No. 20A-_____

IN THE SUPREME COURT OF THE UNITED STATES

UNITED STATES FOOD AND DRUG ADMINISTRATION, ET AL., APPLICANTS

v.

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, ET AL.

APPLICATION FOR A STAY OF THE INJUNCTION ISSUED BY
THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

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PARTIES TO THE PROCEEDING

Applicants (defendants-appellants below) are the United States Food and Drug Administration; Stephen M. Hahn, M.D., in his official capacity as Commissioner of Food and Drugs; the United States Department of Health and Human Services; and Alex Azar, in his official capacity as Secretary of Health and Human Services.

Respondents (plaintiffs-appellees below) are the American College of Obstetricians and Gynecologists; the Council of University Chairs of Obstetrics and Gynecology; the New York State Academy of Family Physicians; SisterSong Women of Color Reproductive Justice Collective; and Honor MacNaughton, M.D.

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Pursuant to Rule 23 of the Rules of this Court and the All Writs Act, 28 U.S.C. 1651, the Acting Solicitor General, on behalf of the United States Food and Drug Administration et al., respectfully applies for a stay of a nationwide preliminary injunction issued on July 13, 2020, by the United States District Court for the District of Maryland (App., infra, 92a-94a), pending the consideration and disposition of the government's appeal from that injunction to the United States Court of Appeals for the Fourth Circuit and, if the court of appeals affirms the injunction, pending the filing and disposition of a petition for a writ of certiorari and any further proceedings in this Court.

This application concerns a nationwide injunction preventing the Food and Drug Administration (FDA) from enforcing, during the COVID-19 pandemic, its longstanding safety requirements for the dispensing of Mifeprex, a drug indicated for termination of

pregnancy during the first ten weeks. Ever since the FDA approved the drug in 2000, the agency has required drug sponsors to ensure that Mifeprex or its generic equivalent (collectively, Mifeprex) is dispensed only by or under the supervision of a certified healthcare provider in a hospital, clinic, or medical office, and only after a patient signs a form acknowledging that she has been counseled about the drug's risks. The FDA has made, and continuously adhered to, the judgment that these requirements mitigate serious health risks associated with the drug, which can increase if the patient delays taking the drug or fails to receive proper counseling about possible complications.

The district court here nevertheless enjoined the enforcement of those longstanding safety regulations on a nationwide basis for the pendency of the COVID-19 pandemic, holding they pose an undue burden on abortion access under Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833 (1992), because of the potential costs associated with visiting a clinic during the pandemic. In a one-sentence order, the court of appeals declined to stay that injunction, thereby allowing a single district judge to dictate national safety requirements for medication abortion in the middle of the current public-health emergency.

In deciding whether to grant a stay in this posture, this Court considers whether an eventual petition for a writ of certiorari in the case would likely be granted, whether there is

a fair prospect that the Court would rule for the moving party, and whether irreparable harm is likely to occur if a stay is not granted. Those criteria are met here.

First, this Court likely would grant review of a decision affirming the preliminary injunction. The Fourth Circuit necessarily would have rejected two settled principles in this Court's precedents: first, that a regulatory requirement imposed on one abortion method is not unconstitutional when another safe abortion method remains readily available; and second, that merely incidental effects on abortion access do not render an otherwise valid law unconstitutional, especially when those effects are not caused by the government. Apart from the merits, the nationwide scope of the injunction independently warrants review. The circumstances here -- in which a single district court, presented with a suit by a single physician and a handful of organizations, displaced the FDA's scientific judgment with respect to every medication abortion provider in the country -- illustrate the problems with allowing district courts to award relief untethered to the established injuries of the specific plaintiffs before them.

Second, this Court likely would vacate, or at the very least narrow, the injunction. Given that surgical methods of abortion remain widely available, the enforcement of longstanding safety requirements for a medication abortion during the first ten weeks of pregnancy does not constitute a substantial obstacle to abortion

access, even if the COVID-19 pandemic has made obtaining any method of abortion in person somewhat riskier. Without a substantial obstacle, respondents cannot prevail under Casey. And even on its own terms, the court erred in its balancing of benefits and burdens. This Court has made clear that judges are not to second-guess how officials address public-health concerns in areas of uncertainty, yet the district court dismissed the FDA's expert judgment in favor of its own view that the safety requirements are medically unnecessary. And setting the merits aside, the scope of the injunction extends well beyond the district court's remedial authority under Article III and basic equitable principles.

Finally, allowing the district court's injunction to remain in effect until this Court has been able to undertake plenary review would irreparably harm both the government and the public. As a result of the injunction, the FDA cannot enforce longstanding safety requirements that have been judged necessary to mitigate serious risks to patients who use Mifeprex to effectuate an abortion. While the district court believed that the terms of its injunction would address those risks, there is no way to rectify the harms to patients if that judicial second-guessing of an expert agency's judgment turns out to be wrong.

For those reasons, the Court should stay the district court's nationwide injunction in its entirety, or at least limit it to

redressing any injuries respondents established before the district court.

