No. 12-1094

In The
Supreme Court of the United States

TERRY CLINE, *ET AL.*,
Petitioners,
v.
OKLAHOMA COALITION FOR REPRODUCTIVE JUSTICE, *ET AL.*,
Respondents.

On Petition for a Writ of Certiorari to the Oklahoma Supreme Court

BRIEF *AMICI CURIAE* OF THE FAMILY RESEARCH COUNCIL AND ALLIANCE DEFENDING FREEDOM IN SUPPORT OF PETITIONERS

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INTERESTS OF AMICI CURIAE[1]

Family Research Council ("FRC") is a non-profit organization located in Washington, D.C. that exists to develop and analyze governmental policies that affect the family. FRC is committed to strengthening traditional families in America and advocates continuously on behalf of policies designed to accomplish that goal. FRC contends that many women who undergo an abortion experience unexpected emotional and physical harms which they might not risk if adequately informed about those potential harms. FRC further contends that chemical abortions have a distinguishable set of adverse effects that State governments are permitted to regulate under federal and State law and the principles established under *Planned Parenthood of Southeastern Pennsylvania v. Casey*. Since the approval of the mifepristone regimen by the FDA in 2000, FRC staff have closely studied the adverse effects of this abortion regimen releasing one such report in May 2012. While FRC believes that the FDA's approved regimen is unsafe and its approval should be rescinded, its evaluation of the data underscores that the use of RU-486 off-label is particularly unsafe and has resulted in an alarming frequency of adverse events, including death. State

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[1] As required by Rule 37.2(a) for the filing of this brief without a motion, all parties, through their counsel of record, have been given ten day's notice of the filing of this brief. The parties have provided written confirmations of their consent to the filing of this brief, which are being contemporaneously filed with the Clerk of Court. Pursuant to Rule 37.6, *Amici* represent that no counsel for a party authored this brief in whole or part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief.

legislators should be empowered to act to protect the health and safety of their citizens by restricting these particularly dangerous and unapproved uses.

Alliance Defending Freedom ("ADF") is a non-profit, public interest legal organization that provides strategic planning, training, funding, and direct litigation services to protect religious freedom, the sanctity of human life, and marriage and the family. Since its founding in 1994, Alliance Defending Freedom has played a role, either directly or indirectly, in many cases before this Court, including: *Gonzales v. Carhart*, 550 U.S. 124 (2007); *Scheidler v. National Organization for Women, Inc.*, 547 U.S. 9 (2006); *Ayotte v. Planned Parenthood of Northern New England*, 546 U.S. 320 (2006); *Washington v. Glucksberg*, 521 U.S. 702 (1997); and *Vacco v. Quill*, 521 U.S. 793 (1997); as well as hundreds more in lower courts.

ADF is deeply concerned about the sanctity of human life, including the protection of the lives of women who choose to end the life of their unborn child. As a legal organization that often advises State legislators, ADF is also concerned about the tendency for abortion to distort the law, in this case erroneously curtailing the authority of State legislators to protect the health and safety of their citizens by regulating the use of dangerous prescription drugs within their borders.

SUMMARY OF ARGUMENT

The States have historically exercised the police power to protect the health, safety and welfare of their citizens by regulating the medical profession, including the use of dangerous drugs, within their borders. While the FDA has a crucial role in assessing the safety and effectiveness of drugs and approving them for use in interstate commerce, this does not diminish the States' most basic responsibility, the protection of their citizens' health and safety. OKLA. STAT. tit. 63 § 1-729a (2012) responds to health risks to women from the unapproved use of RU-486.[2] A review of the FDA's approval of RU-486 and its continued refusal to expand its approval to authorize the methods advocated by Respondents demonstrates that Oklahoma's judgment is sound. The Oklahoma legislature's enforcement of the FDA's restrictions on RU-486 is a common sense, evidence-based regulation of the practice of medicine and a new and unique drug whose use in unapproved methods has resulted in a number of patient deaths. Contrary to the cursory order of the Oklahoma Supreme Court, this law imposes no undue burden on access to abortion, but merely relies on the expertise of the

