicus* Eagle Forum emphatically does not support lesser protections for infants. *Amicus* Eagle Forum is merely describing this Court's holdings.

otherwise, states would be hard-processed to prohibit even “back-alley” abortions, which plainly is not the law. *Connecticut v. Menillo*, 423 U.S. 9, 10-11 (1975). As *Menillo* recognized contemporaneously with *Roe*, states may require that “abortion [be] performed by *medically competent personnel under conditions insuring maximum safety* for the woman.” *Id.* (emphasis added). *Amicus* Eagle Forum respectfully submits that Oklahoma has done no more here.

Statutory Background

The operative part of the challenged Oklahoma statute prohibits off-label uses of RU-486 as follows:

No physician who provides RU-486 (mifepristone) or any abortion-inducing drug shall knowingly or recklessly fail to provide or prescribe the 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. 16.

Litigation Background

Prior to the decision from which Oklahoma now seeks review, the Oklahoma Supreme Court addressed the undue-burden analysis from *Casey* in three relevant decisions. *Davis v. Fieker*, 952 P.2d 505, 1997 OK 156 (Okla. 1998); *In re Initiative Petition No. 395, State Question No. 761*, 286 P.3d 637, 2012 OK 42 (Okla. 2012); *Nova Health Systems v. Pruitt*, 292 P.3d 28, 2012 OK 103 (Okla. 2012). Like the case at bar, both *Initiative Petition No. 395* and *Nova Health Systems* were summary decisions,

without any analysis by the Oklahoma Supreme Court beyond noting that *Casey* controlled and that the state laws or proposed referenda imposed an undue burden under *Casey*.

In *Davis*, the Oklahoma Supreme Court elevated a general statement of the *Casey* undue-burden test into a *Casey* holding that applies across all contexts, *Davis*, 952 P.2d at 512, 1997 OK 156 (“a state may not impose a regulation that has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus”) (internal quotations omitted), which is not what *Casey* held with respect to mother-focused health regulations. *See* Section IV, *infra*.

SUMMARY OF ARGUMENT

The Oklahoma Supreme Court’s summary decision, without analysis, denied Oklahoma due process by mechanistically applying prior precedents of that court that interpret – or rather misinterpret – *Casey* (Section I).

Given that states have traditional police power to protect public health, and the federal government lacks a police power, Oklahoma must retain its ability to regulate public health in a field (namely, *off-label* uses of FDA-approved drugs) where the federal government has not even entered the field under the Commerce Power. The only alternatives left to regulate the abortion industry are medically unqualified judges and the abortion industry itself (Section II.A). Our federal system allows, and *Casey* requires, balancing states’ interests in public health against individuals’ interests in abortions (Section II.B).

The Oklahoma Supreme Court's split with a well-reasoned Sixth Circuit decision on essentially the same question provides a sufficient split in authority to warrant this Court's review (Section III), and the confusion demonstrated by the Oklahoma Supreme Court reveals the need for this Court to clarify the application of the *Casey* undue-burden analysis to state regulations – such as Oklahoma's regulation here – that seek to protect pregnant women from adverse health effects associated with particular abortion methods (Section IV).

ARGUMENT

I. THE DUE PROCESS CLAUSE OF THE FOURTEENTH AMENDMENT REQUIRES THAT OKLAHOMA RECEIVE A FAIR HEARING, WHICH THE LOWER COURTS DENIED OKLAHOMA UNDER THOSE COURTS' FLAWED READING OF *CASEY*

Although *amicus* Eagle Forum respectfully submits that the substantive due-process basis for this Court's *Roe-Casey* jurisprudence is foreign to the Constitution, the Due Process Clause itself is central to our tradition as it applies *procedurally* to litigants like Oklahoma. Perhaps surprisingly, the Oklahoma courts denied Oklahoma a fair hearing, which raises due-process concerns that provide further impetus for this Court to grant review. As explained in Section IV, *infra*, the genesis of Oklahoma's flawed treatment lies in part with the need for more clarity in this Court's undue-burden analysis, underscoring the need for this Court's review.