STATEMENT

1. In 2000, the FDA approved Mifeprex for use to induce an abortion during the first seven weeks of pregnancy. D. Ct. Doc. 62-3, at 2 (June 10, 2020). In doing so, the agency determined that the drug carried serious risks for the patient, such as an incomplete abortion or serious bleeding that could require surgery. App., infra, 3a. To mitigate such risks, the FDA imposed certain restrictions on sponsors of the drug. As relevant here, the agency required drug sponsors to ensure that Mifeprex is dispensed only by or under the supervision of a certified healthcare provider in a hospital, clinic, or medical office, and only after a patient signs a form acknowledging that she has been counseled about the drug's risks (the safety requirements). D. Ct. Doc. 62-3, at 7.

Since then, the FDA has maintained its restrictions on Mifeprex largely without change. Following the enactment of the Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823, the safety requirements were deemed part of a Risk Evaluation and Mitigation Strategy (REMS), a new authority created under that legislation. D. Ct. Doc. 62-5 at 3 (June 10, 2020). Under this framework, the FDA may require drug sponsors to adhere to restrictions that the agency finds "necessary to ensure

that the benefits of the drug outweigh the risks." 21 U.S.C. 355-1(a). If the drug is "associated with a serious adverse drug experience," such restrictions may include the requirement that "the drug be dispensed to patients only in certain health care settings, such as hospitals." 21 U.S.C. 355-1(f)(1)(A) and (3)(C).

The FDA reaffirmed Mifeprex's safety requirements in 2011, 2013, and 2016. D. Ct. Doc. 62-5, at 2-7; D. Ct. Doc. 62-6, at 4, 16 (June 10, 2020); D. Ct. Doc. 62-10, at 2-4 (June 10, 2020). In its 2013 review, the agency identified at least two reasons for keeping the safety requirements. First, the FDA concluded that requiring in-person dispensing permits contemporaneous counseling that could inform patients about possible serious complications and help them know what to do if they experience certain adverse events. D. Ct. Doc. 62-6, at 16-17. Second, the FDA explained, in-person dispensing avoids the possibility of delay that could arise if the drug were dispensed by a party other than the healthcare provider, such as in cases where patients had difficulty finding a pharmacy that stocks the drug. Id. at 17. That concern was particularly important because delay in initiating the abortion could increase the risks of serious complications. Ibid.

In 2016, the FDA conducted another review in response to a supplemental new drug application from a Mifeprex sponsor. It approved several changes, such as extending the approved use of the drug through ten weeks of pregnancy. D. Ct. Doc. 62-10, at 3.

But after a clinical review documenting thousands of adverse events between 2000 and 2014, FDA did not alter the safety requirements at issue here because Mifeprex's safety profile had "not substantially changed." Id. at 4. Accordingly, Mifeprex's current labeling warns that the drug carries serious risks for up to seven percent of patients, including bleeding requiring surgical intervention, and that in rare cases, fatal infections may occur. App., infra, 59a; D. Ct. Doc. 1-3, at 3, 18 (May 27, 2020).

2. Respondents are an individual physician and four organizations that provide professional membership benefits to obstetrician-gynecologists or medical care to various communities. In April 2020, some of the respondents asked the FDA to suspend the Mifeprex safety requirements during the COVID-19 pandemic so that patients could obtain the drug by mail rather than in person. D. Ct. Docs. 1-7 (May 27, 2020), 1-8 (May 27, 2020). Several weeks later, respondents filed suit, contending that enforcement of the safety requirements during the pandemic violates the substantive-due-process rights of their patients and the equal-protection rights of the physicians themselves. Compl. ¶¶ 123, 125.

On July 13, 2020, the district court granted respondents' request for a nationwide preliminary injunction. App., infra, 92a-94a. Although the court concluded that respondents had not established a likelihood of success with respect to their equal-protection claim, it held that they were likely to prevail on their

substantive-due-process challenge. Id. at 31a-68a. In the court's view, the continued enforcement of the safety requirements would impose a substantial obstacle to obtaining an abortion "[i]n light of the convergence" of various "factors stemming from the COVID-19 pandemic." Id. at 49a. In the alternative, the court concluded that "[e]ven if the burdens alone were insufficient to support a finding of a substantial obstacle," respondents would still prevail because those burdens outweighed any benefits from enforcing those requirements during the pandemic. Id. at 62a.

Turning to the other preliminary-injunction factors, the district court concluded that respondents would suffer irreparable harm absent preliminary relief because of the risk that patients would lose their ability to obtain a medication abortion. App., infra, 68a-70a. The court also ruled that the government would "not be harmed" by a nationwide injunction given that enforcement of the safety requirements was likely unconstitutional, and that the injunction would "safeguard public health" by "eliminating unnecessary in-person visits during the pandemic." Id. at 70a, 72a.

Finally, the district court entered a preliminary injunction providing relief to patients of all physicians who are members of respondent organizations, along with all "similarly situated" individuals or entities, App., infra, 93a. In the court's view,

such "categorical relief" was warranted because the safety requirements constituted a "categorical policy." Id. at 76a.

