No. 14-284

In The Supreme Court of the United States

WILLIAM HUMBLE, Director of the Arizona Department of Health Services, in his official capacity,

Petitioner,

v.

PLANNED PARENTHOOD OF 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 United States Court Of Appeals For The Ninth Circuit

AMICUS CURIAE BRIEF OF OKLAHOMA, NEBRASKA, SOUTH CAROLINA, ALASKA, IDAHO, MONTANA, MICHIGAN, AND TEXAS IN SUPPORT OF PETITIONER

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STATEMENT OF THE IDENTITY, INTEREST, AND AUTHORITY OF *AMICUS* TO FILE[1]

In its judgment below, the Ninth Circuit struck down state law regulations requiring that particular abortion procedures comply with drug regimens approved by the FDA. Arizona enacted the statutes authorizing these regulations after evidence came to light that off-label usage of particular abortion-inducing drugs could have adverse safety implications for the women who used them. Arizona thus exercised its powers in furtherance of a legitimate interest in protecting the health of Arizona women. The Ninth Circuit's decision striking down Arizona's regulations undermines that interest and threatens the legitimate regulatory efforts of every other State in the Union. While the State of Oklahoma and the other *amici* states support the State of Arizona and the arguments it has made in its petition, Oklahoma and the other *amici* states write separately to emphasize different aspects of this controversy that they believe will help the Court make its decision whether to grant certiorari.

[1] Pursuant to Rule 37.2, the State of Oklahoma has provided timely notice of its intent to file an *amicus curiae* brief to counsel both for petitioner and respondents.

SUMMARY OF THE ARGUMENT

1. Several states have enacted legislation regulating abortion-inducing drugs in order to protect women from unnecessary risks to their health. These regulations span a range from heightened informed consent requirements to the requirement that physicians follow the FDA's labeling. The Ninth Circuit's approach in the case below threatens *all* of these regulatory responses by – in flat contradiction to this Court's teachings – assigning essentially zero value to states' legitimate interests in women's health.

2. The Ninth Circuit's opinion exemplifies the confusion in the lower courts concerning the application of the undue burden standard to restrictions on medication abortions. In *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992), this Court reasoned that states have several legitimate interests that affect pregnant women considering an abortion. The lower courts have used at least seven different approaches to apply the teachings of *Casey* to the abortion-inducing drugs context. Review of the Ninth Circuit's decision would provide clarity to the lower courts.

3. The Ninth Circuit's decision creates a regulatory vacuum in an area of keen interest to both state and federal governments. The FDA, through enforcement actions brought against drug manufacturers for promoting off-label uses of drugs, has repeatedly and forcibly expressed grave concerns over use of off-label protocols, which by definition have not been approved by the FDA through its rigorous approval process.

However, the FDA has not been given the authority to regulate the actual practice of medicine, and is thus powerless to prevent off-label uses for many drugs even when such usage could be deleterious. Only states can fill this regulatory void. The Ninth Circuit's decision would render state efforts in this area fruitless and leave medication abortions largely unregulated.

ARGUMENT

I. Several states have regulated the use of abortion-inducing drugs, and confusion over the application of the undue burden standard will only deepen as lower courts continue to respond to these states' efforts.

Medication abortions – those involving the use of abortion-inducing drugs like mifepristone – are a relatively recent phenomenon in early-term abortions. For some time, the most common form of early-term abortion has been surgical abortion. *Planned Parenthood Arizona, Inc. v. Humble*, 753 F.3d 905, 907 (9th Cir. 2014). Indeed, when this Court in *Casey* outlined the now-familiar undue burden standard, surgical abortion was the *only* option in the United States.

Arizona, like other states, has done nothing in this case to restrict the availability of surgical abortions. Instead, Arizona has sought to require doctors to adhere to FDA-approved regimens for medication

abortions. *See Humble*, 753 F.3d at 909-10. In other words, this case isn't about restricting access to abortions. Rather, it is about the type of restrictions a state may permissibly place on a particular type of abortion.

A. Medication abortions involving off-label protocols for mifepristone and misoprostol have serious safety implications for women.

