No. 20A34

IN THE
Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, *ET AL.*,

Applicants,

v.

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, *ET AL.*,

Respondents.

On Application for a Stay of the Injunction to the United States Court of Appeals for the Fourth Circuit

MOTION FOR LEAVE TO FILE AMICUS CURIAE BRIEF IN SUPPORT OF APPLICANT BY INDIANA, LOUISIANA, AND 8 OTHER STATES

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The States of Indiana, Louisiana, Alabama, Arkansas, Idaho, Kentucky, Mississippi, Nebraska, Oklahoma, and Texas move the Court for leave to file an amicus brief in support of Applicants' Emergency Application for Stay.

In support of their motion, Amici States assert that the district court ruling at issue enjoins critical aspects of the mifepristone REMS which poses grave harm to women. The Amici States were blocked from intervening in the district court—a decision they have appealed to the Fourth Circuit—but still have significant interests. Amici States have statutes either directly invoking the enjoined ETASU or imposing similar requirements. In addition, many amici states are defending challenges to their own abortion regulations and must contend with lower-court confusion over the meaning of *June Medical Services L.L.C. v. Russo*, 140 S. Ct. 2103 (2020), which the stay application gives the Court a chance to resolve in a highly efficient manner. The district court's ruling, by continuing to enforce the balancing test of *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016), which five Justices of the Court rejected in *June Medical*, creates exceptional circumstances that warrant granting the amici states permission to be heard on Applicants' Emergency Application for Stay. They accordingly request that their motion to file the attached amicus brief be granted.

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On Application for a Stay of the Injunction to the United States Court of Appeals for the Fourth Circuit

BRIEF OF INDIANA, LOUISIANA, AND 8 OTHER STATES AS *AMICI CURIAE* IN SUPPORT OF APPLICANT

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STATEMENT OF INTEREST[1]

The States of Indiana, Louisiana, Alabama, Arkansas, Idaho, Kentucky, Mississippi, Nebraska, Oklahoma, and Texas respectfully submit this brief as amici curiae in support of Applicants' application for stay of injunction.

When a woman ingests mifepristone for the purpose of aborting a fetus, she not only ends the life of her unborn child, but also undergoes significant risks to her own body: infection, hemorrhage, and even death. Federal and state laws require physical examinations and in-person dispensing of mifepristone to ensure that physicians check for contraindications and that women fully understand the risks. Under the correct legal standard, those laws are not unduly burdensome even in the current public health emergency.

Yet the district court issued, for the duration of the COVID-19 Public Health Emergency declared by the Secretary of Health and Human Services, a *nationwide* injunction preventing the FDA from enforcing provisions of the Elements to Assure Safe Use (ETASU) for the mifepristone Risk Evaluation & Mitigation Strategy (REMS). ECF No. 92. It enjoined the requirements that mifepristone be dispensed only in a clinic, medical office, or hospital; patients sign the Patient Agreement Form in the physical presence of the healthcare provider; and the physician attest to following these requirements. *Id.* at 2–3.

[1] Pursuant to Supreme Court Rule 37.6, no counsel for any party authored this brief, in whole or in part, and no person or entity other than *Amici* contributed monetarily to its preparation. *Amici* files this brief along with a motion for leave to file this brief in accordance with Supreme Court Rule 37.2(b).

Amici States have statutes either directly invoking the enjoined ETASU or imposing requirements similar to it, *see, e.g.*, Ind. Code § 16-34-2-1(a)(1), and, except for Texas, moved to intervene to defend the mifepristone REMS ETASU. The district court, however, denied that motion and refused to consider the associated evidence and arguments. The States that moved to intervene have separately appealed to the Fourth Circuit from both the denial of their intervention and the preliminary injunction. *See Am. Coll. of Obstetricians & Gynecologists v. U.S. Food & Drug Admin.*, No. 20-1784 (4th Cir.).