[2] As described on pages 13-14, *infra*, the FDA approved mifepristone or RU-486, under the brand name, Mifeprex, only to be used in a specified regimen and in concert with another drug, misoprostol. When it is successful – a much higher rate prior to 49 days than after - Mifeprex blocks a pregnant woman's natural progesterone from reaching the uterine lining where the embryo is implanted, deteriorating the uterine lining and destroying the embryo. A second drug, misoprostol, is then taken 2 days later to trigger the uterine contractions required to expel the embryo.

FDA to protect the health and safety of Oklahoma women. The health and safety concerns at issue and the rights of States as coequal sovereigns to regulate healthcare within their borders are too important to be disposed of as flippantly and erroneously as has the Oklahoma Supreme Court. The Court should grant the writ and reverse the judgment below.

ARGUMENT

I. STATES HAVE HISTORICALLY EXERCISED THE POWER TO PROTECT THE HEALTH AND WELFARE OF THEIR CITIZENS BY REGULATING POTENTIALLY DANGEROUS DRUGS.

Before the beginning of the Republic, the Colonies possessed and exercised the authority to regulate drugs in order to protect the health and welfare of their citizens. "Drug regulation in the United States began with the Colonies and States when the Colony of Virginia's legislature passed an act in 1736 that addressed the dispensing of more drugs than was 'necessary or useful' because that practice had become 'dangerous and intolerable.'" *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach,* 495 F.3d 695, 703-04 (D.C. Cir. 2007), (quoting EDWARD KREMERS, KREMERS AND URDANG'S HISTORY OF PHARMACY 158 (4th ed.1976)). In fact, just ten years after the Pilgrims landed at Plymouth Rock, Nicholas Knopp of Massachusetts was "'fined five pounds, or was whipped, for vending as a cure for scurvy 'a water of no worth nor value,' which he 'solde att a very deare rate.'" *Abigail Alliance,* 495 F.3d., at 704 n.8, *quoting* JAMES HARVEY YOUNG, THE TOADSTOOL MILLIONAIRES: A SOCIAL HISTORY OF PATENT MEDICINES IN AMERICA

BEFORE FEDERAL REGULATION 16 (1961) and RECORDS OF THE GOVERNOR AND COMPANY OF THE MASSACHUSETTS BAY IN NEW ENGLAND 83 (Boston, W. White 1853). "'By 1870, at least twenty-five States or territories had statutes regulating adulteration (impure drugs).'" *Abigail Alliance,* 495 F.3d at 704 (citing David L. Cowen, *The Development of State Pharmaceutical Law,* 37 PHARMACY IN HISTORY, 54 (1995)).

The creation of the federal Food and Drug Administration did not remove the States' power to regulate drugs that could harm their citizens' health. "It is, of course, well settled that the State has broad police powers in regulating the administration of drugs by the health professions." *Whalen v. Roe,* 429 U.S. 589, 603 n.30 (1977). Indeed, "the State no doubt could prohibit entirely the use of particular … drugs." *Id.* at 603. *See also Planned Parenthood Southwest Ohio Region v. DeWine,* 696 F.3d 490, 496 (6th Cir. 2012) ("States … may limit off-label use" of FDA approved drugs). As the Supreme Court has observed:

> "There can be no question of the authority of the State in the exercise of its police power to regulate the administration, sale, prescription and use of dangerous … drugs. The right to exercise this power is so manifest in the interest of the public health and welfare, that it is unnecessary to enter upon a discussion of it beyond saying that it is too firmly established to be successfully called in question."

Robinson v. California, 370 U.S. 660, 664 (1962) (quoting *Whipple v. Martinson,* 256 U.S. 41, 45 (1921)).

Oklahoma maintains the sovereign right to protect the health and welfare of its citizens by regulating potentially dangerous drugs within its borders.

