SUPREME COURT OF THE UNITED STATES

No. 20A34

FOOD AND DRUG ADMINISTRATION, ET AL. *v.*
AMERICAN COLLEGE OF OBSTETRICIANS
AND GYNECOLOGISTS, ET AL.

ON APPLICATION FOR STAY

[January 12, 2021]

The application for stay presented to THE CHIEF JUSTICE and by him referred to the Court is granted, and the district court's July 13, 2020 order granting a preliminary injunction is stayed pending disposition of the appeal in the United States Court of Appeals for the Fourth Circuit and disposition of the petition for a writ of certiorari, if such writ is timely sought. Should the petition for a writ of certiorari be denied, this stay shall terminate automatically. In the event the petition for a writ of certiorari is granted, the stay shall terminate upon the sending down of the judgment of this Court.

JUSTICE BREYER would deny the application.

CHIEF JUSTICE ROBERTS, concurring in the grant of application for stay.

The question before us is not whether the requirements for dispensing mifepristone impose an undue burden on a woman's right to an abortion as a general matter. The question is instead whether the District Court properly ordered the Food and Drug Administration to lift those established requirements because of the court's own evaluation of the impact of the COVID–19 pandemic. Here as in related contexts concerning government responses to the pandemic, my view is that courts owe significant deference to the politically accountable entities with the "background,

competence, and expertise to assess public health." *South Bay United Pentecostal Church* v. *Newsom*, 590 U. S. ___, ___ (2020) (ROBERTS, C. J., concurring in denial of application for injunctive relief) (slip op., at 2). In light of those considerations, I do not see a sufficient basis here for the District Court to compel the FDA to alter the regimen for medical abortion.

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JUSTICE SOTOMAYOR, with whom JUSTICE KAGAN joins, dissenting from grant of application for stay.

The majority of American women seeking abortion care during the first 10 weeks of pregnancy rely on medication abortion. Medication abortion involves taking two prescription drugs, mifepristone and misoprostol, which together induce the equivalent of an early miscarriage. The Food and Drug Administration (FDA) allows patients to receive all physician consultations for a medication abortion virtually and to take both prescriptions at home without medical supervision. To obtain mifepristone, however, the FDA requires patients to go to a hospital, clinic, or medical office to pick up the drug in person and sign a disclosure form.[1] Of the over 20,000 FDA-approved drugs, mifepristone is the only one that the FDA requires to be picked up in person for patients to take at home.

The FDA's unique treatment of mifepristone has become even more pronounced during the COVID–19 pandemic. After the Secretary of Health and Human Services (HHS) declared the COVID–19 pandemic a public health emergency, the FDA and HHS waived in-person requirements

[1] Misoprostol, meanwhile, can be obtained through a retail or mail-order pharmacy.

for several other drugs, including certain controlled substances, but not for mifepristone. As a result, Government policy now permits patients to receive prescriptions for powerful opioids without leaving home, yet still requires women to travel to a doctor's office to pick up mifepristone, only to turn around, go home, and ingest it without supervision.

In July, a District Court enjoined the FDA's in-person dispensing and signature requirements for mifepristone for the duration of the COVID–19 pandemic. Today, the Court grants extraordinary relief to reinstate them. Because the FDA's policy imposes an unnecessary, unjustifiable, irrational, and undue burden on women seeking an abortion during the current pandemic, and because the Government has not demonstrated irreparable harm from the injunction, I dissent.

I

A

As of early January, the United States has endured over 20 million reported COVID–19 cases and over 350,000 deaths from the disease.[2] COVID–19 spreads easily from person to person and many individuals infected by COVID–19 display no symptoms. The Centers for Disease Control and Prevention (CDC) have therefore advised people to avoid close contact with others, especially in indoor spaces, to the greatest extent possible.[3] The COVID–19 pandemic has thus made many typical activities more difficult and dangerous. A trip to the doctor's office is no exception.

As a result, the Federal Government has urged

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[2] See CDC, United States COVID–19 Cases and Deaths by State (updated Jan. 6, 2021), https://covid.cdc.gov/covid-data-tracker/#cases_casesper100k.