The FDA did not approve the first abortion-inducing drugs to be used in medication abortions until 2000. That year, the FDA approved a regimen using mifepristone (marketed as Mifeprex and also called "RU-486") for distribution and use in the United States. *See Humble*, 753 F.3d at 907. The FDA's approved regimen set out several steps for administering the drug. First, the regimen provides for the doctor to administer a specified dosage of mifepristone that results in the separation of the embryo from the uterine wall. *Id*. Next, the regimen provides for the doctor to administer a specified dosage of misoprostol – a drug causing the expulsion of the uterus's contents – two days later at the doctor's office. *Id*. Finally, the on-label regimen provides that the doctor should request that the patient return to her doctor's office about two weeks after the mifepristone dosage to check whether the pregnancy was terminated as well as for any complications. *See* "FDA Medication Guide for Mifeprex (mifepristone)," United States Food and Drug Administration, June 8, 2011

(available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020687s014lbl.pdf) (last visited Sept. 14, 2014). Notably, the FDA also limited its approval to the administration of the regimen up to 49 days after the patient's last menstrual period ("LMP"). *See id*.

Some abortion providers began administering mifepristone using alternative protocols rather than the one approved by the FDA. These protocols often differ by requiring fewer office visits, specifying different dosages of mifepristone and misoprostol, and allowing the use of the drugs up to 63 days LMP. *Humble*, 753 F.3d at 907-08.

The safety record for these altered protocols has been less than pristine. Eight young women have died from bacterial infections following a medical abortion administered according to one of the off-label protocols. No women have died from such infections following use of the FDA-approved protocol. *See* "Mifeprex Adverse Events Report as of April, 2011," United States Food and Drug Administration, July 19, 2011 (available at http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf) (last visited Sept. 14, 2014).

B. States have taken action to regulate the administration of abortion-inducing drugs like mifepristone.

Several states have acted in response to the health concerns raised by off-label usage of abortion-inducing drugs. These regulations cover several different aspects of the administration of abortion-inducing drugs.

First, many states require that a doctor physically examine a woman to assess the gestational age and location of an embryo or fetus. States have designed this regulation to ensure that the physician makes the best possible choice regarding the risk of complications associated with using abortion-inducing drugs at later gestational ages as well as risks associated with providing abortion-inducing drugs to a woman with an ectopic pregnancy, which mifepristone and misoprostol protocols are not designed to treat. Alabama, Indiana, Mississippi, Wisconsin, Oklahoma, and Texas have physical examination requirements. *See* Ala. Code § 26-23E-7; Ind. Code § 16-34-2-1(1)(a)(1); Miss. Code Ann. § 41-41-107(2); Wis. Stat. § 253.105(2)(a); 2014 Okla. Sess. Laws ch. 121, § 1 (eff. Nov. 1, 2014); Tex. Health & Safety Code Ann. § 171.063(c).

Second, many states have required that only licensed physicians administer abortion-inducing drugs. These regulations insure that a qualified professional be prepared to properly assess the risks associated with abortion-inducing drugs. Alabama, Kansas, Mississippi, North Dakota, Oklahoma, Ohio, and Texas

have physician requirements applying specifically to the medication abortion context. *See* Ala. Code § 26-23E-7; Kan. Stat. Ann. § 65-4a10(a); Miss. Code Ann. § 41-41-107(1); N.D. Cent. Code § 14-02.1-03.5(2); Ohio Rev. Code Ann. § 2919.123(A); 2014 Okla. Sess. Laws ch. 121, § 1 (eff. Nov. 1, 2014); Tex. Health & Safety Code Ann. § 171.063(a)(1).

Third, many states have required that abortion-inducing drugs be administered in the physical presence of the physician or other provider for similar reasons as exist for having physician-only requirements. Kansas, Mississippi, Missouri, Wisconsin, North Dakota, and Oklahoma have physical presence requirements. *See* Kan. Stat. Ann. § 65-4a10(a); Miss. Code Ann. § 41-41-107(3); Mo. Rev. Stat. § 188.021; Wis. Stat. § 253.105(2)(b); N.D. Cent. Code § 14-02.1-03.5(5); Okla. Stat. tit. 68, § 1-729.1.

Fourth, many states have required that the abortion provider schedule a follow-up visit or otherwise provide for follow-up care or emergency care after administering abortion-inducing drugs. Unlike broader on-label requirements, these regulations single out the FDA final printed label's fourteen-day follow-up visit requirement as signaling an important concern for ensuring the safety of women after taking mifepristone and misoprostol. Kansas, Mississippi, Missouri, North Dakota, Oklahoma, and Texas have specific follow-up or other after-procedure care requirements. *See* Kan. Stat. Ann. § 65-4a10(b); Miss. Code Ann. § 41-41-107(5)-(6); Mo. Rev. Stat. § 188.021; N.D. Cent. Code § 14-02.1-03.5(4); 2014

Okla. Sess. Laws ch. 121, § 1 (eff. Nov. 1, 2014); Tex. Health & Safety Code Ann. § 171.063(d)(2), (e)-(f).