3. The government filed motions to stay the injunction pending appeal, which the district court denied on July 30, App., infra, 83a-84a, and the court of appeals denied on August 13, id. at 85a-86a.[1]

ARGUMENT

The government respectfully requests that this Court grant a stay of the district court's nationwide preliminary injunction pending completion of further proceedings in the court of appeals and, if necessary, this Court. A stay pending the disposition of a petition for a writ of certiorari is appropriate if there is (1) "a reasonable probability that four Justices will consider the issue sufficiently meritorious to grant certiorari"; (2) "a fair prospect that a majority of the Court will conclude that the decision below was erroneous"; and (3) "a likelihood that irreparable harm will result from the denial of a stay." Conkright v. Frommert, 556 U.S. 1401, 1402 (2009) (Ginsburg, J., in chambers)

[1] On August 19, the district court granted in part a motion for clarification filed by respondents. App., infra, 87a-91a. The court explained that the terms of its preliminary injunction allow mail-order pharmacies to stock and deliver Mifeprex on behalf of certain healthcare providers. Id. at 89a-91a.

(brackets, citation, and internal quotation marks omitted). All of those requirements are met here.[2]

I. THERE IS A REASONABLE PROBABILITY THAT THIS COURT WOULD GRANT A WRIT OF CERTIORARI IF THE COURT OF APPEALS UPHOLDS THE DISTRICT COURT'S NATIONWIDE PRELIMINARY INJUNCTION

If the court of appeals ultimately affirms the injunction in this case, there is a reasonable probability that this Court will grant a writ of certiorari. That is true for at least two reasons.

First, such a decision would resolve "an important federal question in a way that conflicts with relevant decisions of this Court." Sup. Ct. R. 10(c). This Court has held that a regulation "does not construct a substantial obstacle to the abortion right" when it allows other "commonly used and generally accepted method[s]," Gonzales v. Carhart, 550 U.S. 124, 165 (2007), and also that "[t]he fact that a law which serves a valid purpose, one not designed to strike at the right itself, has the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate it," Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 874 (1992) (plurality opinion). As explained more fully below, to uphold the preliminary

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[2] Under this Court's Rule 23 and the All Writs Act, 28 U.S.C. 1651, a single Justice or the Court has authority to enter a stay pending proceedings in a court of appeals. See, e.g., Department of Homeland Sec. v. New York, 140 S. Ct. 599 (2020); Trump v. International Refugee Assistance Project, 138 S. Ct. 542 (2017).

injunction, the court of appeals would have to reject both propositions. It is at least reasonably probable that this Court would grant a writ of certiorari to review such a conflict, especially given that it concerns the enforcement of important public-health requirements during a global pandemic.

Second, a decision by the court of appeals upholding the injunction here would also squarely present the question whether nationwide injunctions are consistent with the federal courts' limited authority to redress the concrete injuries shown by the parties before them in specific cases or controversies. See Marbury v. Madison, 5 U.S. (1 Cranch) 137, 170 (1803) ("The province of the court is, solely, to decide on the rights of individuals, not to enquire how the executive, or executive officers, perform duties in which they have a discretion."). In the past three years, federal courts have issued dozens of universal injunctions, blocking a wide range of significant policies involving immigration, national security, and domestic issues. If the Fourth Circuit were to uphold the nationwide scope of the injunction here, that result would present an additional "important federal question" warranting a writ of certiorari, and indeed would call out for "an exercise of this Court's supervisory power," Sup. Ct. R. 10(a) and (c). See Department of Homeland Sec. v. New York, 140 S. Ct. 599, 600 (2020) (Gorsuch, J., concurring in the grant of stay) ("It has become increasingly apparent that this

Court must, at some point, confront these important objections to this increasingly widespread practice."); Trump v. Hawaii, 138 S. Ct. 2392, 2429 (2018) (Thomas, J., concurring) ("If federal courts continue to issue [universal injunctions], this Court is duty-bound to adjudicate their authority to do so."); Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania, 140 S. Ct. 2367 (2020) (granting review of nationwide scope of injunction but ultimately resolving case on the merits).

II. THERE IS AT LEAST A FAIR PROSPECT THAT THE COURT WOULD VACATE THE INJUNCTION IN WHOLE OR IN PART

There is also at least a fair prospect that if this Court granted a writ of certiorari, it would vacate the injunction in whole or in part. That is true both because respondents' claim is unlikely to succeed, and because the nationwide scope of the preliminary injunction is not an appropriate means of redressing respondents' asserted injuries.

A. This Court has made clear that a law affecting access to abortion does not violate substantive-due-process rights under Casey unless it poses a substantial obstacle to abortion access; that a regulatory requirement imposed on only one method of abortion cannot be a substantial obstacle when another safe abortion method remains readily available; and that merely incidental effects on abortion access do not invalidate an otherwise constitutional law. Those settled principles foreclose respondents' claim that the COVID-19 pandemic has rendered

unconstitutional the FDA's longstanding, minimally burdensome requirement that patients obtain Mifeprex at a hospital, clinic, or doctor's office after being counseled about the drug's risks.