II. TO ASSURE PATIENT SAFETY, THE FDA'S APPROVAL OF RU-486 WAS EXPRESSLY CONDITIONED ON RESTRICTING ITS USE EXACTLY AS OKLAHOMA HAS DONE.

Drug companies seeking FDA approval for a new drug must typically wait "a long time - sometimes many years - to learn whether a drug actually provides real improvement for patients" and the FDA will approve the drug.[3] This typical drug review process also permits the FDA to fully examine any dangerous side effects, consider any potential off-label uses and their health risks, and other concerns before allowing the drug to be used in interState commerce.

However, Congress has authorized the FDA to "fast track" certain drug applications, bypassing the usual process. 21 U.S.C. § 356. The FDA may use this accelerated process for drug applications where the drug would "treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate

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[3] See FDA, *Fast Track, Accelerated Approval and Priority Review*, available at http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccesstoimportantnewtherapies/ucm128291.htm#compare (last visited April 3, 2013).

substantial improvement over existing therapies." 21 U.S.C. § 356(a)(1). "For a condition to be serious, the condition should be associated with morbidity that has substantial impact on day-to-day functioning." 74 Fed. Reg. 40900, 40909 (2009). Congress intended that the FDA would use this "fast track" authority to expedite to market potentially life-saving drugs and treatments for cancer, AIDS, and other serious diseases where the possibility of adverse effects was deemed worth the risk of any adverse effects. With the exception of RU-486, the FDA has used this process exclusively to approve drugs for cancer, AIDS, and other life threatening diseases.[4]

Because this "fast track" process permits the FDA to approve a drug while clinical trials continue which might indicate potential adverse consequences, regulations authorize specific limitations on the use and marketing of "fast track" drugs to assure their safe use. Promulgated as "Subpart H" of 21 C.F.R. § 314, the FDA's "fast track" regulation provides:

> **Approval with restrictions to assure safe use.**
>
> (a) **If FDA concludes that a drug product shown to be effective can be safely used only if distribution or use is restricted**, FDA will require such postmarketing restrictions as are needed to

[4] See FDA, *Accelerated and Restricted Approvals Under Subpart H*, http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/UCM278506.pdf (last visited April 1, 2013).

> assure safe use of the drug product, such as:
>
> > (1) Distribution restricted to certain facilities or physicians with special training or experience; or
> >
> > (2) Distribution conditioned on the performance of specified medical procedures.
>
> (b) The limitations imposed will be commensurate with the specific safety concerns presented by the drug product.

21 C.F.R. §314.520 (emphasis supplied). Hence, the FDA may approve a drug under the "fast track" process that it ordinarily would not have approved based on the evidence before it at that time. But to compensate for this greater tolerance for risk in introducing drugs onto the market, the regulations also permit the FDA to impose restrictions on these fast tracked drugs. Where employing this process the FDA has concluded that a drug "can be safely used only if distribution or use is restricted," it "will require such postmarketing restrictions as are needed to assure safe use of the drug." *Id.* (emphasis supplied). "[H]igh risk drugs that are approved based on postmarketing restrictions **would not have been approved for use without those restrictions because the risk/benefit balance would not justify such approval**." 57 Fed. Reg. 58942, 58949 (1992). (emphasis added). See also CENTER FOR DRUG EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION, "GUIDANCE FOR

INDUSTRY FAST TRACK DRUG DEVELOPMENT PROGRAMS – DESIGNATION, DEVELOPMENT, AND APPLICATION REVIEW," 58, available at http://www.fda.gov/downloads/Drugs/Guidances/ucm079736.pdf (same).