There are a few other requirements imposed less commonly by various states. For example, Indiana has allowed medication abortions up to 63 days LMP unless the FDA approves a regimen involving the use of abortion-inducing drugs past that time. Ind. Code § 16-34-2-1(1)(a)(1). Mississippi, North Dakota, Oklahoma, and Texas require physicians to give women copies of the FDA's final printed label, a variant on traditional informed consent requirements. *See* Miss. Code Ann. § 41-41-107(4); N.D. Cent. Code § 14-02.1-03.5(3); 2014 Okla. Sess. Laws ch. 121, § 1 (eff. Nov. 1, 2014); Tex. Health & Safety Code Ann. § 171.063(d)(1). Ohio, Oklahoma, and Texas also impose certain reporting requirements regarding adverse events and attempts to provide follow-up care. Ohio Rev. Code Ann. § 2919.123(C); 2014 Okla. Sess. Laws ch. 121, § 1 (eff. Nov. 1, 2014); Tex. Health & Safety Code Ann. § 171.063(g).

Lastly, some states have required that physicians only administer abortion-inducing drugs in compliance with an FDA-approved regimen. Ohio, North Dakota, Oklahoma, and Texas have enacted such laws. Ohio Rev. Code Ann. § 2919.123(A); N.D. Cent. Code § 14-02.1-03.5(2); 2014 Okla. Sess. Laws ch. 121, § 1 (eff. Nov. 1, 2014); Tex. Health & Safety Code Ann. § 171.063(a)(2); *but see id.* at § 171.063(b) (authorizing a protocol developed by the American Congress of Obstetricians and Gynecologists). These requirements go the furthest in mitigating risk by

requiring use of the FDA's tested and approved regimen. Texas and Ohio's on-label requirements were upheld by the Fifth and Sixth Circuits (respectively). *See Planned Parenthood of Greater Texas Surgical Health Services v. Abbott*, 748 F.3d 583, 600-05 (5th Cir. 2014); *Planned Parenthood Southwest Ohio Region v. DeWine*, 696 F.3d 490, 513-18 (6th Cir. 2012). North Dakota's on-label usage requirement is currently being challenged on state law grounds. *See generally* Appellant Brief, *MKB Management Corp v. Burdick*, No. 20130259 (Oct. 2013), 2013 WL 6499415.

States have thus responded to the heightened risks associated with mifepristone and misoprostol in a variety of ways. These range from physician requirements to follow-up requirements to on-label usage requirements. The Ninth Circuit's decision by its terms affects primarily off-label usage of the drugs. However, the decision calls into question the entire breadth of states' attempts to regulate in this area. By using a weighting analysis and effectively assigning a weight of zero to states' legitimate interests in this area, the Ninth Circuit undermines *Casey* as well as states' reasonable and legitimate regulations governing a relatively new category of drugs. By granting review, this Court can clarify the *Casey* test as applied to these regulations and prevent confusion from miring state legislatures in uncertainty.

C. This Court has already granted certiorari before on a similar petition submitted by Oklahoma, and Oklahoma has passed a new statute similar to Arizona's regulation, which may raise the issues implicated in this case again.

The Oklahoma Legislature sought to specifically regulate medication abortions with the on-label usage requirement in 2011 when it passed House Bill 1970. Like the Arizona statute and regulations at issue in this case, the Oklahoma statute required that "[n]o physician who provides . . . any abortion-inducing drug shall knowingly or recklessly fail to provide or prescribe . . . [the] abortion-inducing drug according to the protocol tested and authorized by the [FDA] and as authorized in the drug label for . . . [the] abortion-inducing drug." *Compare* 2011 Okla. Sess. Laws ch. 216, § 1 *with* Ariz. Rev. Stat. § 36-449.03(E)(6) (directing the Director of the Arizona Department of Human Services to adopt rules requiring that "any medication, drug, or other substance used to induce an abortion is administered in compliance with the protocol that is authorized by the [FDA].").

