No. 14-284

In the Supreme Court of the United States

WILLIAM HUMBLE, DIRECTOR OF THE ARIZONA DEP'T OF HEALTH SERVICES, IN HIS OFFICIAL CAPACITY,

Petitioner,

v.

PLANNED PARENTHOOD ARIZONA, INC.; WILLIAM RICHARDSON, M.D., DBA TUCSON WOMEN'S CENTER; WILLIAM H. RICHARDSON, M.D., P.C., DBA TUCSON WOMEN'S CENTER,

Respondents.

On Petition for a Writ of Certiorari to the U.S. Court of Appeals for the Ninth Circuit

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

A plurality of this Court has settled on the appropriate standard for evaluating the constitutionality of abortion regulations: "[o]nly where state regulation imposes an undue burden on a woman's ability to make [the abortion] decision does the power of the State reach into the heart of the liberty protected by the Due Process Clause." *Planned Parenthood of Se. Pa. v. Casey,* 505 U.S. 833, 854 (1992). A State's regulation is invalid if it "has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus." *Id.* at 877. Federal appellate courts have now reached contrary conclusions regarding how a reviewing court determines whether a facially challenged rational abortion regulation creates a substantial obstacle.

The question presented is whether an abortion regulation that is rationally related to the State's interest in maternal health creates an undue burden and is therefore invalid (a) only when it erects a substantial obstacle to obtaining a previability abortion, as the Fifth and Sixth Circuits held, or (b) when "the extent of the burden a law imposes on a woman's right to abortion" outweighs "the strength of the state's justification for the law," as the Ninth Circuit held in the decision below. (App. 15, 19.).

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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

[1] *Amicus* files this brief with consent by all parties, with 10 days' prior written notice; *amicus* has lodged the parties' 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.

traditionally state and local concern. In addition, Eagle Forum has a longstanding interest in 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 Arizona. *See* Pet. at 4-5. In summary, Planned Parenthood Arizona and other abortion providers (collectively, "Plaintiffs") have sued the Director of Arizona's Department of Health Services (hereinafter, "Arizona") to overturn an Arizona statute and regulation, ARIZ. REV. STAT. §36-449.03(E)(6); Ariz. Admin. Code §R9-10-1508(G) (collectively, "Arizona law"), that limit the use of abortion-inducing drugs to the label uses approved by the federal Food & Drug Administration ("FDA"). *See* Pet. at 1-2 (*quoting* Arizona law). Drug-induced abortions are known as "medication abortions," in contrast with the more common "surgical abortions."

Significantly, the abortifacient drug in question is RU-486, which FDA approved in the waning months of the Clinton administration under the "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. The Ninth Circuit repeatedly refers to Plaintiffs' off-label uses as the "evidence-based regimen," ignoring the evidence that FDA requires to approve new drugs' label uses. The Ninth

Circuit also relies on a 1982 "FDA Drug Bulletin" to show how off-label uses fit within FDA's program, Pet. App. 8-9,[2] notwithstanding Subpart H's adoption ten years later. 57 Fed. Reg. 58,942 (1992). Here, the use restrictions on RU-486 were and are serious, and a reviewing court should not lightly disregard them.

Standing against Arizona law are two potential forms of federal authority: FDA's statutory regime for regulating drugs and the rights that this Court adopted in *Roe v. Wade,* 410 U.S. 113 (1973), and modified in *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833 (1992). If Arizona law conflicts with either form of federal authority, Arizona law must yield under the Supremacy Clause. U.S. CONST. art. VI, cl. 2. Because nothing in the Federal Food, Drug & Cosmetic Act preempts states from tying usage of drugs to the FDA-approved label uses, the questions presented here all concern the contours of the *Roe-Casey* rights under the Constitution.

In particular, the questions presented here turn on criteria promulgated in *Casey* for reconciling individual rights to an abortion with states' rights both to regulate maternal health and safety and to protect the life of the unborn child:

> (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

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[2] The Ninth Circuit also cites a meaningless but more-recent, two-paragraph summary guidance document. *Id.*

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 878-79 (emphasis added; citations omitted). Importantly, only clause (c), on maternal-health, asks whether a state regulation is necessary.