Under the Due Process Clause, “[i]n no event ... can issue preclusion be invoked against one who did

not participate in the prior adjudication.” *Baker v. General Motors Corp.*, 522 U.S. 222, 237-38 & n.11 (1998). Moreover, parties cannot assert *non-mutual* estoppel against the government. *U.S. v. Mendoza*, 464 U.S. 154 (1984).³ Similarly, with respect to *stare decisis*, courts can apply their precedents so conclusively as to violate due process. *S. Cent. Bell Tel. Co. v. Alabama*, 526 U.S. 160, 167-68 (1999). Applying these related principles to the decisions below, the Oklahoma courts imported their broad interpretations of *Casey* from *Initiative Petition No. 349* to this case, without any analysis. Oklahoma deserved better, and the Due Process Clause required more.

II. PRINCIPLES OF FEDERALISM REQUIRE THIS COURT TO CLARIFY THE *CASEY* REQUIREMENTS IMPOSED ON STATES

The rulings below are inconsistent with not only federalism but also sound policy. The lower courts’ reading of *Casey* weakened Oklahoma’s police power to protect its citizens in an area of traditional state and local concern (namely, public health) where the federal government has not exercised its commerce powers (namely, *off-label* uses of federally approved drugs). That leaves only the judiciary and abortion

³ Although *Mendoza* applies by its terms to only the *federal* government, its rationale applies equally to states, and the Courts of Appeals have extended its holding to state government. See, e.g., *Hercules Carriers, Inc. v. Florida*, 768 F.2d 1558, 1579 (11th Cir.1985); *Chambers v. Ohio Dept. of Human Serv.*, 145 F.3d 793, 801 n.14 (6th Cir. 1998); *Milton S. Kronheim & Co. v. District of Columbia*, 91 F.3d 193, 205 (D.C. Cir. 1996) (Silberman, J., concurring).

providers to protect the public from abortion providers, which leaves no one who is both qualified and unbiased to protect public health.

A. States Are the Only Government Actor with Authority to Protect the Public Health

By way of background, “[t]hroughout our history the several States have exercised their police powers to protect the health and safety of their citizens,” which “are ‘primarily, and historically, ... matter[s] of local concern.’” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (quoting *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985)) (second and third alterations in *Medtronic*). For their part, the federal Executive and Congress lack a corresponding police power to take up the slack: “we always have rejected readings of the Commerce Clause and the scope of federal power that would permit Congress to exercise a police power.” *U.S. v. Morrison*, 529 U.S. 598, 618-19 (2000). As indicated, if Oklahoma cannot regulate the abortion industry’s excesses, and the federal government cannot, that leaves only the judiciary and the abortion industry.

The judiciary, of course, is ill-suited in training to determine or second-guess what procedures are safe or necessary. *Cf. Parents Involved in Community Schools v. Seattle School Dist. No. 1*, 551 U.S. 701, 766 (2007) (federal courts “are not social engineers”) (Thomas, J., concurring). Indeed, judges are even less qualified to practice medicine than they are to practice social engineering. Because the judiciary cannot be a credible regulator, the Oklahoma

Supreme Court's narrow view of the flexibility that *Casey* gives the states makes abortion essentially a self-regulated industry.

While it might be nice for the public and the states to be able to trust abortion providers, it would also be extremely naïve. Perhaps because of the politicization of this issue in the United States – caused in great part by this Court's unprecedented *Roe* decision – abortion providers appear to regard themselves as civil-rights warriors more than medical providers. As such, many abortion providers apparently believe that they simply cannot disclose anything negative about their abortion mission:

Political considerations have impeded research and reporting about the complications of legal abortions. The highly significant discrepancies in complications reported in European and Oceanic [j]ournals compared with North American journals could signal underreporting bias in North America.

Jane M. Orient, M.D., *Sapira's Art and Science of Bedside Diagnosis*, ch. 3, p. 62 (Lippincott, Williams & Wilkins, 4th ed. 2009) (citations omitted).

