No. 20-1824

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, *et al.*,
Plaintiffs/Appellees,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,
Defendants/Appellants

On Appeal from the United States District Court
for the District of Maryland,

BRIEF OF AMICUS CURIAE STATES OF INDIANA, LOUSIANA, AND 9 OTHERS IN SUPPORT OF MOTION FOR STAY

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

CASES [CONT'D]

STATUTES

OTHER AUTHORITIES

OTHER AUTHORITIES [CONT'D]

STATEMENT OF INTEREST AND SUMMARY OF ARGUMENT

Under Federal Rule of Appellate Procedure 29(a), the States of Indiana, Louisiana, Alabama, Arkansas, Idaho, Kentucky, Mississippi, Missouri, Nebraska, Oklahoma, and Texas respectfully submit this brief as amici curiae in support of Appellants' motion for stay pending appeal.

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.

Amici States have statutes either directly invoking or imposing requirements similar to the enjoined ETASU, *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 this Court 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. 2020). Amici States urge the Court to stay the district court's preliminary injunction pending both appeals.

In barring the mifepristone REMS without considering the States' submissions, the district court applied the incorrect legal test and ignored evidence justifying the regulations. 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.

Plaintiffs' claim is also legally barred because Plaintiffs 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: Plaintiffs 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 ad-

dressing 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 and 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. Chief Justice Roberts'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), invalidating 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.)). This

Court must identify which opinion provides the narrowest *common* ground supporting the judgment. *See, e.g.*, *Manning v. Caldwell for City of Roanoke*, 930 F.3d 264, 280 n. 13 (4th Cir. 2019).

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 *Hellerstedt* (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 regulated

activity"); *see also Manning*, 930 F.3d at 282 n.16 (combining Justice White's concurrence and opinion of four dissenters in *Powell v. State of Texas*, 392 U.S. 514 (1968), noting that "if shared by five Justices, [such views] are binding on lower courts."). 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). That commonality establishes a rule binding lower courts—*no balancing test*.

II. Plaintiffs 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, Plaintiffs 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). Plaintiffs failed to do so, which dooms their claims under this Court's "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, Plaintiffs 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, Plaintiffs 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. Plaintiffs' 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. And despite multiple additional scientific reviews in 2011, 2013, and 2016, FDA 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.

As the United States has outlined, Plaintiffs 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, 927–932 (2011) (finding positive relation between the rate of adverse effects from medical abortion regimens and gestational fetal age).

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; Am. Coll. of Obstetricians and Gynecologists, *Committee Opinion No. 700: Methods for Estimating Due Date*, 129 Obstetrics & Gynecology 5 (2017); ECF No. 63-25 ¶¶ 11–12. 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 Plaintiffs 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 the abortion decision is burdened by a physician's obligation to follow the ordinary standard of care.

Next, Plaintiffs' "burdens" argument rests principally on the purported risks of traveling for in-person medical services during the coronavirus pandemic, but Plaintiffs unjustifiably assume without proof that such travel creates health risks that must be avoided at all costs. The risks faced by Plaintiffs' 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.

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 Anaesthesia 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 Court should stay the preliminary injunction pending appeal.

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CERTIFICATE OF WORD COUNT

I verify that this brief contains 2,562 words according to the word-count function of Microsoft Word, the word-processing program used to prepare this brief.

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CERTIFICATE OF SERVICE

I hereby certify that on August 3, 2020, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

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