As explained in Section III, *infra, amicus* Eagle Forum respectfully submits that only maternal-health-based abortion regulation includes that "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.[3] Were it otherwise, states would be hard-pressed 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 Arizona has done no more here.

SUMMARY OF ARGUMENT

Standing alone, the Ninth Circuit's split with well-reasoned Fifth and Sixth Circuit decisions on essentially the same question provides a sufficient

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[3] *Amicus* Eagle Forum emphatically does not support lesser protections for the unborn child. *Amicus* Eagle Forum is merely describing this Court's holdings.

split in authority to warrant this Court's review (Section I). Moreover, the fact that these circuits used very different modes of analysis for the same legal question demonstrates the need for this Court to clarify the *Casey* undue-burden test.

Given that states have police power to protect public health, and the federal government lacks a police power, Arizona and the other states must retain their ability to regulate public health in a field – *i.e., off-label* uses of FDA-approved drugs – that the federal government has not even entered 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, reconciling the states' interests in public health with individuals' interests in abortions (Section II.B). Specifically, this Court should: (1) avoid reading the Fourteenth Amendment to deny states the police power to protect public health here, and instead give them leeway to regulate in the face of medical uncertainty (Section II.B.1); (2) decline to *expand* the substantive-due-process *Roe-Casey* right to abortion to include a right to choice of abortion procedures (Section II.B.2); (3) resolve the circuit split on the standard for reviewing the underlying need for maternal-health regulations (Section II.B.3); and (4) clarify the standards for facial challenges – or, preferably, the need for as-applied challenges – under the undue-burden test (Section II.B.4).

Finally, the confusion demonstrated by the implicit splits in authority over how to evaluation *Roe-Casey* rights reveals the need for this Court to

clarify the application of the *Casey* undue-burden analysis to state regulations – such as Arizona's regulation here – that seek to protect pregnant women from adverse health effects associated with particular abortion methods (Section III).

ARGUMENT

I. THIS COURT SHOULD RESOLVE THE NINTH CIRCUIT'S SPLIT WITH THE FIFTH AND SIXTH CIRCUITS OVER SIMILAR ABORTION RESTRICTIONS

As Arizona explains, Pet. at 11-18, the Ninth Circuit's decision splits with well-reasoned Fifth and Sixth Circuit decisions 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); *Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott,* 748 F.3d 583 (5th Cir. 2014). Even if the Ninth Circuit's underlying reasoning were not wildly different from the other two circuits, the different appellate answer to the same legal question for an important issue like abortion would justify review in this Court. Here, however, review is even more pressing because the circuits used divergent legal standards to analyze burdens under *Casey*.

The *DeWine* and *Abbott* decisions recognize that banning an *abortion method* – such as off-label uses of RU-486 – was not equivalent to *banning abortion itself*. *DeWine,* 696 F.3d at 514-15; *Abbott,* 748 F.3d at 601-05. Of course, women within the gestational limits allowed by the FDA-approved label will have access not only to medication abortions under the FDA label regimen but also to surgical abortions.

But even women in the gestational ranges covered by the off-label uses, but not covered by the FDA-approved labeling, could continue to obtain surgical abortions after FDA's RU-486 window has closed.

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 Fifth Circuit relied primarily on *Gonzales v. Carhart,* 550 U.S. 124 (2007) to uphold the Texas statute from facial challenge because women still could get abortions via another method (*e.g.,* surgical abortions), and there was medical uncertainty on the relative safety of the proscribed method vis-à-vis the allowed methods of abortion. *Abbott,* 748 F.3d at 603-04. By contrast, the Ninth Circuit here engaged in a weighing analysis – which the Fifth and Sixth Circuits did not use – to find the Arizona law to impose an undue burden. *See* Pet. at 20-24. In sum, the Ninth Circuit is completely split from the Fifth and Sixth Circuits, both on the answer and on the analysis used to find an answer.

Amicus Eagle Forum respectfully submits that this split on the answer alone would be reason for this Court to grant review, even without the lower

courts' confusion on how to apply *Casey*. Indeed, this Court previously granted a writ of *certiorari* in litigation arising out of the Oklahoma Supreme Court on the same question, although this Court subsequently dismissed it as improvidently granted on state-law grounds. *Cline v. Okla. Coalition for Reprod. Justice,* 134 S.Ct. 550 (2013). As with *Cline,* however, the mere fact of the different outcome is reason enough to grant the writ here. In the interval since *Cline* split with the Sixth Circuit, the split in authority has only deepened, with the Fifth and Ninth Circuits' reaching opposite results.

