No. 20A34

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.

REPLY IN SUPPORT OF APPLICATION FOR A STAY

JEFFREY B. WALL
Acting Solicitor General
Counsel of Record
Department of Justice
Washington, D.C. 20530-0001
SupremeCtBriefs@usdoj.gov
(202) 514-2217

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Since 2000, the Food and Drug Administration (FDA) has required and repeatedly reaffirmed that patients may obtain Mifeprex or its generic equivalent (collectively, Mifeprex) only at a hospital, clinic, or doctor's office after being counseled about the drug's risks in terminating an early pregnancy (the safety requirements). Respondents do not suggest that these longstanding safety requirements in and of themselves have the purpose or effect of creating a substantial obstacle to abortion access. Rather, they contend that because the COVID-19 pandemic has made going anywhere riskier or more difficult than in normal times, the Constitution mandates their suspension so that patients can obtain a medication-abortion drug by mail.

That position contravenes this Court's precedents. As this Court has made clear, the Constitution does not guarantee access to the abortion method of one's choice where, as here, reasonable alternatives remain available. Nor does it require the government to remove incidental effects on abortion access caused by an

unforeseen global pandemic. Because the nationwide injunction here departs from those principles and irreparably harms the government and the public, it warrants a stay.

I. THERE IS A REASONABLE PROBABILITY THAT THIS COURT WOULD GRANT A WRIT OF CERTIORARI

Respondents do not seriously dispute that a decision by the Fourth Circuit affirming the nationwide injunction here would warrant this Court's review. At most, they suggest that this Court would not grant certiorari to address a "time-limited" injunction concerning "the sui generis conditions of a global pandemic." Resp. Opp. To Appl. For Stay (Opp.) 22. But this Court regularly stays injunctions that are guaranteed to be temporary, such as in the election context, and has continued to do so during the current pandemic. See, e.g., Barnes v. Ahlman, No. 20A19, 2020 WL 4499350 (Aug. 5, 2020) (staying injunction requiring county to implement pandemic-related safety measures in its jail); Merrill v. People First of Ala., No. 19A1063, 2020 WL 3604049 (July 2, 2020) (staying injunction barring State from prohibiting curbside voting in upcoming primary). Respondents' speculation (Opp. 22) that this case may become moot at some unknown point in the future provides no basis for declining to address the unjustified effects of the district court's injunction today.[1]

[1] The FDA also had no obligation "to move for expedited review" in the Fourth Circuit after that court denied the agency's stay motion and adopted a schedule in which briefing will finish by the end of November. Opp. 22; see C.A. Doc. 10, at 1 (Aug. 24, 2020).

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

A. Respondents Are Unlikely To Prevail On The Merits

1. a. Respondents cannot make the necessary showing that the safety requirements place "a substantial obstacle in the path of a woman seeking an abortion." Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 877 (1992) (plurality opinion). At the outset, they fail to grapple meaningfully with this Court's holding in Gonzales v. Carhart, 550 U.S. 124 (2007), that a regulation "does not construct a substantial obstacle to the abortion right" if it allows other "commonly used and generally accepted method[s]," even if those "procedures have different risks." Id. at 165, 166. Respondents do not deny that surgical methods of abortion are "commonly used and generally accepted." Id. at 165. Nor do they dispute that any woman who prefers a medication abortion may obtain one so long as she sees the prescriber in person (and is otherwise eligible). Instead, they object that the safety requirements do not permit a medication-abortion drug to be dispensed by mail -- an option that has never been available in the 20 years since Mifeprex's approval.

Respondents attempt to cabin Gonzales to its facts, dismissing its reasoning as mere "isolated phrases." Opp. 26. But this Court's holding that abortion providers "are not entitled to ignore regulations that direct them to use reasonable alternative procedures," Gonzales, 550 U.S. at 163, reflects a

fundamental legal premise. Casey recognized only a woman's right to "mak[e] the ultimate decision to terminate her pregnancy," Gonzales, 550 U.S. at 146 (quoting Casey, 505 U.S. at 879), not the right to an "early abortion," Opp. 26. Accordingly, a regulation that merely makes it more difficult to obtain an early abortion does not create a substantial obstacle to that ultimate decision so long as "standard medical options are available" for later abortions, Gonzales, 550 U.S. at 166. Indeed, the latter are the only options for women past the tenth week of pregnancy (or who are otherwise ineligible to use Mifeprex), and were the only options for all women before the drug's approval in 2000.