Although an application for approval for RU-486 had been pending with the FDA since 1996, the FDA continued to have unresolved concerns about the drug that prevented its approval. Then, in 2000, the FDA decided to approve RU-486 under this "fast track" process. On February 18, 2000 it issued an Approvable Letter, informing the sponsor:

> We have concluded that adequate **information has not been presented to demonstrate that the drug**, when marketed in accordance with the terms of distribution proposed, **is safe and effective for use as recommended**. The restrictions on distribution will need to be amended.
>
> We have thus considered this application under the restricted distribution regulations contained in 21 CFR 314.500 (Subpart H) and have concluded that **restrictions as per CFR 314.520 on the distribution and use of mifepristone are needed to assure safe use of this product.**

FDA, *Feb. 2000 Approvable Letter*, in Exhibit R to Defendants' Response to Plaintiffs' Motion for Summary Judgment (emphasis supplied). The Approvable Letter also "remind[ed]" the sponsor of

its "commitments" to certain studies concerning the effects, safety and efficacy of RU-486. *Id.*

In September 2000, using this accelerated process under "Subpart H," the FDA approved RU-486 without the benefit of full, completed clinical trials on its efficacy and adverse effects. In fact the approval letter again reiterates that the drug's sponsor had made "commitments" to the FDA of certain further studies of "safety outcomes." FDA, *Approval Letter MIFEPREX (mifepristone) Tablets*.[5] *See also Mifeprex Final Printed Label* (*Mifeprex FPL*)[6] ("There are no data on the safety and efficacy of mifepristone in women with chronic medical conditions" and warning caution with women over 35 and who smoke because "such patients were generally excluded from clinical trials of mifepristone."). Based upon the data before it, the FDA concluded that RU-486 "can be safely used only if distribution or use is restricted" and describes its approval thus: "Restricted - Approval with restrictions to assure safe use as recorded in 21 CFR 314.520 (Subpart H)." *Accelerated and Restricted Approvals Under Subpart H*, *supra* note 4. Thus, reviewing the evidence before it the FDA expressly conditioned its "fast track" approval of RU-486 on its placement of certain restrictions on the drug's use.

The FDA approved Mifeprex with restrictions "for the medical termination of intrauterine

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[5] Available at http://www.accessdata.fda.gov/drugsatfda_docs?appletter?2000/20687appltr.htm (last visited April 2, 2013).

[6] Available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020687s013lbl.pdf (last visited April 2, 2013).

pregnancy **through 49 days' pregnancy."** Approval Letter (emphasis added). It further directed: "Marketing of this drug product and related activities are to be in accordance with the substance and procedures of the referenced regulations." *Id.* The FDA also required that "final printed labeling (FPL) … the Medication Guide … the Patient Agreement Form, and the Prescriber's Agreement Form … must be identical" to those submitted and approved by the FDA. *Id.* It warned: "Marketing the product with FPL that is not identical to the approved labeling text may render the product … an unapproved new drug." *Id.* In addition to its approval of Mifeprex only for use "through 49 days' pregnancy," the FDA placed the following specific restrictions on its use:

> Under 21 CFR §314.520, distribution of the drug is restricted as follows:
>
> Mifeprex must be provided by or under the supervision of a physician who meets the following qualifications:
>
> - Ability to assess the duration of pregnancy accurately.
> - Ability to diagnose ectopic pregnancies.
> - Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through other qualified physicians, and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.

- Has read and understood the prescribing information of Mifeprex.
- Must provide each patient with a Medication Guide and Patient Agreement, give her an opportunity to read and discuss both the Medication Guide and the Patient Agreement, obtain her signature on the Patient Agreement and must sign it as well.
- Must notify the sponsor or its designate in writing as discussed in the Package Insert under the heading DOSAGE AND ADMINISTRATION in the event of an ongoing pregnancy, which is not terminated subsequent to the conclusion of the treatment procedure.
- Must report any hospitalization, transfusion or other serious events to the sponsor or its designate.
- Must record the Mifeprex package serial number in each patient's record.