Amici States urge the Court to stay the district court's preliminary injunction pending both appeals. They submit this brief to emphasize the urgent need for review in light of the Court's fractured decision in *June Medical Services L.L.C. v. Russo*, 140 S. Ct. 2103 (2020), which did not generate a majority opinion.

In amici's view, under the narrowest grounds rule of *Marks v. United States*, 430 U.S. 188 (1977), Chief Justice Roberts's concurring opinion controls. But nationwide, circuits are already in conflict over which *June Medical* opinion, if any, controls. *See Whole Woman's Health v. Paxton*, No. 17-51060, 2020 WL 4998233, at *1–2 (5th Cir. Aug. 21, 2020) (holding that none of this Court's opinions in *June Medical* control); *Hopkins v. Jegley*, No. 17-2879, 2020 WL 4557687, at *2 (8th Cir. Aug. 7, 2020) (holding that Chief Justice Roberts's concurrence in the judgment is controlling).

The answer to that question will determine the standard for reviewing FDA's safety requirements for dispensing Mifeprex amidst the pandemic; equally important, it will impact challenges to state abortion statutes pending across the country, which are already mired in the basic threshold question as to what *June Medical* means. *See, e.g.*, *Dobbs v. Jackson Women's Health Org.*, No. 19-1392 (U.S.); *Whole Woman's Health v. Smith*, No. 18-50730 (5th Cir.); *Planned Parenthood of Ind. & Ky., Inc. v. Box*, No. 17-2428 (7th Cir.); *Whole Woman's Health All. v. Hill*, No. 1:18-cv-01904 (S.D. Ind.).

If, in granting the stay application, the Court could at least clarify whether lower courts should balance benefits and burdens of abortion regulations—as the district court did here—or merely examine the record for evidence of a substantial obstacle—as the Chef Justice indicated in his *June Medical* concurrence—lower courts could address those pending disputes using the proper test.

SUMMARY OF THE ARGUMENT

In barring aspects of the mifepristone REMS, the district court applied the incorrect legal test, purporting to balance the REMS burdens and benefits during the pandemic. That mode of analysis, of course, is precisely what five justices of this Court rejected in *June Medical Services L.L.C. v. Russo*, 140 S. Ct. 2103, 2182 (2020) (Kavanaugh, J., dissenting), yet lower courts—including circuits—are already in conflict over how to apply the splintered *June Medical* decision.

Some, such as the district court here, proceed as if *June Medical* means nothing and continue to take their cues from *Whole Woman's Health v. Hellerstedt*, including its "neutral utilitarian calculus" yielding an "unanalyzed exercise of judicial will," 140 S. Ct. at 2136 (Roberts, C.J., concurring in the judgment), which five justices have now rejected. The Court should intervene immediately to stop this burgeoning resistance to its *June Medical* holding.

Respondents' claim is also legally barred because Respondents failed to exhaust their administrative remedies, ignoring the ordinary requirement that they submit scientific evidence for expert review by FDA regulators. 21 C.F.R. § 10.20(c). That error in turn infected the factual record: Respondents presented a carefully curated—but untested—record of expert declarations, which the district court adopted without the initial agency review that administrative exhaustion ensures.

Nor does evidence establish a uniform nationwide burden that justifies a national injunction, which forecloses evidence-based, local responses. Other courts addressing questions about in-person abortion services during the COVID-19 pandemic have reached a variety of conclusions based on *local* facts. *Compare In re Rutledge,* 956 F.3d 1018, 1023 (8th Cir. 2020) (upholding temporary postponement of elective and non-emergency surgical procedures in Arkansas), *and In re Abbott*, 954 F.3d 772, 796 (5th Cir. 2020) (upholding temporary postponement of non-essential surgeries and procedures in Texas), *with Adams & Boyle, P.C. v. Slatery*, 956 F.3d 913, 917 (6th

Cir. 2020) (affirming a preliminary injunction against a temporary postponement of elective and non-urgent surgical and invasive procedures in Tennessee).