1. Under Casey, a regulation does not impose an undue burden on abortion access unless it "has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion." 505 U.S. at 877 (plurality opinion). Respondents cannot show that enforcement of the Mifeprex safety requirements during the pandemic creates such an obstacle to abortion access.

a. In Gonzales, this Court held that a regulation "does not construct a substantial obstacle to the abortion right" if it allows other "commonly used and generally accepted method[s]." 550 U.S. at 165. That is true, the Court explained, even "if some procedures have different risks than others," and even if "there is uncertainty over whether the barred procedure is ever necessary to preserve a woman's health." Id. at 166-167.

That principle applies a fortiori in this case. The safety requirements here concern only medication abortions using Mifeprex, which is approved for use only during the first ten weeks of pregnancy. They have no effect on the availability of surgical abortions, a method that this Court has treated as safe for women. See Stenberg v. Carhart, 530 U.S. 914, 923-926 (2000). Accordingly, any women seeking abortions during the first ten weeks of pregnancy who do not wish to comply with the in-person

dispensing requirements are in the same position as women for whom Mifeprex is not medically appropriate (such as those with more advanced pregnancies) and as all women were before 2000. If requiring an in-person surgical abortion for women who seek abortions after ten weeks does not impose an undue burden, then requiring in-person interaction for a medication abortion is not an undue burden for earlier abortions simply because respondents would prefer another alternative. See Gonzales, 550 U.S. at 163 (rejecting claim of undue burden from law barring certain abortion procedures where "reasonable alternative procedures" remained available). Indeed, the contrary conclusion would imply that the FDA was constitutionally required to approve Mifeprex in 2000.

The district court nevertheless held that a regulation may create a substantial obstacle if it results in patients "seek[ing] a more invasive form of abortion." App., infra, 50a. That ruling contravenes Gonzales. In that case, challengers to a law prohibiting one form of abortion (intact dilation and evacuation) contended that this method was "safer" and took "less time to complete" than a readily available alternative (standard dilation and evacuation). 550 U.S. at 161. This Court nevertheless held that the government could ban the former given the availability of the latter, explaining that "[w]hen standard medical options are available, mere convenience does not suffice to displace them; and if some procedures have different risks than others, it does not

follow that the State is altogether barred from imposing reasonable regulations." Id. at 166.

That holding should have led the district court to reject respondents' challenge here. The court did not contest that surgical abortion is a "standard medical option[]." Gonzales, 550 U.S. at 166; cf. App., infra, 39a. Nor did the court explain how its reasoning could be reconciled with this Court's holding in Gonzales. Cf. App., infra, 39a. Instead, it relied on statements in Stenberg, supra, in which this Court ruled a Nebraska law prohibiting certain partial-birth abortions imposed an undue burden notwithstanding the availability of other methods of abortion. App., infra, 39a. But in holding here that a restriction on one method of abortion can impose an undue burden even if "a woman ultimately can obtain an abortion through other available and generally accepted methods," ibid., the district court never grappled with the fact that this Court's later decision in Gonzales expressly distinguished Stenberg and squarely held that a regulation on one form of abortion does not pose a substantial obstacle if it allows other "commonly used and generally accepted method[s]," 550 U.S. at 165; see id. at 154 (explaining that in Stenberg, the Court found the statute outlawed standard dilation and extraction).

b. The district court compounded its error by holding that a regulatory requirement may become unconstitutional because of

the incidental effects caused by an unforeseen global pandemic. See App., infra, 49a. That ruling also contravenes this Court's precedents. In Casey, the controlling three-Justice opinion acknowledged that "[t]he fact that a law which serves a valid purpose, one not designed to strike at the right itself, has the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate it." 505 U.S. at 874 (plurality opinion). That "was not an idle assertion," Gonzales, 550 U.S. at 158, but rather a reflection of the fact that although "[a]ll abortion regulations interfere to some degree with a woman's ability to decide whether to terminate her pregnancy," only some will actually "deprive[] women of the ultimate decision," Casey, 505 U.S. at 875. It is also consistent with the fact that the government "need not remove" obstacles to abortion access that are "not of its own creation." Harris v. McRae, 448 U.S. 297, 316 (1980); cf. Whole Woman's Health v. Hellerstedt, 136 S. Ct. 2292, 2313 (2016) (challengers to an abortion regulation bear the "burden to present evidence of causation").

The district court's decision is inconsistent with those principles. The court never suggested that the Mifeprex safety requirements -- adopted in 2000 and repeatedly reaffirmed since -- are "designed to strike at the right itself." Casey, 505 U.S. at 874 (plurality opinion). Nor did it conclude that the

requirements in and of themselves erect a substantial obstacle to abortion access. Indeed, the court could not have done so under this Court's precedents: a one-time clinic visit, even if an obstacle, is not a substantial one. Cf. id. at 886 (mandatory 24-hour waiting period requiring "at least two visits to the doctor" not a substantial obstacle). Accordingly, even the district court acknowledged "that a single in-person visit" to obtain Mifeprex "may not appear particularly onerous in normal times." App., infra, 61a.