Certainly, the abortion industry throws great public-relations and advocacy efforts into fighting disclosure of correlated health effects that other medical disciplines readily would disclose. *See, e.g., Planned Parenthood Minnesota, North Dakota, South Dakota v. Rounds*, 686 F.3d 889, 898 (8th Cir. 2012) (*en banc*) (opposition to disclosing abortion's correlation with suicide ideation). The U.S. abortion

industry also has sought to deny the correlation between breast cancer and abortion:

[I]t will surely be agreed that open discussion of risks is vital and must include the people – in this case the women – concerned. I believe that if you take a view (as I do), which is often called “pro-choice,” you need at the same time to have a view which might be called “pro-information” without excessive paternalistic censorship (or interpretation) of the data.

Stuart Donnan, M.D., *Abortion, Breast Cancer, and Impact Factors – in this Number and the Last*, 50 J. EPIDEMIOLOGY & COMMUNITY HEALTH 605 (1996).⁴ The industry’s lack of transparency calls out for heightened regulation, vis-à-vis other, non-politicized medical practices.

In other words, claims that states have targeted the abortion industry for *unwarranted* scrutiny have it precisely backwards. Here, Oklahoma has regulated an industry that cuts corners and hides information by requiring that that industry stick with safer measures that have been expressly approved by relevant governmental authorities (*i.e.*, not self-approved by the regulated industry). Legislatures have wide authority to solve only part of a perceived problem, leaving the balance to future legislation, *Williamson v. Lee Optical of Oklahoma*, 348 U.S. 483, 487-89 (1955), and Oklahoma has

⁴ Consistent with the *Bedside Diagnosis* suggestion of possible North American bias, Dr. Donnan is a Professor of Epidemiology and Public Health at the University of Manchester in England.

acted appropriately in seeking to increase medical supervision and to minimize unnecessary death and injury – *i.e.*, to ensure “medically competent personnel under conditions insuring maximum safety for the woman,” *Menillo*, 423 U.S. at 10-11 – in its regulations here.⁵

Under such circumstances, “legislatures [have] wide discretion to pass legislation in areas where there is medical ... uncertainty,” and “medical uncertainty ... provides a sufficient basis to conclude in [a] facial attack that the Act *does not* impose an undue burden.” *Gonzales v. Carhart*, 550 U.S. 124, 164 (2007) (emphasis added). Significantly, the Constitution does “not give abortion doctors unfettered choice in the course of their medical practice, nor should it elevate their status above other physicians in the medical community.” *Gonzales*, 550 U.S. at 163. That holding from *Gonzales* applies even more so here.

In summary, to allow Oklahoma to protect its citizens as contemplated by *Casey*, this Court should review the trammeling of Oklahoma’s police power by the lower courts’ cramped reading of *Casey*.

⁵ The heightened restrictions are particularly appropriate for off-label uses of RU-486, which FDA approved under its “Subpart H” authority for “Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses.” 21 C.F.R. §§314.500-.560, notwithstanding that pregnancy is not a “serious or life-threatening illness[]” as required for approvals under Subpart H. 21 C.F.R. §314.500. FDA granted the approval on September 28, 2000, *see* 73 Fed. Reg. 16,313 (2008), late in President Clinton’s second term.

**B. The Constitution Allows Balancing
Roe-Casey Rights with States'
Rights in Our Federal System**

Accepting *arguendo* that this Court will not reverse *Roe* and *Casey* in this case does not mandate the result reached by the Oklahoma Supreme Court. Instead, there are numerous intermediate positions in which this Court can balance Oklahoma's interest in protecting the health of its citizens with the personal interests first advanced in *Roe*. Indeed, as *amicus* Eagle Forum reads *Casey*, that is precisely what the *Casey* majority intended.