ARGUMENT

I. The Chief Justice's Opinion in *June Medical* Controls and Precludes the Balancing Test Employed by the District Court

The district court misapplied the Supreme Court's recent decision in *June Medical Services v. Russo*, 140 S. Ct. 2103 (2020), enjoining a Louisiana law requiring abortion providers to have hospital admitting privileges. The Court's judgment lacks a majority opinion, so identifying its legal rule hinges on *Marks v. United States*, 430 U.S. 188 (1977), which said that in such circumstances "'the holding of the Court may be viewed as that position taken by those Members who concurred in the judgments on the narrowest grounds[.]'" *Id.* at 193 (quoting *Gregg v. Georgia*, 428 U.S. 153, 169 n. 15 (1976) (opinion of Stewart, Powell, and Stevens, JJ.)).

Both Justice Breyer's four-justice plurality, *June Med.*, 140 S. Ct. at 2112, and Chief Justice Roberts' solo concurrence, *id.* at 2133, concluded that the Louisiana admitting-privileges requirement created a "substantial obstacle" for women choosing abortion, and was therefore unduly burdensome. *Id.* at 2130 (plurality), 2139 (concurrence). *That* test provides the narrowest common ground between the two opinions and therefore supplies the controlling rule of the case.

The plurality—echoing the balancing test applied by the district court in this case—*subsequently* compared the law's benefits and burdens. *Id.* at 2130–31. The

Chief Justice, however, treated the substantial-obstacle finding as conclusive. He specifically *objected* to evaluating abortion regulations by balancing benefits and burdens. *Id.* at 2135–36. Particularly given the diversity of interests and values associated with abortion regulation, balancing "would require us to act as legislators, not judges, and would result in nothing other than an 'unanalyzed exercise of judicial will' in the guise of a 'neutral utilitarian calculus.'" *Id.* at 2136 (quoting *New Jersey v. T.L.O.*, 469 U.S. 325, 369 (1985) (Brennan, J., concurring in part and dissenting in part)). A balancing test that would invalidate laws without a substantial obstacle lies outside common ground shared with the Chief Justice, and therefore does not control.

Similarly, the Chief Justice's application of the undue-burden standard is narrower because less radical, situating *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016), (the putative source of any balancing test) within a broader doctrinal framework, particularly *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992), and *Mazurek v. Armstrong*, 520 U.S. 968 (1997). He stressed that the Court "should respect the statement in [*Hellerstedt*] that it was applying the undue burden standard of *Casey*," *June Med.*, 140 S. Ct. at 2138, under which a substantial obstacle is the *sine qua non* of a successful challenge to an abortion law. Insofar as the plurality opinion authorizes *other* grounds for abortion challenges, it reflects an ambitious revision of abortion precedents. Because the Chief Justice did not accept such a revision, it cannot be the law under *Marks*.

Furthermore, a Supreme Court case's controlling rules include *all* propositions of law that command a majority of the Court, even majorities that combine justices who disagree on the judgment. *See, e.g.*, *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 572 (2012) (combining the dissent and the sole opinion of Justice Roberts in stating that the "Court today holds that our Constitution protects us from federal regulation under the Commerce Clause so long as we abstain from the regulated activity"); *Alexander v. Choate*, 469 U.S. 287, 293, nn.8–9 (1985) (discussing the Court's "holding" in *Guardians Ass'n v. Civil Serv. Comm'n*, 463 U.S. 582 (1983), by combining the votes of the plurality with those of dissenters in that case); *United States v. Jacobsen*, 466 U.S. 109, 117–18 (1984) (deriving the holding of *Walter v. United States*, 447 U.S. 649, 659–60 (1980), by adding the concurrence of two Justices to the dissent of four Justices); *Moses H. Cone Mem. Hosp. v. Mercury Const. Corp.*, 460 U.S. 1, 17 (1983) (stating that "the Court of Appeals correctly recognized that the four dissenting Justices and Justice Blackmun formed a majority to require application of the Colorado River test"); *see also* Bryan A. Garner et al., *The Law of Judicial Precedent* 206–13 (2016). As Justice Kavanaugh observed, five members of the *June Medical* Court (the Chief Justice and the four dissenters) expressly *rejected* application of a balancing test rather than (or in addition to) the substantial obstacle test. 140 S. Ct. at 2182 (Kavanaugh, J., dissenting).