[3] See CDC, Things To Know About the COVID–19 Pandemic (updated Dec. 31, 2020), https://www.cdc.gov/coronavirus/2019-ncov/your-health/need-to-know.html.

healthcare providers and patients to take advantage of telemedicine. For example, the CDC has advised medical providers to use telemedicine "whenever possible" because it is "the best way to protect patients and staff from COVID–19."[4] The CDC has likewise informed patients that they should use telemedicine "[t]o reduce the risk of COVID–19 and keep you and your family healthy."[5] As mentioned above, the FDA and HHS have waived many in-person drug distribution requirements because they could "put patients and others at risk for transmission of the coronavirus."[6] For instance, the FDA no longer requires patients to undergo in-person procedures, such as laboratory tests or MRIs, before being prescribed certain drugs. Similarly, HHS now permits physicians to use telemedicine, rather than in-person evaluations, before prescribing certain controlled substances, including opioids.

The Government has thus recognized that in-person healthcare during the COVID–19 pandemic poses a significant risk to patients' health, and it has acted to help patients "'access healthcare they need from their home, without worrying about putting themselves or others at risk during the COVID–19 outbreak.'"[7] Yet the Government has refused to extend that same grace to women seeking

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[4] See CDC, Prepare Your Practice for COVID–19 (updated June 12, 2020), https://www.cdc.gov/coronavirus/2019-ncov/hcp/preparedness-resources.html.

[5] See CDC, Telemedicine: What Does It Mean and Why Should You Care? (updated Sept. 15, 2020), https://www.cdc.gov/coronavirus/2019-ncov/downloads/global-covid-19/Telemedicine-Factsheet-MIT.pdf.

[6] FDA, Policy for Certain REMS Requirements During the COVID–19 Public Health Emergency: Guidance for Industry and Health Care Professionals 7 (Mar. 2020), https://www.fda.gov/media/136317/download.

[7] Dept. of Health & Human Servs., Secretary Azar Announces Historic Expansion of Telehealth Access To Combat COVID–19 (Mar. 17, 2020), https://www.hhs.gov/about/news/2020/03/17/secretary-azar-announces-historic-expansion-of-telehealth-access-to-combat-covid-19.html.

medication abortions. Women must still go to a clinic in person to pick up their mifepristone prescriptions, even though physicians may provide all counseling virtually, women may ingest the drug unsupervised at home, and any complications will occur long after the patient has left the clinic.

B

This summer, representatives of the Nation's healthcare providers, including the American College of Obstetricians and Gynecologists (ACOG) and the Council of University Chairs of Obstetrics and Gynecology (CUCOG), along with SisterSong Women of Color Reproductive Justice Collective, filed suit to enjoin the Federal Government from enforcing mifepristone's in-person requirements during the COVID–19 pandemic. In a thorough opinion, the District Court concluded that the in-person requirements likely placed a "substantial obstacle" in the path of women seeking abortions during the pandemic. 472 F. Supp. 3d 183, 216 (D Md. 2020) (internal quotation marks omitted). The court preliminarily enjoined the Government from enforcing mifepristone's in-person requirements during the pandemic. *Id.,* at 233. The Court of Appeals for the Fourth Circuit denied the Government's request for a stay of that injunction. The Government then applied for a stay from this Court.

In early October, this Court issued an order holding the Government's application in abeyance so the District Court could consider a yet-to-be-filed motion from the Government to dissolve, stay, or modify the injunction, "including on the ground that relevant circumstances have changed." 592 U. S. ___ (2020) (slip op., at 1). The Government filed such a motion, but the District Court concluded that no changed circumstances justified a stay or dissolution of the injunction. ___ F. Supp. 3d ___, ___, 2020 WL 7240396, *14 (D Md., Dec. 9, 2020). Indeed, the District Court found that

the pandemic had gotten only worse since the summer. *Id.,* at *7. The number of COVID–19 cases in the United States had increased four-fold, the number of deaths had more than doubled, and the pandemic was expected to intensify in the coming winter months. *Ibid.* The District Court therefore denied the motion.