Contrary to respondents' suggestion (Opp. 29-30), neither Whole Woman's Health v. Hellerstedt, 136 S. Ct. 2292 (2016), nor June Medical Services L. L. C. v. Russo, 140 S. Ct. 2103 (2020), abandoned that settled principle. Rather, those cases involved laws that burdened a woman's ability "'to have an abortion,'" id. at 2134 (Roberts, C.J., concurring in the judgment) (citation omitted); accord Whole Woman's Health, 136 S. Ct. at 2311, and therefore at most indicate that lesser burdens can contribute to an undue burden on the ultimate ability to obtain an abortion, not that lesser burdens on preferred methods are sufficient by themselves despite the availability of reasonable alternatives.

In any event, respondents' proposed limitation of Gonzales fails on its own terms. For instance, they contend (Opp. 26-28)

that the abortion method outlawed in Gonzales was less prevalent than medication abortion is today, but the popularity of medication abortion consistent with the safety requirements has no bearing on whether the FDA must allow, for the first time, medication abortion without those requirements. Likewise, respondents' assertion that any method of abortion requiring in-person contact undeniably imposes "greater COVID-19 risk," Opp. 26, even if true, would say nothing about whether medication abortion without the safety requirements imposes greater risk overall given the serious complications associated with Mifeprex. Under such conditions of "medical uncertainty," "[c]onsiderations of marginal safety, including the balance of risks," are not within the province of the judiciary. Gonzales, 550 U.S. at 166. Rather, Congress has tasked the FDA with determining whether a particular restriction is "necessary to ensure that the benefits of the drug outweigh the risks." 21 U.S.C. 355-1(a)(1).[2]

[2] Respondents contend that the government has "inflate[d] the risks" associated with Mifeprex "by a factor of 70" because "major adverse events" are rare. Opp. 8 (brackets and citation omitted). That is misleading. The drug's current labeling warns that "[a]bout 2 to 7 out of 100 women taking Mifeprex will need a surgical procedure," including "to stop bleeding." D. Ct. Doc. 1-3, at 18 (May 27, 2020). Rather than dispute the accuracy of that labeling, respondents ignore it, focusing only on the FDA's separate conclusion that Mifeprex could result in "[m]ajor adverse events including death, hospitalization, [and] serious infection," and that those events are "below 0.1%" and thus "exceedingly rare." D. Ct. Doc. 62-11, at 49 (June 10, 2020).

b. Respondents likewise do not account for this Court's admonition that merely "incidental effect[s]" on abortion access do not render an otherwise valid law unconstitutional, Casey, 505 U.S. at 874, especially when those effects are "not of [the government's] own creation," Harris v. McRae, 448 U.S. 297, 316 (1980). They make no attempt to explain how the burdens alleged here are anything more than the ordinary risks and hardships of life during the unforeseen COVID-19 pandemic, even though they, as challengers to an abortion regulation, bear the "burden to present evidence of causation," Whole Woman's Health, 136 S. Ct. at 2313.

Instead, respondents try to obscure these central premises by pointing to inapposite cases. For example, they observe (Opp. 30-31) that Casey deemed Pennsylvania's spousal-notification requirement unconstitutional notwithstanding the Commonwealth's lack of responsibility for domestic abuse. But that holding at most reflects an implicit conclusion that the government cannot disavow causal responsibility for the actions of a third party when the purpose and effect of its challenged regulation is to involve the third party in the woman's ultimate decision. See Casey, 505 U.S. at 897 (observing that the spousal-notification requirement gave an abusive husband "an effective veto over his wife's decision"); see also Hodgson v. Minnesota, 497 U.S. 417, 450-451 (1990) (adopting similar analysis for two-parent notification requirement). Likewise, the discussions in Whole

Woman's Health and June Medical concerning "poverty among abortion patients," Opp. 31, at most suggest that when the government adopts an abortion regulation, it must take into consideration the existing circumstances of the women the regulation governs. None of those authorities remotely indicates that the government must revisit longstanding abortion regulations whenever an unforeseen, temporary event happens to occur. Otherwise, for example, the mandatory 24-hour waiting period that was upheld in Casey, even though it necessitated "at least two visits to the doctor," would be imperiled if the pandemic or some other unexpected event temporarily exacerbates that requirement's "effect of 'increasing the cost and risk of delay of abortions.'" 505 U.S. at 886 (citation omitted).

c. In any event, respondents fail to explain how the pandemic's interaction with the safety requirements creates a substantial obstacle to abortion access. They do not contend that visiting a clinic to obtain Mifeprex is riskier than going anywhere else during the current public-health crisis. Nor do they dispute that women who wish to obtain a medication-abortion drug by mail are in the same position as women for whom Mifeprex is not approved at all (such as those with more advanced pregnancies). And they never claim that women in the latter situation face a substantial obstacle to abortion access, even during the pandemic.