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

As signaled in the previous section, the Ninth Circuit not only reached a different conclusion on Plaintiffs' claims than the Fifth and Sixth Circuits reached, but also did so via wildly different form of analysis. Given that the public-health area here is one of traditional state concern and that the federal government lacks a corresponding police power, the petition raises important questions not only of federalism but also of separation of powers. This Court's *Casey* decision is inadequate to guide the lower courts and state legislators on the permissible means of regulating abortion. In this Section, *amicus* Eagle Forum analyzes areas where this Court's *Roe-Casey* decisions require further clarification, as evidenced by the Ninth Circuit's decision below.

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

The panel's reading of *Casey* weakened Arizona's police power to protect its citizens in an area of traditional state 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 providers to protect the public from abortion providers, which leaves no one who is both qualified and unbiased to protect 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 Arizona 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: federal courts are not "the

country's *ex officio* medical board." *Gonzales,* 550 U.S. at 164 (interior quotations omitted); *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 Ninth Circuit's narrow view of the flexibility that *Casey* gives the states makes abortion essentially a self-regulated industry.

While some might argue that the public and the states should be able to trust abortion providers, that approach would be extremely naïve. Perhaps because of the politicization of this issue in the United States – caused in great part by the unprecedented *Roe* decision – abortion providers appear to regard themselves more as civil-rights warriors than as medical providers. Sadly, many abortion providers 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).

Under the circumstances, state legislatures could reasonably conclude regulatory oversight of the abortion industry is insufficient due to "agency capture"[4] or "political correctness" in the regulators:

> [Pennsylvania Department of Health Senior Counsel Kenneth] Brody confirmed some of what [Janice] Staloski [the Director of the Pennsylvania Department of Health unit responsible for overseeing abortion clinics] told the Grand Jury. He described a meeting of high-level government officials in 1999 at which a decision was made not to accept a recommendation to reinstitute regular inspections of abortion clinics. The reasoning, as Brody recalled, was: "there was a concern that if they did routine inspections, that they may find a lot of these facilities didn't meet [the standards for getting patients out by stretcher or wheelchair in an emergency], and then there would be less abortion facilities, less access to women to have an abortion."

In re County Investigating Grand Jury XXIII, Misc. No. 9901-2008, at 147 (Pa. C.P. Phila. filed Jan. 14, 2011) (fourth alteration in original). A legislature

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[4] "'Agency capture' … is the undesirable scenario where the regulated industry gains influence over the regulators, and the regulators end up serving the interests of the industry, rather than the general public." *Wood v. GMC,* 865 F.2d 395, 418 (1st Cir. 1988) (*citing* Wiley, *A Capture Theory of Antitrust Federalism,* 99 HARV. L. REV. 713, 724-26 (1986); Richard B. Stewart, *The Reformation of American Administrative Law,* 88 HARV. L. REV. 1667, 1684-87, 1713-15 (1975)).

seeking to protect public health might well conclude that it needed to take extra legislative action to counteract regulatory inertia on the part of both state and federal regulators.

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). The industry's lack of transparency calls out for heightened regulation, vis-à-vis other, less-politicized medical practices.

In short, claims that states have targeted the abortion industry for *unwarranted* scrutiny have it precisely backwards. Here, Arizona has regulated an industry that cuts corners and hides information by

requiring that the 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 Arizona has 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.

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,* 550 U.S. at 164 (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 Arizona to protect its citizens as contemplated by *Casey,* this Court should review the trammeling of Arizona's police power by the Ninth Circuit's cramped reading of *Casey*.

B. The Constitution's Federalist Structure Requires Reconciling *Roe-Casey* Rights with States' Reserved Powers

Accepting *arguendo* that this Court will not reverse *Roe* and *Casey* in this case does not mandate the result reached by the Ninth Circuit. Instead, there are numerous intermediate positions in which this Court could reconcile the states' interest in protecting the health of their citizens with the personal interests first advanced in *Roe.* Indeed, as *amicus* Eagle Forum reads *Casey,* that is precisely what the *Casey* plurality intended. Whatever *Casey* intended, the states (and the lower courts) need this Court's further guidance to clarify the standards that guide the *Roe-Casey* analysis.