Still, among lower courts the meaning of *June Medical* remains disputed, and it is fundamental that this Court should resolve that question. In this case, the district court applied the *Hellerstedt* balancing test. *Am. Coll. of Obstetricians & Gynecologists v. U.S. Food & Drug Admin.*, No. TDC-20-1320, 2020 WL 3960625, at *16–17 (D. Md. July 13, 2020). But as noted, the circuits have already split over which *June Medical* opinion controls. The Eighth Circuit applied Chief Justice Roberts's opinion. *See Hopkins v. Jegley*, No. 17-2879, 2020 WL 4557687, at *2 (8th Cir. Aug. 7, 2020). A split panel from the Fifth Circuit disagreed; the majority said that no opinion controls for lack of a "common denominator," but Judge Willett sided with the Eighth Circuit in dissent. *Whole Woman's Health v. Paxton*, No. 17-51060, 2020 WL 4998233, at *4, *8 (5th Cir. Aug. 21, 2020). That split, in turn, has prompted Texas to request en banc rehearing of the Fifth Circuit's interim order, Petition for Rehearing En Banc, *Whole Woman's Health v. Paxton*, No. 17-51060 (5th Cir.); meanwhile, Indiana has asked the Seventh Circuit to sit en banc when it considers this Court's remand in *Box v. Planned Parenthood of Ind. & Ky.*, No. 19-816, 2020 WL 3578672 (U.S. July 2, 2020), *see* Petition for Rehearing En Banc, ECF No. 62, *Planned Parenthood of Ind. & Ky., Inc. v. Comm'r, Ind. State Dep't of Health*, No. 17-2428 (7th Cir.), in part because of the ongoing dispute over which *June Medical* opinion controls.

The Court should seize this opportunity to resolve at least that narrow question so that lower courts can address pending challenges to state abortion laws using the proper test.

II. Respondents Did Not, as Required, File a Citizen Petition with FDA To Lift the Mifepristone REMS

Before raising a challenge to the FDA REMS in federal court, Respondents were required to file a formal petition for relief with FDA based on science justifying the relief they seek. *See Ass'n of Am. Physicians & Surgeons v. FDA*, 358 F. App'x. 179, 180–81 (D.C. Cir. 2009). Respondents failed to do so. For good reason, the Fourth Circuit has a "consistent and unambiguous line of cases rejecting the contention that constitutional claims should be exempt from exhaustion requirements." *Nationsbank Corp. v. Herman*, 174 F.3d 424, 429 (4th Cir. 1999); *see also Thetford Props. v. U.S. Dep't Hous. & Urban Dev.*, 907 F.2d 445, 448 (4th Cir. 1990) ("[E]xhaustion is particularly appropriate when the administrative remedy may eliminate the necessity of deciding constitutional questions.") (quoting *Am. Fed. of Gov't Employees, AFL-CIO v. Nimmo*, 711 F.2d 28, 31 (4th Cir. 1983)).

After the Secretary declared a public health emergency on January 31, 2020, Respondents spent months challenging the application to abortion of emergency medical regulations limiting elective surgical procedures, urging (in tension with their positions here) that medication and surgical abortions are inherently safe and that abortion clinics pose little risk of facilitating transmission of COVID-19. *See, e.g.*, Br. Am. Coll. of Obstetricians & Gynecologists et al. as Amici Curiae, *In re Abbott*, 954

F.3d 772 (5th Cir. 2020) (No. 20-50264). What Plaintiffs did *not* do was petition FDA for any relief from the mifepristone REMS.