Instead, the district court's finding of a substantial obstacle reduces to the observation that COVID-19 has made going anywhere riskier or more difficult than in normal times. See App., infra, 41a-50a. Yet that undifferentiated difficulty arising from an unforeseen global pandemic is an "incidental effect" not traceable to the safety requirements. Casey, 505 U.S. at 874 (plurality opinion). In barring enforcement of the requirements because of such incidental effects, the court inappropriately created an affirmative duty for the FDA to "remove [obstacles] not of its own creation." McRae, 448 U.S. at 316.

c. Even on its own terms, the district court was mistaken in concluding that the pandemic creates a substantial obstacle to obtaining medication abortions using Mifeprex. Respondents have not established that visiting a clinic to obtain the drug is substantially riskier than traveling anywhere else during the

COVID-19 pandemic. And although the court expressed generalized concerns that travel and childcare are more difficult during the pandemic, those concerns do not show that a one-time visit to obtain Mifeprex in person is any more of a burden than visiting any other place, or that the ordinary burdens of life during the pandemic erect a substantial obstacle to abortion access. Moreover, the court's only particularized evidence consisted of examples taken from a few declarations, see App., infra, 47a-48a, even though respondents are challenging the effect of the challenged requirements on all women seeking medication abortions throughout the country during the pandemic. A few anecdotes do not justify a generalization about all of those patients, and even the curated incidents do not show a substantial obstacle. The alleged burden here comes nowhere close to the burdens that this Court has found to be unconstitutional. See, e.g., Whole Woman's Health, 136 S. Ct. at 2312 (noting that the challenged law had caused nearly half the clinics in the state to close).

The district court also speculated that the pandemic's effects could cause so much delay (because some clinics have closed or reduced services) that patients would lose the ability to obtain a medication abortion within the first ten weeks of pregnancy. App., infra, 50a. But as noted, there is no constitutional right to the abortion method of one's choice, so long as there are, as here, other "reasonable alternative procedures" or "commonly used

and generally accepted method[s]." Gonzales, 550 U.S. at 163-165; cf. Ohio v. Akron Ctr. for Reprod. Health, 497 U.S. 502, 513-514 (1990) (upholding parental-consent provision even if it could result in "a 3-week delay" that "could increase by a substantial measure both the costs and the medical risks of an abortion"). Moreover, the court cited no evidence that the challenged requirements would as a general matter delay a medication abortion beyond the ten-week limit. To the contrary, preventing delay is one of the justifications the FDA has provided for the requirements. See D. Ct. Doc. 62-6, at 16-17.

2. a. Respondents' failure to show that the challenged requirements pose a substantial obstacle should end the judicial inquiry. Yet the district court alternatively concluded that even if respondents had not established a substantial obstacle, it could balance the benefits and burdens of the safety requirements under this Court's decision in Whole Woman's Health. App., infra, 62a. That was mistaken. In June Medical Services L. L. C. v. Russo, 140 S. Ct. 2103 (2020), every Justice of this Court stressed the importance of demonstrating that a law poses a substantial obstacle to abortion access in order to obtain relief. See id. at 2112, 2120, 2130 (plurality opinion); id. at 2135-2139 (Roberts, C.J., concurring in the judgment); id. at 2153-2154 (Alito, J., dissenting). And at least five Justices explicitly rejected the balancing test that the district court here adopted. See id. at

2135-2139 (Roberts, C.J., concurring in the judgment); id. at 2153-2154 (Alito, J., dissenting); id. at 2182 (Kavanaugh, J., dissenting).

The district court nevertheless held that it could weigh the safety requirements' benefits and burdens based on its conclusion that June Medical did not "overrule[]" "Whole Woman's Health and its balancing test." App., infra, 37a. But Whole Woman's Health contains no holding adopting such a test. As the Chief Justice explained, "the discussion of benefits in Whole Woman's Health was not necessary to its holding," and that decision "explicitly stated that it was applying 'the standard, as described in Casey.'" June Medical, 140 S. Ct. at 2139 & n.3 (concurring in the judgment) (quoting Whole Woman's Health, 136 S. Ct. at 2309). The standard described in Casey, as the Chief Justice further observed, "'squarely foreclosed'" any argument that a law not posing a substantial obstacle is "invalid" merely because it lacks "'any health basis.'" Id. at 2138 (quoting Mazurek v. Armstrong, 520 U.S. 968, 973 (1997) (per curiam)). Accordingly, June Medical confirms that the undue-burden standard adopted in Casey continues to "requir[e] a substantial obstacle before striking down an abortion regulation." Id. at 2139; see also Hopkins v. Jegley, No. 17-2879, 2020 WL 4557687, at *2 (8th Cir. Aug. 7, 2020) (per curiam) (vacating preliminary injunction of abortion regulations

in light of June Medical because the district court had applied a "cost-benefit standard").[3]

b. Even on its own terms, the district court's balancing of benefits and burdens does not withstand scrutiny. In 2016, the FDA reaffirmed the safety requirements after reviewing thousands of adverse events resulting from the use of Mifeprex. D. Ct. Doc. 62-10, at 4. The agency concluded that in-person counseling at the time of dispensing could help patients understand possible serious complications and what to do if they experienced an adverse event. D. Ct. Doc. 62-6, at 16-17. It also determined that delay in taking the drug could increase the risk a patient would suffer serious complications, and that in-person dispensing could help avoid potential delay associated with obtaining the drug from a pharmacy, such as in instances where local pharmacies did not stock the drug. Ibid. Those considerations readily justify the safety requirements.