At the outset, notwithstanding that *Casey* rejects limiting due-process rights incorporated by the Fourteenth Amendment to "only those practices ... protected against government interference ... when the Fourteenth Amendment was ratified," *Casey*, 505 U.S. at 847, this case requires reflecting on what the states ratified in the Fourteenth Amendment. If *Roe-Casey* abortion rights had come instead via federal legislation, the resulting preemption would be subject to a presumption against preemption for fields – such as medical practice and public health – traditionally occupied by the states. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). When this "presumption against preemption" applies, courts do not assume preemption "unless that was the *clear and manifest purpose* of Congress." *Id.* (emphasis added). *Casey* in no way "clearly and manifestly" forecloses Oklahoma's regulation here.

Even preemptive laws are subject to the presumption against preemption to determine the *scope* of their preemption. *Medtronic*, 518 U.S. at

485. “When the text of an express pre-emption clause is susceptible of more than one plausible reading, courts ordinarily ‘accept the reading that disfavors pre-emption.’” *Altria Group, Inc. v. Good*, 555 U.S. 70, 77 (2008) (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)). Although preemption does not apply *per se*, analogy to that analysis should give states the benefit of the doubt where, as here, they work in areas of medical uncertainty. Of course, the actual facts suggest that off-label uses of RU-486 correlate with death and injury to a markedly greater degree than the alternatives that Oklahoma law favors. *Amicus Eagle Forum* respectfully submits that courts should hesitate to second-guess states under these circumstances.

Even without adopting a presumption against preemption, this Court readily can recognize that *Roe-Casey* abortion rights must yield to the states’ rights to regulate in the interest of public health. *Cf. Hill v. Colorado*, 530 U.S. 703, 714-18 (2000) (state interest in health and safety can warrant regulation of enumerated rights such as the First Amendment); *cf. McDonald v. City of Chicago, Ill.*, 130 S.Ct. 3020, 3126 (2010) (Breyer, J., dissenting) (“examples in which the Court has deferred to state legislative judgments in respect to the exercise of the police power are legion”). Indeed, the *Casey* framework rests on balancing competing state and individual interests. On the application of the police power to protecting the *mother’s* health, this Court never has ruled that the right to a particular abortion method trumps the states’ interest in public health.

III. THIS COURT SHOULD RESOLVE THE SPLIT WITH THE SIXTH CIRCUIT'S WELL-REASONED DECISION

As Oklahoma notes, Pet. at 11-15, the Oklahoma Supreme Court's decision splits with a well-reasoned Sixth Circuit decision on essentially the same issue (namely, whether states can restrict RU-486 to its FDA-approved label uses). *Planned Parenthood Sw. Ohio Region v. DeWine*, 696 F.3d 490 (6th Cir. 2012). The Oklahoma and Ohio statutes differ in that the Oklahoma statute applies not only to RU-486 but also to "any abortion-inducing drug." Pet. App. 13. Insofar as Plaintiffs wish to employ off-label uses of only RU-486, that is a distinction without a difference for purposes of federal justiciability.

The *DeWine* panel recognized that banning an abortion method – such as off-label uses of RU-486 – was not equivalent to banning abortion itself. For women within the gestational limits allowed by the FDA-approved label, of course the label uses and surgical abortions remained available alternatives. But even women in the gestational ranges covered by the off-label uses and not covered by the FDA-approved labeling, could continue to obtain surgical option after the time for using RU-486 has passed.

Citing *Casey* and its own Circuit precedent, the Sixth Circuit reduced the question presented to "whether in a large fraction of the cases in which [the Act] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion." *DeWine*, 696 F.3d at 514 (internal quotations omitted, alteration in *DeWine*). In finding the Ohio law constitutional under *Casey*, the majority relied

on the absence of a holding (or even a suggestion) from this Court that “the right to choose abortion encompasses the right to choose a particular abortion method.” *DeWine*, 696 F.3d at 514-15. By contrast, the dissenting judge reasoned that the subset of women who preferred medical abortion over surgical abortion, but who had passed the gestational limits for FDA-approved uses of RU-486, constituted a sufficiently “large fraction” of women contemplating an abortion within that gestational range. *DeWine*, 696 F.3d at 509-10 (Moore, J., dissenting). Although the *DeWine* majority’s reasoning more closely follows *Casey*, the *DeWine* dissent provides a further split in reasoning that may aid this Court’s consideration of the issues presented here.