Instead, when FDA responded to the pandemic by issuing non-enforcement guidance with respect to other REMS, Respondents ACOG and NYSAFP submitted *comments*. ECF No.1-7; 1-8. Those comment letters did not comply with the requirements for an FDA citizen petition, *see* 21 C.F.R. § 10.30, and did not include technical information on which FDA could rely, *see* 21 C.F.R. § 10.20(c). The record includes no evidence of a petition by any holder of a mifepristone drug application, *see* 21 U.S.C. § 355-1(g)(4)(A), or any suggestion that a holder would release any doctor from the Provider Agreement which restricts distribution of the drug. Respondents' failure to exhaust administrative remedies should bar a preliminary injunction. *See Guerra v. Scruggs*, 942 F.2d 270, 277 (4th Cir. 1991).

III. Requiring Mifepristone Be Dispensed Only at a Clinic Rather than Through Mail-Order Does Not Impose an Undue Burden

Over twenty years ago, evidence submitted as part of the original drug application for Mifeprex (the brand name of mifepristone) revealed serious abortifacient efficacy problems. ECF No. 63-5 at 18. FDA's medical review explained that "medical follow-up is required to ensure that surgical termination is performed in case the medical termination attempt fails." *Id.* at 18. A restricted distribution system was *proposed by the sponsor*, *see id.* at 21–22, and made part of FDA's approval of the drug, ECF No. 63-4 at 2 (referencing 21 C.F.R. § 314.520). In 2007, Congress authorized the Secretary of Health and Human Services to require a REMS if "necessary to

ensure that the benefits of [a] drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a)(1). Because mifepristone was approved subject to 21 C.F.R. § 314.520, FDA deemed mifepristone to have a REMS in effect.

FDA conducted multiple additional scientific reviews in 2011, 2013, and 2016, yet continued to find a REMS necessary, including the requirement that mifepristone be dispensed only in person. Those requirements have never imposed an undue burden on abortion, and the COVID-19 pandemic does not call them into question. This case represents an end run around the REMS, where a judge has substituted his judgment for that of dozens of trained medical & pharmaceutical experts who have twice recommended this protocol—as recently as 2016. This is the very "balancing" that the Chief Justice said judges were ill-suited to undertake, and it provided an excuse for the district court to substitute the views of plaintiffs' "experts" for those of the neutral science-based panels who compose REMS review panels. COVID does not justify completely upending the highly regulated FDA review process.

Moreover, as the United States has outlined, Respondents have not come forward with concrete evidence showing that a "large fraction" of women will be unable to obtain an abortion during the COVID-19 national health emergency owing to the FDA REMS. Instead, ample evidence shows that the REMS is consistent with the standard of care and advances substantial interests in maternal health.

First, even apart from the REMS and comparable state statutes, the medical standard of care requires an in-person physical examination for every woman receiving a medication abortion. ECF No. 63-2 ¶¶ 28–38; *see also,* Am. Coll. of Obstetricians and Gynecologists, *Practice Bulletin 143,* 123 Obstetrics & Gynecology 3 (2014); ECF No. 63-25 ¶¶ 7–13. Medication abortion is significantly more dangerous and less reliable than surgical abortion. *See* ECF No. 63-2 ¶¶ 10–27; Maarit Niinimaki et al., *Immediate Complications after Medical Compared with Surgical Termination of Pregnancy,* 114 Obstetrics & Gynecology 4 (2009). Mifepristone is approved strictly through 10 weeks of pregnancy, ECF No. 1-3 at 17, with later use involving a higher risk of failure and infection, ECF No. 63-2 ¶¶ 6, 16–18; Melissa Chen & Mitchell Creinin, *Mifepristone with Buccal Misoprostol for Medical Abortion: A Systematic Review*, 126 Obstetrics & Gynecology 1 (2015); *see also* Maarit Mentula et al., *Immediate Adverse Events after Second Trimester Medical Termination of Pregnancy: Results of a Nationwide Registry Study*, 26 Human Reproduction 4, 932 (2011) (concluding that medical abortions during the second trimester are associated with increased frequency of adverse events, excluding surgical evacuation or infection, when compared to first trimester medical abortions).