An abortion rights group and an abortion provider filed suit against Oklahoma mounting a facial challenge against Oklahoma's House Bill 1970 under state constitutional law provisions. *See Oklahoma Coalition for Reproductive Justice v. Cline*, No. CV-2011-1722, slip op. at 1-2 (Okla. Cnty. Dist. Ct. May 11, 2012). The state district court construed the

Oklahoma constitution to contain an abortion right on par with the federal right and struck down the Oklahoma statute as an undue burden on a woman's abortion right. *See id*. at 3-5. The Oklahoma Supreme Court affirmed the district court with a vague statement about *Casey* controlling. *See Oklahoma Coalition for Reproductive Justice v. Cline*, 292 P.3d 27, 27-28 (Okla. 2012).

Oklahoma filed a petition for certiorari with this Court seeking review of the Oklahoma Supreme Court's decision under *Casey*; the Court granted certiorari but issued to the Oklahoma Supreme Court a certified question involving the scope of Oklahoma's statute. *See Cline v. Oklahoma Coalition for Reproductive Justice*, 133 S.Ct. 2887, 2887 (2013). The Oklahoma Supreme Court interpreted Oklahoma's statute to effectively ban all medication abortions and to prevent the use of any drugs in treating ectopic pregnancies, *Cline v. Oklahoma Coalition for Reproductive Justice*, 313 P.3d 253, 260, 262 (Okla. 2013), after which this Court dismissed certiorari as improvidently granted, *Cline v. Oklahoma Coalition for Reproductive Justice*, 134 S.Ct. 550, 550 (2013).

Unlike Oklahoma's petition, the lower court has not implied that the Arizona statute effectively bans all medication abortions. The Ninth Circuit expressly declined to resolve that issue, instead assuming as correct that the law only does what it purports to do: regulate medication abortions, not ban them. *See Humble*, 753 F.3d at 911. Hence, unlike the Oklahoma case, Arizona's petition squarely presents the

issue of how the undue burden analysis applies to abortion-inducing drugs.

Further, Oklahoma may present the same issue before this Court again in the near future. Only a few months ago, the Oklahoma Legislature passed a new statute, House Bill 2684, which again prohibits off-label use of abortion-inducing drugs. *See* 2014 Okla. Sess. Laws ch. 121, § 1. That statute will become effective on November 1 of this year. *Id.* at § 2. The statute includes specific findings regarding mifepristone, repudiates the Oklahoma Supreme Court's decision interpreting House Bill 1970, and clearly states the Legislature's intent to require that abortion providers administer abortion-inducing drugs in line with their FDA labels, not to ban them altogether or ban the use of methotrexate to treat ectopic pregnancies. *Id.* at § 1. The statute has recently become the subject of litigation challenging its constitutionality. *See generally* Verified Petition, *Oklahoma Coalition for Reproductive Justice v. Cline*, No. CV-2014-1886 (Okla. Cnty. Dist. Ct. Sept. 30, 2014), http://www.oscn.net/applications/oscn/GetCaseInformation.as?number=cv-2014-1886&db=Oklahoma&submitted=true.

Reviewing the Ninth Circuit's decision in this case could allow the Court to both resolve Arizona's dispute and impact those future controversies related to the efforts of various states – including Oklahoma – to properly regulate medication abortions.

II. The lower courts have experienced confusion when applying *Casey*'s undue burden standard, and the Ninth Circuit's opinion offers an opportunity to provide guidance to the lower courts.

The Court in *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992), reaffirmed the central holding of *Roe v. Wade*, 410 U.S. 113 (1973), by holding that a woman may "choose to have an abortion before viability and to obtain it without undue interference from the State," *Casey*, 505 U.S. at 846. The *Casey* Court, however, also reaffirmed *Roe* when it noted that the State has important interests in "protecting the health of the woman and the life of the fetus that may become a child" even before viability. *Id*.

The plurality in *Casey* articulated the undue burden standard as the proper analysis for determining whether state laws infringe on a woman's right to an abortion. *Id.* at 876-79. The Ninth Circuit departed from this undue burden standard in several important respects. Its reasoning should be corrected and its judgment reversed.

A. The Ninth Circuit erred in its application of *Casey*'s undue burden standard to abortion-inducing drugs.

In the decision below, the Ninth Circuit was called upon to determine whether a preliminary injunction had been properly rejected by the district

court. *Planned Parenthood Arizona, Inc. v. Humble*, 753 P.3d 905, 911 (9th Cir. 2014). A plaintiff seeking such an injunction must establish, among other things, that the claim "is likely to succeed on the merits." *Id.* (quoting *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). The Ninth Circuit concluded that the district court's opinion erred in its analysis of likelihood of success on the merits.