Instead, respondents principally argue (Opp. 24-25) that the FDA did not introduce evidence supporting its position before the district court. But it was respondents' burden to prove, "'by a clear showing,'" that an alleged obstacle is substantial in order to obtain the "drastic remedy" of a preliminary injunction, not the FDA's responsibility to prove a negative. Mazurek v. Armstrong, 520 U.S. 968, 972 (1997) (per curiam) (citation and emphasis omitted). And respondents cannot carry that burden merely by observing (Opp. 24) that the government, based on its assessment of context-specific risks and benefits, has encouraged telehealth services as a general matter and declined to enforce some in-person requirements for other drugs. Respondents ignore that, despite the government's general encouragement of telemedicine during the pandemic, the FDA has not announced its intent to exercise its enforcement discretion with respect to "in-person dispensing or administration requirement[s]" for "15 other drugs" in addition to Mifeprex. Appl. App. 67a. And the few cases in which the FDA has done so are, as even the district court recognized, readily distinguishable. See id. at 65a-68a.

Respondents fall back to the narrower assertion (Opp. 24) that Mifeprex is "the only drug" that must be dispensed in-person during the pandemic yet may "be self-administered without supervision," but their reliance on that status is unavailing. It merely reflects the FDA's 2016 decision to allow patients to take

Mifeprex at home to provide "increased convenience, autonomy and privacy for the woman." D. Ct. Doc. 62-11, at 64 (June 10, 2020). As explained, the FDA's acceptance of the delay involved with allowing at-home use in light of those considerations does not call into question its 2016 decision to maintain an in-person dispensing requirement in light of its larger concerns about potentially unpredictable delays associated with having patients obtain the drug from pharmacies. See Appl. 23-24.[3]

2. Having failed to establish a substantial obstacle, respondents largely abandon (Opp. 32-33) the district court's alternative holding that it could balance the benefits and burdens of the safety requirements regardless of their effect on abortion access. At most, they contend that the safety requirements' alleged lack of benefits is not "constitutionally irrelevant" because abortion regulations "must be 'reasonably related' to a legitimate interest." Opp. 33 (quoting June Medical, 140 S. Ct. at 2138 & n.2 (Roberts, C.J., concurring in the judgment)). But

[3] For example, the FDA observed that in-home medication abortions allow patients to "be in a convenient, safe place" when "the expected uterine cramping and vaginal bleeding" occur. D. Ct. Doc. 62-11, at 43; see Appl. 23. Respondents object (Opp. 36 n.12) that it is "the second drug in the medication abortion regimen, taken 24 to 48 hours after" Mifeprex, that "causes the bleeding and cramping." But that does not refute the more fundamental point that the FDA's willingness to tolerate any delay associated with the in-home use of both drugs does not render its concern about delays in obtaining Mifeprex unfounded. See ibid. (acknowledging that the decision to permit in-home use of Mifeprex was based on "the benefits" of that option); id. at 9 (same).

this minimal requirement plainly is satisfied here. Cf. Gonzales, 550 U.S. at 158 (observing that so long as the government "does not impose an undue burden," it needs only "a rational basis to act"). Despite their assertion (Opp. 34) that the safety requirements "provided no medical benefit even before the pandemic," neither they nor the district court contend that the FDA's original decision to impose the requirements in 2000, and its subsequent decisions to reaffirm them in 2011, 2013, and 2016, were themselves unconstitutional.

For good reason: even assuming for the moment respondents' erroneous premise that the safety requirements have "no medical benefit," Opp. 34, Casey "'squarely foreclosed'" any argument that a law not posing a substantial obstacle is "invalid" merely because it lacks "'any health basis,'" June Medical, 140 S. Ct. at 2138 (Roberts, C.J., concurring in the judgement) (quoting Mazurek, 520 U.S. at 973). Thus, in Mazurek, even if "all health evidence contradict[ed] the claim that there is any health basis" for a law providing that only physicians could provide abortions, that did not mean that the requirement lacked a reasonable relation to a legitimate purpose. 520 U.S. at 973 (citation omitted). Rather, this Court explained, "the Constitution gives the States broad latitude to decide that particular functions may be performed only by licensed professionals," which was sufficient to foreclose an

undue-burden claim given the absence of a substantial obstacle. Ibid. (quoting Casey, 505 U.S. at 885).

In any event, respondents' attempt (Opp. 33-39) to brush aside the benefits of these longstanding requirements fails even on its own terms. In respondents' view, the FDA has declined to enforce in-person requirements for comparably dangerous drugs, the FDA should trust prescribers to do what is best, and the risks the FDA sought to address are insufficiently likely to occur. But as explained (Appl. 24-25), the FDA is allowed to, and indeed must, evaluate the risks of each drug individually. As the district court acknowledged, Congress has mandated that the FDA must consider factors including "the estimated size of the population likely to use the drug, the seriousness of the condition to be treated, the expected benefits of the drug, the duration of treatment with the drug, the seriousness of potentially adverse events, and the drug's molecular entity." Appl. App. 67a (citing 21 U.S.C. 355-1(a)(1)(A)-(F)). By contrast, Congress has not required the FDA to assume that prescribers will always exercise sound judgment on their own. See Appl. 22-23. Nor is the FDA barred from taking precautions to address the "serious complications" that respondents acknowledge Mifeprex can cause, Opp. 35, merely because most women will not experience them. Indeed, that is precisely the sort of judgment that the FDA was established to make.