1. Courts Should Avoid Interpreting the Fourteenth Amendment to Reorder the State-Federal Balance in Public-Health Areas that the Amendment Did Not Clearly and Manifestly Address

At the outset, notwithstanding that *Casey* rejects limiting due-process rights under 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). Indeed, because repeals by implication face the same skeptical, clear-and-manifest-intent standard, *Nat'l Ass'n of Home Builders v. Defenders of Wildlife,* 551 U.S. 644, 662 (2007), courts should not conclude lightly that constitutional amendments altered other constitutional provisions not directly affected by an amendment. *Casey* in no way "clearly and manifestly" forecloses Arizona'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 state legislatures leeway where, as here, they work in areas of medical uncertainty in an area of traditional state concern. 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 Arizona 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 reconciling 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. As indicated, these circumstances require courts to provide "wide discretion to pass legislation in areas where there is medical … uncertainty," which in itself "provides a sufficient basis" to reject "facial attack[s] that the Act *does not* impose an undue burden." *Gonzales,* 550 U.S. at 164 (emphasis added).

2. <u>This Court's *Glucksberg* Restrictions on Finding New Substantive Due-Process Rights Should Apply to Claims that Seek to Expand *Roe-Casey* Rights</u>

Another way to avoid trenching upon states' reserved powers would be to recognize – as the Sixth Circuit did, *DeWine,* 696 F.3d at 514-15 – that Plaintiffs seek to *expand* their rights to include not only abortion but also their *choice of abortion procedures.* Significantly, the creation of new due-process rights must meet the rigorous analysis that

this Court set in *Washington v. Glucksberg,* 521 U.S. 702, 720-21 (1997). Under *Glucksberg,* no such right exists here.

After *Casey,* this Court prospectively foreclosed using the Due Process Clause to create new substantive rights without a painstaking analysis, requiring "the utmost care … lest the liberty protected by the Due Process Clause be subtly transformed into the policy preferences of the of the members of this Court." *Glucksberg,* 521 U.S. at 720. Under that analysis, to "extend[] constitutional protection to an asserted right or liberty interest," the right or interest must be both "deeply rooted in this Nation's history and tradition" and "implicit in the concept of ordered liberty." *Id.* at 720-21. Even those who could find a right to medication abortion in the second prong must admit that there is no such right in the first. Under *Glucksberg,* therefore, federal courts cannot expand *Casey,* at the expense of limiting states' reserved police-power and Tenth Amendment rights: "Having sworn off the habit of venturing beyond Congress's intent, we will not accept [the] invitation to have one last drink." *Alexander v. Sandoval,* 532 U.S. 275, 287 (2001) (declining to expand an existing implied right of action after having prospectively rejected the creation of such rights of action). Similarly here, this Court must not expand *Casey* without satisfying *Glucksberg.*

3. <u>This Court Should Resolve the Circuit Split on the Standard of Review for Determining the Necessity of State Regulations that Protect Maternal Health</u>

As Arizona explains, the Ninth Circuit weighed abortion's perceived benefits to the individual versus the state's interests in public health to determine whether any burden was "undue." Pet. at 20-24; *accord Planned Parenthood of Wisconsin, Inc. v. Van Hollen,* 738 F.3d 786, 798 (7th Cir. 2013). While the Ninth Circuit's resort to the dictionary definition of "undue" has some surface appeal, Pet. App. at 16, this Court already has defined "undue burden" in *Casey:*

> A finding of an undue burden is a shorthand for the conclusion that a state regulation has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus.

505 U.S. at 877. As indicated, the maternal-health clause of *Casey* – clause (c) quoted *supra* – alone among the *Casey* clauses includes the precondition that only *unnecessary* regulations trigger the undue-burden inquiry. *Id.* at 878. As such, the question of whether something is "undue" does not even arise for *necessary* maternal-health regulations. *See* Section III, *infra.* Moreover, unlike the Seventh and Ninth Circuits, the Fifth and Sixth Circuits do not engage in that balancing. *DeWine,* 696 F.3d at 515; *Abbott,* 748 F.3d at 593-94, 597. While *amicus* Eagle Forum supports the Fifth and Sixth Circuit's approach on the merits, the point now is that the Circuits are

split, and this Court must resolve the split in their undue-burden tests.