The Government has now returned to this Court, asking again for a stay of the District Court's injunction. Although the COVID–19 pandemic has only worsened since October, the Court now grants the Government's request.

A stay of a district court's injunction is "'extraordinary'" relief. See *Williams* v. *Zbaraz*, 442 U. S. 1309, 1311 (1979) (Stevens, J., in chambers). "An applicant for a stay must meet a heavy burden of showing not only that the judgment of the lower court was erroneous on the merits, but also that the applicant will suffer irreparable injury if the judgment is not stayed pending his appeal." *Ruckelshaus* v. *Monsanto Co.*, 463 U. S. 1315, 1316 (1983) (Blackmun, J., in chambers) (internal quotation marks omitted); see also *Maryland* v. *King*, 567 U. S. 1301, 1302 (2012) (ROBERTS, C. J., in chambers). The District Court was correct to conclude that the FDA's unique regulation of mifepristone during the COVID–19 pandemic "plac[es] a substantial obstacle in the path of a woman seeking an abortion." *Planned Parenthood of Southeastern Pa.* v. *Casey*, 505 U. S. 833, 877 (1992) (plurality opinion); see also *June Medical Services L. L. C.* v. *Russo*, 591 U. S. ___, ___ (2020) (plurality opinion) (slip op., at 1) ("'"[H]ealth regulations that have the purpose or effect of presenting a substantial obstacle to a woman seeking an abortion"' . . . are . . . 'constitutionally invalid'" (quoting *Whole Woman's Health* v. *Hellerstedt*, 579 U. S. ___, ___ (2016) (slip op., at 1)); *June Medical,* 591 U. S., at ___ (ROBERTS, C. J., concurring in judgment) (slip op., at 11) ("In this case, *Casey*'s requirement of finding a substantial obstacle before invalidating an abortion regulation is . . . a

sufficient basis for the decision"); *id.*, at ___ (ALITO, J., dissenting) (slip op., at 3) ("Under our precedent, the critical question . . . is whether [a] challenged . . . law places a 'substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus'" (quoting *Casey*, 505 U. S., at 877 (plurality opinion))). The Government has moreover failed to demonstrate irreparable harm. For these reasons, I would deny the Government's request.

II

A

Due to particularly severe health risks, vastly limited clinic options, and the 10-week window for obtaining a medication abortion, the FDA's requirement that women obtain mifepristone in person during the COVID–19 pandemic places an unnecessary and undue burden on their right to abortion. Pregnancy itself puts a woman at increased risk for severe consequences from COVID–19. In addition, more than half of women who have abortions are women of color, and COVID–19's mortality rate is three times higher for Black and Hispanic individuals than non-Hispanic White individuals. On top of that, three-quarters of abortion patients have low incomes, making them more likely to rely on public transportation to get to a clinic to pick up their medication. Such patients must bear further risk of exposure while they travel, sometimes for several hours each way, to clinics often located far from their homes.[8] Finally,

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[8] For instance, according to the most recently available data, Arkansas has just three abortion clinics, and 77% of women of childbearing age live in a county without any clinic. Mississippi has just one abortion clinic, and 91% of women of childbearing age live in a county without any clinic. Missouri has just three abortion clinics, and 78% of women of childbearing age live in a county without a clinic. North Dakota has just one abortion clinic, and 72% of women of childbearing age live in a county without any clinic. See Guttmacher Institute, R. Jones, E. Witwer, & J. Jerman, Abortion Incidence and Service Availability in the United States, 2017, pp. 17–18 (2019).

minority and low-income populations are more likely to live in intergenerational housing, so patients risk infecting not just themselves, but also elderly parents and grandparents. These risks alone are significant deterrents for women seeking a medication abortion that requires in-person pickup.