Looking to the teachings of *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992), the Ninth Circuit should have identified whether Arizona's regulation had a legitimate state purpose, identified the relevant population, and then considered whether the regulation erected a substantial obstacle preventing the relevant population from making the "ultimate decision" regarding an abortion. Instead, the Ninth Circuit departed from *Casey* by fashioning its own approach and then concluding that the district court below it had committed legal error. *See Humble*, 753 P.3d at 912-13.

The Ninth Circuit's unique approach stands in contrast to the undue burden standard employed by the Court in *Casey* and in *Gonzalez v. Carhart*, 550 U.S. 124 (2007). First, the Ninth Circuit determined that an increase in cost of about $200 and minor inconveniences constituted an undue burden. *Id.* at 915-16. This conclusion clearly flies in the face of *Casey*'s holding that cost increases and inconveniences on this order of magnitude do not constitute an undue burden. *See Casey*, 505 U.S. at 876, 887, 901.

Second, the Ninth Circuit's special approach conflates the separate analyses of purpose and effect evident in *Casey* and *Gonzalez*. The Ninth Circuit purports to be using a balancing test that weighs the substantiality of a burden against a state's justification for a regulation. *Humble*, 753 P.3d at 912-13. However, this sort of analysis has no place in the *Casey* or *Gonzalez* framework. *See Casey*, 505 U.S. at 877 (noting that an undue burden may exist because of an improper "purpose or effect"); *Gonzalez*, 550 U.S. at 156-64 (addressing purpose and effect separately).

Third, the Ninth Circuit's distinct position robs States of their freedom to act in the face of medical uncertainty. Rather than allowing that "[c]onsiderations of marginal safety, including the balance of risks, are within the legislative competence when the regulation is rational and in pursuit of legitimate ends," *Gonzalez*, 550 U.S. at 166, the Ninth Circuit adopted what amounts to a "zero tolerance policy" that "strike[s] down legitimate abortion regulations," *id*. The Ninth Circuit approach simply ignores evidence presented by a State. *See Humble*, 753 P.3d at 914-15.

Fourth, the Ninth Circuit's analysis attaches zero weight to the availability of a common, safe alternative. The *Gonzalez* Court clearly thought this an important element for consideration, 550 U.S. at 164-65, but the Ninth Circuit attempted to distinguish the clear fact that surgical abortions were left untouched by the Arizona regulations by distinguishing

Gonzalez, 753 F.3d at 917. However, the distinctions pointed out by the Ninth Circuit have little relevance – the alternative in *Gonzalez*, so the argument goes, was similar to the banned alternative, whereas medication abortions and surgical abortions are too different. The Ninth Circuit had no justifiable basis in its opinion for placing so much weight on differences between medication and surgical abortions.

The Ninth Circuit panel below thus departed from *Casey* and *Gonzalez*. The opinion below stems from confusion over the law, and this Court should grant certiorari to reverse it.

B. The Ninth Circuit's opinion represents another instance of confusion about how the undue burden standard should be applied to regulations of abortion-inducing drugs.

The Ninth Circuit's erroneous position on how to conduct an undue burden analysis under *Casey* and *Gonzalez* stands among a number of lower-court opinions conducting different undue burden analyses in the context of medication abortions. These different methods of analysis are particularly troubling given the wide efforts by states detailed above to regulate abortion-inducing drugs in light of their potential health implications.

The district court reviewed by the Ninth Circuit in this case relied almost entirely on the high bar of rational basis review and the availability of a

common, safe alternative to medication abortions. The district court applied a rational basis review to the Arizona regulation at issue. *See Planned Parenthood Arizona, Inc. v. Humble*, No. 14-1910, 2014 WL 1377827, at *4-5 (D. Ariz. Mar. 31, 2014). Given the availability of alternative procedures and the high bar of rational basis review combined with a facial challenge, the district court concluded that the plaintiff abortion providers were not likely to succeed on their claims. *See id.* at *6-7.