Id. As reflected by the restrictions to use under the supervision of a physician, the FDA expressly rejected the sponsor's suggestion that the FPL include information on self-administering misoprostol at home. UNITED STATES GOVERNMENT ACCOUNTABILITY OFFICE, *GAO Report: Approval and Oversight of the Drug Mifeprex,*, at 23.[7] As a Subpart H drug on which clinical trials were still ongoing to establish its efficacy and safety, these restrictions on distribution or use of RU-486 were necessary to its

[7] Available at http://www.gao.gov/new.items/d08751.pdf (last visited April 2, 2013).

approval and it is unlikely that the FDA would have approved it without its ability to impose these restrictions. 57 Fed. Reg. 58942, 58949 (Drugs approved with postmarketing restrictions under 21 CFR §314.520 are those that "**would not have been approved for use without those restrictions because the risk/benefit balance would not justify such approval**") (emphasis added).

The FPL that the FDA required to be used in "identical" form to that it reviewed, provides the approved dosage and administration of RU-486. It States at the top of the first page in bold font: **"For Oral Administration Only."** *See Mifeprex FPL*. The FPL specifies that "Mifepristone is indicated for use in the termination of pregnancy (through 49 days' pregnancy) and has no other approved indication for use during pregnancy." *Id*. at 9. Again, the FPL States that a "wom[a]n should not take Mifeprex" if "[i]t has been more than 49 days (7 weeks) since your last menstrual period began." *Id*. at 17. **"It is not approved for ending later pregnancies"** (after 49 days from the patient's last menstrual period). *Id*.at 16 (emphasis added).

The FDA also provided specific instructions on dosage and administration of Mifeprex, and the use of misoprostol as part of the regimen.

> Treatment with Mifeprex and misoprostol for the termination of pregnancy requires three office visits by the patient. Mifeprex should be prescribed only in a clinic, medical office, or hospital, by or under the supervision of a

physician, able to assess the gestational age of an embryo and to diagnose ectopic pregnancies. Physicians must also be able to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others, and be able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.

Day One: Mifeprex Administration

Patients must read the MEDICATION GUIDE and read and *sign the PATIENT AGREEMENT* before Mifeprex is administered. Three 200 mg tablets (600 mg) of Mifeprex are taken in a single dose.

Day Three: Misoprostol Administration

The patient *returns to the health care provider* two days after ingesting Mifeprex. Unless abortion has occurred and has been confirmed by clinical examination or ultrasonographic scan, the patient takes two 200 ug tablets (400 ug) of misoprostol orally….

Day Fourteen: Post-Treatment Examination

Patients *will return for a follow-up visit approximately 14 days after* the administration of Mifeprex. The visit is very important to confirm by clinical examination or ultrasonographic scan that a complete termination of pregnancy has occurred.

Id. at 13-14 (emphasis added).

The FDA not only specified this "required" regimen, it also mandated that physicians ensure that the patient sign the "Patient Agreement." *Id.* at 17 and 19-20. That agreement further demonstrates the FDA's intention to restrict the use of Mifeprex to those circumstances where the FDA believed sufficient evidence was available to conclude that the benefit outweighed the risks. *See* 57 FED. REG. 58942, 58949. The FDA required that the patient sign this agreement, attesting that, *inter alia*: (1) "I believe I am no more than 49 days (7 weeks) pregnant;" (2) "I will take misoprostol in my provider's office two days after I take Mifeprex (Day 3)"; (3) "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"; and (4) "I will … return to my provider's office about 14 days after beginning treatment to be sure that my pregnancy has ended and that I am well." *Mifeprex FPL,* at 19. The abortion provider must also sign this Patient Agreement attesting that the patient "signed the Patient Agreement in my presence." *Id.* In its Approval Letter, the FDA took this Patient Agreement seriously, reminding the drug's sponsor of its commitment to "an audit of signed Patient Agreement forms." *Approval Letter*, *supra*. *See also GAO Report,* p. 24 (noting requirement of an "audit of signed patient agreement forms").