The district court nonetheless agreed with respondents' view that the requirement is "'medically unnecessary.'" App., infra,

[3] The district court also concluded that the Chief Justice's opinion in June Medical rejecting the court's reading of Whole Woman's Health is not the narrowest one under Marks v. United States, 430 U.S. 188 (1977), and therefore is not controlling. But that is beside the point here, because the four dissenting Justices in June Medical agreed with the Chief Justice on the substantial-obstacle requirement, 140 S. Ct. at 2154 (Alito, J.), and thus the district court's contrary view is likely to be reversed by this Court if affirmed by the Fourth Circuit.

51a-52a, 56a (citation omitted). Observing that the FDA had not considered the availability of telehealth counseling in 2016, the court concluded that, in light of several declarations submitted by respondents, telehealth counseling is just as effective as counseling in person. Id. at 55a-57a. But the court failed to appreciate questions that it should have left for the FDA to resolve, such as whether counseling at the time of dispensing might be more effective because it might be closer in time to when the patient takes the drug or more effective at communicating risks. Analysis of such questions requiring data and expertise should have led the court to stay its hand, because the FDA retains "wide discretion" to adopt reasonable safety requirements in the face of medical uncertainty. June Medical, 140 S. Ct. at 2136 (Roberts, C.J., concurring in the judgment) (quoting Gonzales, 550 U.S. at 163).

The district court also brushed aside the FDA's concern that the requirements are necessary to prevent dangerous delay, reasoning that "healthcare provider[s]" can and will exercise their own "medical judgment" about what is safest. App., infra, 57a-58a. But federal law grants the FDA authority to impose conditions on the dispensing of a drug without having to assume that providers will always exercise sound judgment. See Gonzales, 550 U.S. at 163 ("The law need not give abortion doctors unfettered choice in the course of their medical practice."); cf. Casey, 505

U.S. at 886 (plurality opinion) ("[W]hile the waiting period does limit a physician's discretion, that is not, standing alone, a reason to invalidate it."). On the court's view, a regulatory requirement imposed on abortion providers would always lack any benefit because it would either be redundant of, or contrary to, the "medical judgment" of such providers. The Constitution, however, does not "elevate" the status of "abortion doctors * * * above other physicians in the medical community," much less above the FDA. Gonzales, 550 U.S. at 163.

The district court also made much out of the fact that since 2016, the FDA has allowed patients to take Mifeprex at home instead of at a clinic. App., infra, 51a-52a, 54a-55a, 58a. But that regulatory decision does not mean, as the court assumed, that the safety requirements "do[] not actually address any interest in having the patient take the [drug] as soon as possible." Id. at 58a. To the contrary, the FDA's 2016 decision to allow taking Mifeprex at home after obtaining it in person simply reflected the agency's judgment that at-home use would allow the patient "to be in a convenient, safe place" when "the expected uterine cramping and vaginal bleeding" occur. D. Ct. Doc. 62-11, at 43 (June 10, 2020). That the agency tolerated the delay associated with at-home use in light of that consideration does not undermine its larger concerns about delays associated with having patients obtain the drug from pharmacies on their own. Given that the

government "need not address all aspects of a problem in one fell swoop" even under strict scrutiny, Williams-Yulee v. Florida Bar, 575 U.S. 433, 449 (2015), the FDA was entitled to address causes of delay that it concluded were especially problematic. Cf. Gonzales, 550 U.S. at 160 (rejecting argument that because "the standard D&E is in some respects as brutal, if not more, than the intact D&E," prohibiting intact D&E "accomplishes little").

The district court was similarly mistaken in concluding that the FDA failed to reaffirm the safety requirements in 2016. App., infra, 53a. As part of its 2016 review, the agency explained that it had "evaluated the current REMS program to determine whether each Mifeprex REMS element remains necessary to ensure the drug benefits outweigh the risks." D. Ct. Doc. 62-10, at 3. And based on data showing thousands of adverse events, the FDA concluded that the drug's safety profile had "not substantially changed." Id. at 4. Accordingly, the agency specifically reaffirmed that the safety requirements "mitigate the risk of serious complications" by "[e]nsuring that Mifeprex is only dispensed in certain health care settings." Id. at 4-5.

The district court also observed that the FDA has encouraged telehealth services and suspended some in-person requirements for a few different drugs. App., infra, 61a. But that has no bearing on the challenged requirements concerning this drug. The FDA evaluates the necessity of in-person dispensing for each drug

individually, not en masse. Indeed, in the course of rejecting respondents' equal-protection claim, the court thoroughly addressed the relevant differences between Mifeprex and the other drugs at issue, such as their regulation under a different statutory regime or their use for a different medical condition. See id. at 65a-68a.

Tellingly, nothing about the district court's dismissal of the safety requirements' benefits was limited to the context of the COVID-19 pandemic. See App., infra, 51a-59a. Yet the court did not question that these requirements were "reasonably related" to a "legitimate purpose" before the current public-health crisis, Casey, 505 U.S. at 878, 882 (plurality opinion) -- as evidenced by its decision to enjoin their enforcement only through the pandemic's duration. Accordingly, the court's determination that those requirements are "'unnecessary health regulations,'" App., infra, 51a (citation omitted), reduces to the conclusion that the burdens associated with an in-person visit to a clinic during the pandemic -- which respondents have not established is substantially riskier than a trip anywhere else -- outweigh the safety requirements' underlying benefits.