Two other appellate courts have addressed the on-label regimen requirement: the Sixth Circuit and the Fifth Circuit. *Planned Parenthood Southwest Ohio Region v. DeWine*, 696 F.3d 490 (6th Cir. 2012); *Planned Parenthood of Greater Texas Surgical Health Services v. Abbott*, 748 F.3d 583 (5th Cir. 2014). The Sixth Circuit emphasized in its opinion that a right to abortion represents the "freedom to decide whether to terminate" a pregnancy, *DeWine*, 696 F.3d at 516 (quotation omitted), and that the evidence presented in that case showed that *every* woman who stated a preference for medication abortions still went on to have a surgical abortion when medication abortions were unavailable, *id.* at 515-16. The Sixth Circuit also reasoned that plaintiff abortion providers in that case had failed to adduce sufficient evidence that increased costs from higher dosages would create an undue burden. *Id*. at 517-18.

The district court in *DeWine* relied on different aspects of the controversy to dismiss plaintiff abortion providers' suit. There, the court reasoned that

there was a generally available, common, safe alternative. *Planned Parenthood Southwest Ohio Region v. DeWine*, No. 1:04-CV-493, 2011 WL 9158009, at *17 (S.D. Ohio May 23, 2011). The court also relied on *Casey*'s pronouncement that minor cost increases do not rise to a level that invalidates an abortion regulation. *See id*.

The Fifth Circuit, on the other hand, approached the on-label regimen requirement for abortion-inducing drugs in Texas with an emphasis on health exceptions. There, the court noted the dearth of developed scientific evidence concerning whether a subset of women needed medication abortion to avoid health risks related to surgical procedures. *See Abbott*, 748 F.3d at 604. Further, the court reasoned that the proper avenue for redress regarding health exceptions would be an as-applied challenge, not a facial challenge to the statute. *See id.* at 604-05.

The district court in *Abbott* reasoned that "there are certain situations where medication abortion is the only safe and medically sound option for women with particular physical abnormalities or preexisting conditions." *Planned Parenthood of Greater Texas Surgical Health Services v. Abbott*, 951 F.Supp.2d 891, 907 (W.D. Tex. 2013). Thus, while inconveniences and an available alternative did not render the Texas statute unconstitutional, *id.* at 906-07, the district court there interpreted the Texas statute to include a broad health exception, *id.* at 907-08.

Likewise, in answering the certified questions asked of it by this Court, the Oklahoma Supreme Court expressed its view that the validity of Oklahoma's statute turned on whether the law's purpose was to either "prevent women from obtaining abortions" or "to punish and discriminate against those who do." *Cline*, 313 P.3d at 262. The Oklahoma court gave no explanation as to how the Oklahoma law did either of those things, but in any event, the standard endorsed by the Oklahoma court is completely foreign to this Court's jurisprudence, which requires an examination of the law's actual effects on access to abortions in the jurisdiction, rather than a freewheeling examination of legislative intent.

The lower courts have thus applied seven different lines of reasoning to the question of whether states' efforts to regulate abortion-inducing drugs by requiring compliance with the FDA-approved regimen for those drugs constitute an undue burden. Although some variation has no doubt arisen because of the differing waves of evidence and argument presented by litigants, such confusion among the lower courts about women's constitutional rights and states' legitimate regulatory interests begs for resolution by this Court.

C. The Ninth Circuit's approach to undue burden analysis threatens to undermine all state regulatory efforts in this area.

Reviewing the Ninth Circuit's opinion would be the best vehicle for the Court to resolve confusion regarding the proper analysis to apply to state regulations of abortion-inducing drugs. As mentioned above, the Ninth Circuit's particular analysis is clearly incorrect under the Court's approach in *Casey* and *Gonzalez*.

Beyond straying from the Court's teachings on *how* to conduct an undue burden analysis, the Ninth Circuit's opinion has troubling repercussions by not understanding *why Casey* employed the undue burden analysis in the first place. The *Casey* plurality emphasized that states have a "profound interest" in potential life and that a "State may enact regulations to further the health or safety of a woman seeking an abortion." *Casey*, 505 U.S. at 878. To allow states to advance these legitimate interests, *Casey* sought to develop a standard that would provide the "necessary reconciliation of the liberty of the woman and the interest of the State in promoting prenatal life." *Id*. at 873; *see also id*. at 871-77. The undue burden standard was intended to achieve this reconciliation, and it attempted to do so by requiring separate analyses for purpose and effect. *See, e.g.*, *id*. at 877 ("Unnecessary health regulations that have the purpose *or* effect of presenting a substantial obstacle . . . impose an undue burden.") (emphasis added).