4. This Court Should Clarify the Availability of, and the Parameters for, Facial Challenges under the *Casey* Undue-Burden Test

This litigation also presents questions about how undue-burden challenges can or should proceed as facial challenges, with respect to both how courts determine the required degree of facial invalidity and what evidence courts consider.

First, there is uncertainty as to what facial validity even means between the *Salerno* "no set of circumstances" test or the *Casey* "large fraction of the cases" test. *Compare U.S. v. Salerno,* 481 U.S. 739, 745 (1987) *with Casey,* 505 U.S. at 895. If the latter, the uncertainty persists here into what would constitute a sufficiently "large fraction." Of course, where a measure fails both criteria, the Court could avoid deciding that issue. *See Gonzales,* 550 U.S. at 167-68. Here, however, it seems that the issue could potentially be dispositive, as in *DeWine,* where the dissenting judge reasoned that the subset of women who preferred medication 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). While *amicus* Eagle Forum respectfully submits that the *DeWine* majority more closely follows *Casey,* the *DeWine* dissent provides a further split in reasoning that this Court can and should address.

Second, this Court also needs to make clear to litigants what evidentiary standards apply to these supposedly facial challenges under the undue-burden test. Here, Arizona reasonably relied on legislative facts about the dangers of off-label uses of RU-486 over the FDA-approved regimen, as well as the safety of the respective abortion methods, but the Ninth Circuit viewed Arizona to have not contested Plaintiffs' evidence. Pet. App. at 6, 24. Rather than proceed with such facial challenges, in which it is "undesirable for [courts] to consider every conceivable situation which might possibly arise in the application of complex and comprehensive legislation," it would be more appropriate to require "[a]s-applied challenges," which "are the basic building blocks of constitutional adjudication." *Gonzales,* 550 U.S. at 168 (quotations and citations omitted). Plaintiffs should not be able to invalidate public-health legislation facially under the undue-burden test.

To overturn Arizona's legislative decision on the need for these maternal-health protections under the rational-basis test, Plaintiffs must do more than marshal "impressive supporting evidence … [on] the probable consequences of the [statute]" vis-à-vis the legislative purpose; they instead must negate "the *theoretical* connection" between the two. *Minnesota v. Clover Leaf Creamery Co.,* 449 U.S. 456, 463-64 (1981) (emphasis in original); *F.C.C. v. Beach Comm., Inc.,* 508 U.S. 307, 315 (1993) ("legislative choice is not subject to courtroom fact-finding and may be based on rational speculation unsupported by evidence or empirical data"). Even if it were possible

to "negate" that "*theoretical* connection" between these medical procedures and safety, Plaintiffs still would not have made the required showing.

III. THIS COURT MUST CLARIFY *CASEY* TO RESOLVE THE IMPORTANT PUBLIC-HEALTH ISSUES AT STAKE HERE

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 *unborn child* 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 maternal-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.

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, this Court needs to address two such "disagreements" that have developed, one between the Ninth Circuit 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 Sections I and II.B.4, *supra*). Both issues warrant this Court's review.

As *amicus* Eagle Forum understands *Casey* – and contrary to how the Ninth Circuit 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* Pet. App. 14-16 (any regulation of abortion triggers the substantial-obstacle inquiry). As indicated, an undue burden is "shorthand" for that 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,* 505 U.S. at 878. In *Casey,* the maternal-health prong's only prohibition 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 state maternal-health regulation requires that the plaintiff establish both of two elements: (1) a maternal-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 implicit in the test for maternal-health regulations:

- First, if a regulation is necessary (*i.e.,* not unnecessary), that ends the inquiry: 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, Arizona law does not create a substantial obstacle to abortions. *See* Section I, *supra.*

In light of the foregoing, the Ninth Circuit's decision and the circuit precedents on which it was based require this Court's review to ensure uniformity of federal law, to cure the split in authority with the Fifth and Sixth Circuits, and to clarify the important public-health and federalism issues here.

CONCLUSION

The petition for a writ of *certiorari* should be granted.

October 10, 2014

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