It would be nonsensical for the FDA to require that patients and their abortionists read and sign the Patient Agreement forms attesting to the

regimen detailed therein, and that the drug's sponsor would commit to auditing these Patient Agreement forms, if the FDA was agnostic about the need to actually comply with the single regimen it approved as sufficiently safe to merit approval. Indeed, because the FDA requires that abortionists provide this Patient Agreement to patients and obtain their signatures, providers that are nevertheless knowingly having their patients falsely sign these agreements where they are using a different, unapproved regimen and do not intend to comply with the approved regimen, are knowingly creating false documents. The FDA simply did not mandate a signed "Patient Agreement" that it did not intend for the patient and the abortionist to actually follow.

While it would be fully empowered to lift its restrictions, in the years since it approved Mifeprex, the FDA has never concluded that any other regimen would provide the assurance of safe use necessary for approval. Thus, the FDA continues to identify the regimen outlined in the Mifeprex FPL as the only "approved" use. *See, e.g.*, FDA, *Mifeprex Questions and Answers*[8] ("FDA is aware that medical practitioners may be using modified regimens. … [T]he safety and effectiveness of Mifeprex dosing regimens, other than the one approved by FDA … has not been established by the FDA.").

The FDA's caution in refusing to authorize other regimens for RU-486 has unfortunately been

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[8] Available at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111328.htm (last visited April 2, 2013).

validated. While reporting of adverse events from RU-486 – or any drug – is incomplete, there are no known deaths associated with the administration of RU-486 as approved by the FDA. GAO Report, at 7 ("FDA investigated the deaths of six U.S. women who developed a fatal infection following treatment with Mifeprex for medical abortion. FDA has determined that in all six of the deaths, the women used a Mifeprex treatment regimen that has not been approved by FDA."); FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary,*[9] (Through April 2011, 8 fatalities from sepsis from Mifeprex use, all of which involved a use other than the FDA approved regimen). *See also* Brief *Amici Curiae* of Dr. John Thorpe, *et al.* concerning the health risks of Mifeprex filed in support of this petition.

While the FDA can make determinations about the effectiveness and safety of a drug, it is not equipped to police the off-label use of a drug it has approved. But the States are so empowered. Oklahoma, through its legislature, has the sovereign right to protect the health and safety of its citizens by restricting the use of Mifeprex to those circumstances where the FDA's review and over a decade of experience shows the drug can be administered in a way that is relatively safe. Likewise, Oklahoma legislators were free to conclude, just as the FDA did, that regimens other than those approved by the FDA were insufficiently safe to permit because the potential benefit did not

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[9] Available at http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf (last visited April 3, 2013).

outweigh the risk. 57 FED. REG. 58942, 58949. "Where it has a rational basis to act, and it does not impose an undue burden, the State may use its regulatory power to bar certain procedures and substitute others, all in furtherance of its legitimate interests in regulating the medical profession." *Gonzales v. Carhart*, 550 U.S. 124, 158 (2007). Oklahoma easily passed this test when it restricted the use of this dangerous new drug to the only protocol deemed safe by the FDA – and the protocol that has uniquely not resulted in the death of a patient since its approval.

As the Petitioner and the Court's other *amici* ably explain, Oklahoma's law imposes no undue burden on access to abortion. The law simply enforces the restrictions that the FDA determined were "necessary to assure safe use" and is well supported by medical evidence and the FDA's own conclusions that the FDA approved regimen is the only regimen for administering RU-486 that the FDA has concluded is worth the risks that it poses. Oklahoma's determination is patently reasonable, solidly rooted in the medical evidence reviewed by the FDA and the experience of over a decade of real world evidence that off-label uses pose a greater risk of adverse events, including fatalities, than the FDA's approved regimen.

Oklahoma women remain free to obtain medication abortions prior to 49 days gestation – as approved by the FDA. They also remain free to obtain surgical abortions before and after that point in their pregnancies. The unexplained conclusion of the Oklahoma Supreme Court that Oklahoma has

placed an undue burden on access to abortion with its reasonable limitation on RU-486 to its FDA approved regimen, particularly where even that regimen was unavailable to women at all until September 2000, defies reason. For almost 40 years, surgical abortion was the only option for inducing an abortion. Whatever the merits of the FDA's decision to approve RU-486 in 2000, Oklahoma's limitation on the use of this still relatively new drug to its FDA approved regimen imposes no undue burden on abortion access but merely assures its safe use.