IV. THIS COURT MUST RECOGNIZE – AND ADDRESS – THE IMPORTANT PUBLIC-HEALTH ISSUES AT STAKE HERE BY CLARIFYING THE CASEY FRAMEWORK

This litigation presents issues of exceptional importance to the ongoing efforts of legislatures and courts to define the roles of state and federal law in elective abortions generally and in public-health issues surrounding abortion procedures specifically. Significantly, *Roe* concerned states’ ability to *prohibit* abortions in the interest of the *infant* and the state’s interest in that new life. By contrast, this litigation concerns the states’ ability to *regulate* abortions in the interest of *pregnant women* who contemplate and receive abortions. Although *Casey* laid out a test for this category of mother-focused health regulations, the language in *Casey* has not been understood by lower courts and requires further clarification, now

that an actual case or controversy has reached this Court.⁶

As *Casey* itself recognizes, “disagreement is inevitable,” “[e]ven when jurists reason from shared premises,” and “[w]e do not expect it to be otherwise with respect to the undue burden standard.” *Casey*, 505 U.S. at 878. Here, the Court needs to address two such “disagreements” that have developed, one between the Oklahoma Supreme Court and *Casey* on the states’ latitude to regulate to protect the health of pregnant mothers (discussed in this Section) and one between the *DeWine* majority and dissent on the scope of states’ authority to regulate access to abortion versus access to particular abortion procedures (discussed in Section III, *supra*). Both issues warrant this Court’s review.

As *amicus* Eagle Forum understands *Casey* – and contrary to how the Oklahoma Supreme Court understands *Casey* – the undue-burden analysis does not enter the equation for “necessary” regulation of abortion procedures to protect women seeking an abortion. Compare *Casey*, 505 U.S. at 878 (only *unnecessary* regulations of women’s health trigger the substantial-obstacle inquiry) with *Davis*, 952 P.2d at 512, 1997 OK 156 (any regulation of abortion triggers the substantial-obstacle inquiry).

Under *Casey*, states “may enact regulations to further the health or safety of a woman seeking an abortion,” “[a]s with any medical procedure.” *Casey*,

⁶ *DeWine* did not address the distinction drawn in *Casey* between state regulations designed to protect the pregnant woman, as in this case and in *DeWine*, and state regulation to further states’ interests in the unborn child, as in *Gonzales*.

505 U.S. at 878. The only prohibition in the mother-focused prong of *Casey* is 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.” *Id.* (emphasis added). To unpack this language to its constituent parts, an undue-burden violation for mother-focused state regulation requires that the plaintiff establish each of two elements: (1) a mother-based health regulation is *unnecessary*; and (2) that regulation either has the purpose or effect of presenting a *substantial* obstacle. Here, the plaintiffs cannot meet either prong of the test.

Amicus Eagle Forum notes two significant points that flow from the test for mother-focused health regulations:

- First, if the regulation is “necessary (*i.e.*, not “unnecessary”), that ends the analysis: there is no *Casey-Roe* violation. Because no court is in a position to rule that states cannot regulate off-label uses (*i.e.*, uses that the federal government *has not approved*) where those off-label uses correlate more highly with death and injury than label uses, plaintiffs cannot meet their burden at the first test.
- Second, if the second prong applies, legislative intent is essentially irrelevant because a “substantial obstacle” will trigger the undue-burden prong with either intent or effect. Here, the challenged law does not create a substantial obstacle to abortions for the reasons set out in Section III, *supra*.

In light of the foregoing, the Oklahoma Supreme Court's summary order and the Oklahoma precedent on which it was based require this Court's review to ensure uniformity of federal law, to cure the split in authority with the Sixth Circuit, and to clarify the important public-health and federalism issues here.

CONCLUSION

The Court should grant the petition for a writ of *certiorari*.

April 8, 2013

Respectfully submitted,
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