The Ninth Circuit's test does away with any semblance of reconciliation and replaces it with a cudgel to be wielded in a political fashion by any court engaging in an undue burden inquiry. To be sure, balancing tests by their nature tend to involve discretion on the part of the court applying the test. However, the Ninth Circuit's balancing test in this particular context is particularly troubling both because of the breadth of balancing to be conducted and because of the highly controversial nature of the subject matter.

First, the Ninth Circuit would allow courts to make trade-offs concerning the importance of regulations, the medical evidence as to the effects of regulations, and any evidence concerning the impact on abortion. A lower court would be free simply to choose not to credit any evidence supporting a State's position, downplay the State's legitimate interests at hand, and overplay minor inconveniences affecting the availability of abortions. Such a test could roll back the clock on *Casey* and return to the rigid, everything-gets-struck-down regime rejected in *Casey*. *See Casey*, 505 U.S. at 875 ("[T]he court's experience applying the trimester framework has led to the striking down of some abortion regulations which in no real sense deprived women of the ultimate decision. Those decisions went too far. . . .").

To be clear, this is not a claim that the sky will fall under the Ninth Circuit's approach. It already has fallen: the Ninth Circuit's decision below exemplifies the concerns raised above. The Court of Appeals

determined to credit no evidence presented by the state. *Humble*, 753 F.3d at 916. That determination in hand, the court could find an undue burden for even minor cost increases.

Second, the unbounded discretion enabled by the balancing test fashioned below places States seeking to advance their legitimate interests as well as women attempting to obtain abortions in limbo on almost every possible regulation of abortion that can be passed. Regulations of abortion already routinely find themselves the subject of a lawsuit; when power rests in district court hands to construe evidence in a balancing test, this phenomenon can only grow worse. The Court should grant certiorari to reverse the Ninth Circuit's erroneous position and alleviate confusion in the lower courts.

III. Widespread off-label use of abortion-inducing drugs implicates important federal interests in areas where the FDA lacks authority to act.

Mislabeling a drug or promoting off-label use of a drug is a federal crime, even if that drug has been approved by the FDA. *See* 21 U.S.C. § 331. The federal government has, in fact, aggressively prosecuted drug manufacturers who do so.

For example, in 2012 the Department of Justice obtained an order requiring Abbot Laboratories to pay a criminal fine of $500 million and a forfeiture of $198.5 million for marketing a drug for an unapproved use.

Dept. of Justice Press Release, Oct. 2, 2012, "Abbott Laboratories Sentenced for Misbranding Drug" (available at http://www.justice.gov/opa/pr/abbott-laboratories-sentenced-misbranding-drug). As recently as November 2013, Johnson and Johnson agreed to pay $2.2 billion as part of a settlement to resolve investigations of various crimes including off-label use marketing. Dept. of Justice Press Release, Nov. 4, 2013, "Johnson & Johnson to Pay More Than $2.2 Billion to Resolve Criminal and Civil Investigations" (available at http://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations).

These massive cases reflect the federal government's important interest in the labeling and use of drugs. As the court recognized in *Gonzalez v. Oregon*, 546 U.S. 263, 269-71 (2006), the regulation of medicine is historically a local concern. However, the federal government has an interest in various aspects of the practice of medicine, including in significantly dangerous substances categorized as "controlled substances" whose prescription and usage the federal government strictly regulates. *See id*. at 271-74.

The federal government has substantial interests even in drugs that do not fall under the "controlled dangerous substance" category. The FDA has for several decades regulated such drugs under a regime that restricts drugs' distribution until approved as safe for a particular use and then continues to restrict marketing for unapproved uses. *See generally* Food, Drug, and Cosmetic Act, Pub. L. 75-717, June 25, 1938, 52 Stat. 1040 (codified as amended at 21 U.S.C.

§§ 301 *et seq*.); *see also United States v. Generix Drug Corp.*, 460 U.S. 453 (1983) (discussing the "new drug" approval regime and ruling on the breadth of "new drug"); *United States v. Sullivan*, 332 U.S. 689, 698 (1948) (examining the FDCA's regulatory regime for distribution with approved labels).

The FDCA regime for drugs involves an extensive process for ensuring the safety of new drugs. *See* 21 U.S.C. § 355. The Act also regulates manufacturers' and distributors' marketing efforts to ensure they contain adequate information. *See* 21 U.S.C. § 352. Under the FDCA, the FDA may even regulate physicians' prescriptions of unapproved drugs. *See generally United States v. Regenerative Sciences, LLC*, 741 F.3d 1314 (D.C. Cir. 2014). However, the FDCA regime does not directly regulate physicians to ensure they comply with the labels developed in the FDCA process or otherwise meet safety requirements when prescribing approved drugs under the "practice of medicine" exception.