B. The Nationwide Injunction Is Overbroad

Respondents fare no better in their defense of the nationwide scope of the preliminary injunction. They do not dispute that as a general matter, nationwide injunctions transgress both Article III and equitable principles. Appl. 26-30. Instead, they defend (Opp. 39, 42) this nationwide injunction as justified given the "unique and narrow circumstances," and argue that it presents a "poor vehicle" for addressing the larger problems with this growing practice. But their handful of allegedly case-specific defenses do not address the enduring defects common to all nationwide injunctions, this one included.

Respondents principally seek to justify (Opp. 39-40, 42-43) the nationwide injunction here on the basis of the scope of the membership of their organizations. But respondents cannot claim to represent the interests of all patients who seek an abortion using Mifeprex or their providers. Rather, even under the district court's analysis, they have established that only one physician member (Dr. Paladine) of only one of respondent organizations (the New York State Academy of Family Physicians) has standing to bring a substantive-due-process claim on behalf of her patients. Appl. App. 30a. Respondents offer no reason why providing relief to patients of other physicians throughout the country -- some of whom may agree with the safety requirements -- is in any way necessary to prevent the asserted injuries to that physician's

patients during these proceedings. And even if respondent organizations may have standing to sue on the basis of a member's injuries, Opp. 40, that does not excuse them from their separate duty to "demonstrate standing separately for each form of relief sought," because "standing is not dispensed in gross," Town of Chester v. Laroe Estates, Inc., 137 S. Ct. 1645, 1650 (2017) (citations omitted).

Respondents' remaining points are no more persuasive. They contend that this injunction "avoids 'practical, administrative complexities' " that could burden "the FDA," Opp. 44 (citation omitted), but ignore that the appropriate party to account for such considerations is the FDA. Appl. 31-32. They also observe (Opp. 40) that "this is the sole lawsuit of its kind," but all that shows is that suits seeking nationwide injunctions reduce the incentives for non-parties to bring challenges themselves. That is both inequitable to the government (which effectively must litigate a one-way class action) and also imprudent for the judiciary (which loses the benefits of percolation of complex legal questions). See Department of Homeland Sec. v. New York, 140 S. Ct. 599, 600 (2020) (Gorsuch, J., concurring in the grant of stay). Respondents further note (Opp. 43) that the safety requirements establish a "uniform nationwide scheme," but that observation would justify a nationwide injunction of any rule of general applicability, even though the scope of the plaintiff's

injury, not the defendant's policy, should determine the permissible breadth of a remedy. Appl. 30-31. And the "time-limited" nature of the injunction here, Opp. 41, only counsels in favor of a stay. Respondents should not be permitted to put the Mifeprex safety requirements on hold during the pandemic after a "single loss" by the government, New York, 140 S. Ct. at 601 (Gorsuch, J., concurring), and then evade review here based on their "hopes" that the pandemic will be over before this Court can hear the case, Opp. 41.

III. THE REMAINING FACTORS WEIGH IN FAVOR OF A STAY

Respondents do not dispute that the FDA suffers irreparable harm whenever it is enjoined from enforcing requirements adopted to protect patient safety. Nor do they contest that even if the agency ultimately prevails on the merits, the risks to patients caused by the injunction, and any harms that materialize, cannot be undone. And they do not explain why those injuries to the government and the public are outweighed by any burdens associated with a one-time clinic visit to secure a drug that is merely one method of obtaining an abortion. See Appl. 32-33.

Instead, respondents contend (Opp. 45-46) that the nationwide injunction here does not irreparably harm the FDA or the public because the agency has announced its intent to exercise enforcement discretion with respect to "other kinds of in-person requirements" and because prescribers will use their "medical judgment to provide

care to their patients in the safest possible manner." But all that these contentions establish is that respondents' position on the equities collapses into their arguments on the merits. Accordingly, this Court should enter a stay if it concludes that the government is likely correct that respondents have not shown a substantial obstacle merely by identifying inapposite regulatory decisions concerning other drugs and elevating the status of abortion providers above the FDA, see supra pp. 8-11.

CONCLUSION

This Court should stay the district court's injunction 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.

JEFFREY B. WALL
Acting Solicitor General

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