That sort of judicial management of public-health policy is inappropriate. The "Constitution principally entrusts 'the safety and the health of the people'" to officials who must "'act in areas fraught with medical and scientific uncertainties,'" and who

generally "should not be subject to second-guessing by an 'unelected federal judiciary,' which lacks the background, competence, and expertise to assess public health." South Bay United Pentecostal Church v. Newsom, 140 S. Ct. 1613, 1613-1614 (2020) (Roberts, C.J., concurring in denial of application for injunctive relief) (brackets and citations omitted). And that is especially true when the second-guessing amounts to a conclusion that a "woman's liberty interest" outweighs "the State's interests" in protecting her "health" -- a comparison of "imponderable values" that is not "a job for the courts." June Medical, 140 S. Ct. at 2136 (Roberts, C.J., concurring in the judgment).

B. Apart from the merits, there is a fair prospect that this Court would, at a minimum, vacate in part any decision of the court of appeals upholding the district court's injunction, on the ground that the injunction's nationwide scope is overbroad. Nationwide injunctions like the one here transgress both Article III and equitable principles by affording relief that is not necessary to redress any cognizable, irreparable injury to the parties in the case. They also frustrate the development of the law, while obviating the requirements of class-action litigation.

1. a. "Article III of the Constitution limits the exercise of the judicial power to 'Cases' and 'Controversies.'" Town of Chester v. Laroe Estates, Inc., 137 S. Ct. 1645, 1650

(2017) (citation omitted). Of particular relevance here, a federal court may entertain a suit only by a plaintiff who has suffered a concrete "injury in fact," and the court may grant relief only to remedy "the inadequacy that produced [the plaintiff's] injury." Gill v. Whitford, 138 S. Ct. 1916, 1929-1930 (2018) (citations omitted). In short, neither standing nor remedies are "dispensed in gross." Lewis v. Casey, 518 U.S. 343, 358 n.6 (1996). This Court has accordingly narrowed injunctions that extended relief beyond the harms to "any plaintiff in th[e] lawsuit," id. at 358, and refused to adjudicate claims by plaintiffs whose harms "ha[ve already] been remedied," Summers v. Earth Island Inst., 555 U.S. 488, 494 (2009).

Principles of equity reinforce those limitations. A court's equitable authority to award relief is generally confined to relief "traditionally accorded by courts of equity" in 1789. Grupo Mexicano de Desarrollo, S. A. v. Alliance Bond Fund, Inc., 527 U.S. 308, 318, 319 (1999). And it is a longstanding principle that injunctive relief may "be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs" in that case. Califano v. Yamasaki, 442 U.S. 682, 702 (1979); see Hawaii, 138 S. Ct. at 2427 (Thomas, J., concurring) (explaining that English and early American "courts of equity" typically "did not provide relief beyond the parties to the case"). To be sure, in some cases, such as properly certified class actions, relief

may extend to a broad range of plaintiffs, Califano, 442 U.S. at 702 (nationwide class action), and some plaintiffs' injuries can be remedied only in ways that incidentally benefit nonparties, see, e.g., Dayton Bd. of Educ. v. Brinkman, 433 U.S. 406, 414 (1977) (school-desegregation remedy). But even in those cases, courts are adjudicating only the rights of the parties before them, not passing on laws or issues as a general matter.

b. Nationwide injunctions are irreconcilable with those constitutional and equitable limitations. By definition, a nationwide injunction extends relief to parties that were not "plaintiff[s] in th[e] lawsuit." Lewis, 518 U.S. at 358. The district court made that clear here, expressly extending its injunction to allow non-parties to disregard the FDA's safety requirements if they are "similarly situated" to respondents or respondents' members. App., infra, 93a. But as this Court has explained, such non-parties are "not the proper object of th[e court's] remediation." Lewis, 518 U.S. at 358. And when a court awards relief to non-parties, it transgresses the boundaries of relief "traditionally accorded by courts of equity" in 1789. Grupo Mexicano, 527 U.S. at 319; see Samuel L. Bray, Multiple Chancellors: Reforming the National Injunction, 131 Harv. L. Rev. 417, 424-445 (2017) (detailing historical practice).

Nationwide injunctions create other legal and practical problems. They circumvent the procedural rules governing class

actions, which permit relief to absent parties only if rigorous safeguards are satisfied. Fed. R. Civ. P. 23. They enable forum shopping, and empower a single district judge to effectively nullify the decisions of all other lower courts by barring application of a challenged policy in any district nationwide. See New York, 140 S. Ct. at 601 (Gorsuch, J., concurring). And they operate asymmetrically. A nationwide injunction anywhere freezes the challenged action everywhere. So the government must prevail in every suit to keep its policy in force, while plaintiffs can derail a federal statute or regulation nationwide with a single district-court victory. See ibid. (describing a recent example). That dynamic defies both class-action requirements and the usual rule that nonparties may not bar the government from relitigating issues in subsequent cases in different forums. See United States v. Mendoza, 464 U.S. 154, 158-163 (1984).