The reasoning behind the "practice of medicine" exemption originally centered on the legislative history at the time of the Act's original passage and the FDA's position on the Act's scope. *See Chaney v. Heckler*, 718 F.2d 1174, 1179-81 (D.C. Cir. 1983), *rev'd on other grounds*, *Heckler v. Chaney*, 470 U.S. 821 (1985). Since 1997, however, the FDCA as amended has included an express statement that Congress did not intend for the FDCA to regulate the practice of medicine. 21 U.S.C. § 396. The FDCA thus entails a hands-off policy with regard to various aspects of

medicine, including doctors' decisions to prescribe drugs for off-label uses. *See* "'Off-Label' and Investigational Use of Marketed Drugs, Biologics, and Medical Devices – Information Sheet," United States Food and Drug Administration, June 25, 2014 (available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm) (last visited Sept. 12, 2014).

This hands-off policy should not be taken as a blanket endorsement of the off-label usage of drugs, however. In the context of abortion-inducing drugs, the FDA has repeatedly warned about the potential dangers of off-label usage, emphasizing time and again that "[t]he safety and effectiveness of other Mifeprex dosing regimens, including use of oral misoprostol tablets intravaginally, has not been established by the FDA." "Mifeprex (mifepristone) Information," United States Food and Drug Administration, July 19, 2011 (available at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111323.htm) (last visited Sept. 27, 2014); "Mifeprex Questions and Answers," United States Food and Drug Administration, Feb. 24, 2010 (available at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111328.htm) (last visited Sept. 27, 2014); "Public Health Advisory: Sepsis and medical abortion with mifepristone (Mifeprex)," United States Food and Drug Administration, Mar. 17, 2006 (available at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051298.htm) (last visited Sept. 27, 2014).

In addition, the FDA has placed significant marketing restrictions on abortion-inducing drugs. For example, the FDA requires that a patient being prescribed with mifepristone sign a "Patient Agreement." *See* Mifepristone Approval Letter, United States Food and Drug Administration, Sept. 28, 2000 (available at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.htm) (last visited Sept. 27, 2014). The "Patient Agreement" – which must be signed by both the abortion provider and the patient – requires that the patient attest to the following:

> 4) I believe I am no more than 49 days (7 weeks) pregnant;
>
> . . .
>
> 6) I understand that I will take misoprostol in my provider's office two days after I take Mifeprex (Day 3).
>
> . . .
>
> 14) I will . . . return to my provider's office in 2 days (Day 3) to check if my pregnancy has ended. My provider will give me misoprostol if I am still pregnant.

"Patient Agreement," United States Food and Drug Administration, July 19, 2005 (available at http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM111332.pdf) (last visited Sept. 27, 2014). In other words, the FDA requires that both the abortion provider and patient affirm that they will follow the approved drug regimen. But that is *all* the FDA can

do here: extract promises from providers and patients.

Thus, even where it has grave concerns about off-label use of particular drugs, federal law ties the hands of the FDA from requiring physicians to only use drugs according to their labels or to otherwise regulate the off-label use of approved drugs. The states, in the exercise of their inherent police power, thus step into this void to protect their interests in the health and welfare of their residents. These efforts complement the FDA's regulatory regime and also serve the federal government's own interests in the safety of American citizens.

Here, Arizona has stepped into the void to regulate the practice of medicine pursuant to its inherent police powers. It has done so in order to further its legitimate interest in the safety and health of Arizona women. Arizona's actions also serve federal interests regarding Americans' health in a context where Congress has appropriately tied the FDA's hands.

To hold as the Ninth Circuit has done that Arizona cannot so regulate because doing so involves a moderate increase in cost and imposes mild inconveniences would threaten the overall protective framework spanned by the States and the federal government. The Ninth Circuit's opinion opens a regulatory vacuum in which both the FDA and the States lack the authority to regulate off-label procedures that may threaten the wellness of women across the country. The Court should grant certiorari

to fill the chasm opened by the Ninth Circuit and thus uphold the complementary interests of the States and federal government in the health and safety of women.

CONCLUSION

For the above reasons, this Court should grant certiorari to review the judgment below.

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