The standard of care thus requires a physician to date the pregnancy accurately—which requires an ultrasound, as even ACOG acknowledges. ECF No. 63-2 ¶¶ 29–31; ECF No. 63-25 ¶¶ 11–12; Am. Coll. of Obstetricians and Gynecologists,

Committee Opinion No. 700: Methods for Estimating Due Date, 129 Obstetrics & Gynecology 5 (2017). In-person dispensing likewise allows the abortion provider to control the date the woman receives mifepristone, in contrast with unpredictable order placement, pharmacy processing, and mail delivery. ECF No. 63-2 ¶ 41.

Medication abortions are also subject to several critical contraindications. Doctors should not prescribe mifepristone without ruling out an ectopic pregnancy using an ultrasound. ECF No. 63-2 ¶¶ 32–33; ECF No. 63-25 ¶¶ 11–12. And even where not strictly contraindicated, medication abortion requires other precautions such as blood-typing. ECF No. 63-2 ¶¶ 34, 36; Am. Coll. of Obstetricians and Gynecologists, *Practice Bulletin No. 181*, 130 Obstetrics & Gynecology 2 (2017).

COVID-19 has not watered down standards of care or justified fewer safety protections. ECF No. 63-25 ¶¶ 14–25. If Respondents and their members are following the standard of care, they are *already* seeing medication abortion patients in person. If they wish to deliver medication abortion without *any* in-person examination, they are seeking to *violate* the standard of care. No case suggests that the abortion decision is burdened by a physician's obligation to follow the ordinary standard of care.

Next, Respondents' "burdens" argument rests principally on the purported risks of traveling for in-person medical services during the coronavirus pandemic, but Respondents unjustifiably assume without proof that such travel creates health risks

that must be avoided at all costs. The risks faced by Respondents' patients are unknown, ECF No. 63-24 ¶ 10, the means of transmission are uncertain, *id.* ¶ 12, and the incidence of the disease at any given time and place can only be guessed at. *Id.* ¶ 11. Responsible medical providers have safely adjusted to providing in-person elective services, and States lifted mandatory postponement of elective procedures months ago. *States Limiting Elective Procedures in Hospitals, Resuming Surgery in All Settings*, Am. Acad. of Ophthalmology (Jul. 16, 2020), https://www.aao.org/practice-management/article/states-begin-easing-elective-procedure-restriction. Doubtless an emergency existed at the outset of the pandemic in March that required use of telemedicine. But after nearly six months of the COVID-19 virus, with more medical and scientific information available, the fear and uncertainty concerns of the virus are more remote. Most states and local governments are "opening up" society by lifting and modifying restrictions on activities, including non-urgent, elective medical procedures. Mitigation measures, such as wearing masks or taking temperatures, allow operations of businesses, schools, and hospitals to resume. So burdens of in-person services at this point are non-existent, and certainly not uniform across the country for the duration of the public health emergency.

Recent studies indicate that standard measures such as screening patients, wearing masks, reducing visitors, and improving hygiene make possible in-person meetings when necessary to meet the standard of care. *See, e.g.,* T.M Cook, *Personal*

Protective Equipment During the COVID-19 Pandemic: a Narrative Review, 75 Anesthesia 7 (2020) (finding that standard surgical facemasks reduce transmission by at least 80% and N95 masks can reduce transmission upwards of 95%). On the other hand, if providers prescribe medication abortions without an in-person meeting, women are more likely to present at a hospital in need of (possibly life-saving) surgical intervention.

Plaintiffs' burden argument based on coronavirus risks degenerates into an impossible muddle. They do not know which women would be burdened, where, when, how much, or by what influences. Their record is not sufficient to show a likelihood of success on the merits, let alone justify an injunction of nationwide scope. *See In re Abbott*, 954 F.3d 772, 786 n.19 (5th Cir. 2020).

CONCLUSION

The stay should be granted.

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