Moreover, the prospect that a single district-court decision can enjoin a policy nationwide while the ordinary appellate process unfolds often leaves the Executive Branch with little choice but to seek emergency relief. See New York, 140 S. Ct. at 600-601 (Gorsuch, J., concurring). That in turn deprives the judicial system, including this Court, of the benefits that accrue when numerous courts grapple with complex legal questions. Ibid.

In short, nationwide injunctions "take a toll on the federal court system." Hawaii, 138 S. Ct. at 2425 (Thomas, J.,

concurring). And that toll is growing. According to the Department of Justice's best estimates, federal district courts have issued more than 50 nationwide injunctions in the past three years, nearly as many as were issued in the entire history of the United States before that time. As courts' issuance of such disruptive injunctions grows "increasingly widespread," the need for correction by this Court has become acute. New York, 140 S. Ct. at 600 (Gorsuch, J., concurring).

2. The sweeping relief awarded in this case illustrates the problems with nationwide injunctions. The district court's injunction extends well beyond any injuries respondents established before that court, covering all patients of physicians who are members of respondent organizations, and even all "similarly situated" non-parties. App., infra, 93a.

The district court claimed authority to effectively turn this case into a one-sided class action -- binding the government as to all potential claimants but not binding all potential claimants as to the government -- principally on the theory that a "categorical policy warrants categorical relief." App., infra, 76a. But under settled constitutional and equitable principles, it is the scope of the plaintiff's injury, not the defendant's policy, that governs the permissible breadth of a remedy. See, e.g., Whitford, 138 S. Ct. at 1921, 1930-1931 (holding that the proper remedy in a vote-dilution challenge brought by an individual voter entailed

"revising only such districts as are necessary to reshape the voter's district" rather than "restructuring all of the State's legislative districts," notwithstanding that the alleged gerrymandering was "statewide in nature" rather than limited to each plaintiff's particular district) (citation omitted).

The district court also sought to justify the scope of its injunction on efficiency grounds, claiming that (1) other non-parties may face "challenges bringing suits on their own behalf"; (2) other lawsuits could be "'duplicative'"; (3) a tailored injunction could "create practical, administrative complexities"; and (4) respondent organizations represented most of the "OB/GYN physicians in the United States." App., infra, 76a-77a (citation omitted). Contrary to the court's approach, the legal principle that the remedy should be "'no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs'" is not something to be "balanced against" other considerations. Id. at 73a (citation omitted). For example, the court expressed concern that it "would be practically difficult" for the FDA "to comply with" a tailored injunction, App., infra, 77a, but the appropriate party to make that determination is the government, not respondents or the court. In supplanting the agency's determinations about whether it would be preferable to suspend the enforcement of the safety requirements more broadly than is necessary to redress respondents' asserted injuries, the court

"undert[ook] tasks assigned to the political branches" in just the way that Article III is intended to prevent. DaimlerChrysler Corp. v. Cuno, 547 U.S. 332, 353 (2006) (citation omitted).

III. THERE IS A LIKELIHOOD THAT IRREPARABLE HARM WILL RESULT FROM THE DENIAL OF A STAY

Finally, the government will likely suffer irreparable harm if a stay is denied. "Any time a [government] is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." Maryland v. King, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers) (brackets and citation omitted). And that is especially true when the injunction subjects the decisions of public officials entrusted with "'the safety and the health of the people'" in "'areas fraught with medical and scientific uncertainties'" to "second-guessing by an unelected federal judiciary." South Bay United Pentecostal Church, 140 S. Ct. at 1613-1614 (Roberts, C.J., concurring) (brackets and citations omitted). Congress has vested the FDA with the authority to impose restrictions "necessary to ensure that the benefits of the drug outweigh the risks," 21 U.S.C. 355-1(a)(1), including the requirement that "the drug be dispensed to patients only in certain health care settings, such as hospitals," 21 U.S.C. 355-1(f)(3)(C). Consistent with that authority, for the past 20 years the FDA has mandated that healthcare providers dispense Mifeprex in a hospital, clinic, or medical office. The agency has made the expert judgment that the

drug carries serious risks, including bleeding requiring surgical intervention, D. Ct. Doc. 1-3, at 18, and that in-person dispensing mitigates those risks by allowing patients to receive in-person counseling about possible complications and by avoiding potential delays associated with patients trying to obtain the drug from a pharmacy on their own, D. Ct. Doc. 62-6, at 16-17.

By suspending enforcement of the safety requirements on a nationwide basis, the district court has irreparably harmed both the government and the public more generally. Even if the FDA ultimately prevails on the merits, the risks to patients, and any harms that materialize, cannot be undone. Those costs outweigh any burdens associated with a one-time clinic visit to receive a drug that is merely one means of obtaining an abortion.

CONCLUSION

For the foregoing reasons, this Court should stay the district court's injunction in its entirety pending the completion of further proceedings in the court of appeals and, if necessary, this Court. At a minimum, this Court should stay the nationwide scope of the injunction.

Respectfully submitted.

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