III. ABORTION DRUGS ARE NOT CONSTITUTIONALLY PRIVILEGED OVER OTHER PRESCRIPTION DRUGS.

As explained in Section I, Oklahoma may exercise its police power to regulate the practice of medicine within its borders and particularly to regulate the use of dangerous drugs with potentially – as experience has demonstrated – lethal adverse effects. Oklahoma "could prohibit entirely the use of particular … drugs." *Whalen*, 429 U.S. at 603 n30. And as the Sixth Circuit held in reviewing a law substantively identical to Oklahoma's law, "States … may limit off-label use" of FDA approved drugs – including RU-486. *DeWine,* 696 F.3d at 496.

Thus, State laws may permit, restrict, encourage or discourage the off-label use of FDA approved drugs or devices. For example, while the FDA has approved several cancer drugs under Subpart H, many States have enacted statutes encouraging the off-label use of those drugs by requiring insurance companies to cover off-label uses. *See, e.g.,* COLO. REV. STAT. §10-16-104.6; KAN. STAT. ANN. §40-2,168.

Of course, many States have no such laws, thus permitting insurers to deny coverage for off-label uses. And some States, even while generally requiring coverage for off-label use, expressly permit insurers to deny coverage for these drugs where the FDA has determined, as it has determined with respect to the use of Mifeprex after 49 days,[10] that the use is specifically not indicated. *See* ALA.CODE § 27-1-10.1(C)(3); ME REV. STAT. tit. 24, §2320-F(2)(C); MD CODE ANN., INS. §15-804(B)(2); 8 VT. STAT. ANN. tit. 8, §4100e(a)(3). Thus, it is not surprising for a State, following FDA approval of a drug, to nevertheless impose restrictions or seek to expand use of an approved drug. And it is particularly unsurprising that a State would choose to discourage uses that the FDA has deemed contraindicated.

The decision of the Oklahoma Supreme Court would give abortion drugs a constitutionally privileged position even over drugs used to treat cancer, AIDS, or other life-threatening illnesses. The Oklahoma Supreme Court did not hold, nor could it, that Oklahoma was generally prohibited from limiting any drug's use to the FDA's approved regimen. Instead, the Court held that because RU-486 is an abortion drug, Oklahoma's limitation of the drug to the FDA's approved protocol imposed an unconstitutional undue burden on the right to an abortion. The result is that Oklahoma might regulate the use of experimental cancer drugs – either to encourage their use or to provide safety

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[10] "Mifepristone is indicated for use in the termination of pregnancy (through 49 days' pregnancy) and has no other approved indication for use during pregnancy." *Mifeprex FPL*, at 9.

precautions beyond those imposed by the FDA – and Oklahoma can prohibit the off-label use of other drugs. But because RU-486 is an abortion drug, Oklahoma is powerless because regulation of that drug would, the Court determined without explanation, impose an undue burden on the abortion right.

Abortion drugs are not entitled to receive constitutionally favorable treatment over drugs to treat cancer, HIV or other serious diseases. It is no undue burden for Oklahoma to simply ensure that abortion drugs in the State are administered according to the only protocol deemed safe and effective by the FDA. Oklahoma's sovereign authority to regulate the use of drugs to protect the health and safety of its citizens is not diminished by the fact that the dangerous drug in this case induces abortion.

CONCLUSION

The Court should grant the writ and set this case for oral argument. Alternatively, the Court should grant the writ and summarily reverse and remand to the Oklahoma Supreme Court with instructions to reconsider the case in light of *Planned Parenthood v. Casey* and *Gonzales v. Carhart*.

Respectfully submitted,

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