The obstacles are even greater, however, because medical offices have dramatically reduced availability during the pandemic. The District Court received unrebutted evidence that some healthcare facilities that normally provide medication abortion services have closed at various times during the pandemic, making it impossible for women to pick up their mifepristone. Even those practices that remain open may operate at decreased capacity to maintain social distancing, sometimes seeing just 10% to 25% of their typical patient load. One doctor described how the pandemic caused her hospital system to stop in-person visits to all but three primary care clinics. Abortion patients were referred to distantly located family planning clinics that were open only a half day per week.[9]

The District Court found that these obstacles can cause women to miss the 10-week window for a medication abortion altogether. The average American woman does not discover that she is pregnant until 5.5 weeks, and nearly a quarter of women do not discover their pregnancies until 7

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[9] Data has begun to bear out the difficulties women have faced in accessing reproductive care. In a June 2020 survey, one in three women reported that they had delayed or canceled a visit for sexual or reproductive care or had trouble accessing birth control during the pandemic. See L. Lindberg, A. VandeVusse, J. Mueller, & M. Kirstein, Early Impacts of the COVID–19 Pandemic: Findings From the 2020 Guttmacher Survey of Reproductive Health Experiences, p. 4 (June 2020), https://www.guttmacher.org/report/early-impacts-covid-19-pandemic-findings-2020-guttmacher-survey-reproductive-health. Such delays were higher among Black, Hispanic, and low-income women. *Ibid.*

weeks or later.[10] A woman seeking a medication abortion may therefore be left with fewer than three weeks to find an accessible clinic that will provide mifepristone, schedule and receive the required counseling,[11] and make an appointment to collect the medication in person, all while trying to determine the safest way to travel to the clinic and perhaps wondering whether she will bring COVID–19 back home with her.

What rejoinder does the Government have to the possibility that refusing to suspend the FDA's in-person requirements for mifepristone during the COVID–19 pandemic will cause some women to miss the 10-week window altogether? No cause for concern, the Government assures this Court, because even if the FDA's in-person requirements cause women to lose the opportunity for a medication abortion, they can still seek out a surgical abortion. What a callous response.

As the Government acknowledges, surgical abortions are far more invasive than medication abortions. Medication abortion involves taking two pills and the equivalent of an early miscarriage. When a woman undergoes surgical abortion, she requires local anesthesia and sometimes sedation, her cervix is stretched with dilating rods, a tube is inserted through her cervix into her uterus, and, depending on the particular procedure, various medical tools are used to remove fetal tissue from her uterus. On top of this, surgical abortions carry all the same (and likely greater) risks of exposure to COVID–19 as do medication abortion's in-person requirements.

The Government insists that requiring women to un-

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[10] See Branum & Ahrens, Trends in Timing of Pregnancy Awareness Among US Women, 21 Maternal & Child Health J. 715, 719, 721–722 (2017).

[11] The required counseling can take place in person or via telemedicine, although the patient must then sign a disclosure form in person.

dergo a far more invasive abortion procedure does not impose an undue burden on women's right to abortion. In support, the Government points to *Gonzales* v. *Carhart*, 550 U. S. 124 (2007), in which this Court held that a ban on a rare, second-trimester abortion procedure was not unconstitutional, in part because "the vast majority" of second-trimester abortions remained available. *Id.*, at 156. This Court has never held that the Government can ban one of the most common and safest early abortion procedures without running into constitutional problems. Indeed, in *Stenberg* v. *Carhart*, 530 U. S. 914 (2000), this Court concluded that a state ban on dilation and evacuation abortion, "the most commonly used method for performing previability second trimester abortions," imposed an undue burden on the right to choose abortion itself. *Id.*, at 945–946. The same reasoning extends to a regulation that, when applied in the context of a deadly pandemic, prevents women from accessing the most commonly used and safest method for early abortions.

The Government also argues that the pandemic has not caused the FDA's regulation to impose a meaningful burden on women seeking medication abortions because in two States that independently require in-person visits for medication abortions (Indiana and Nebraska), there were more abortions in 2020 than in 2019. This comparison, however, provides little insight. For one, the Government does not compare Indiana and Nebraska to States where the in-person requirements for medication abortion have been suspended, which may have seen even larger increases over 2019. Second, the Government provides data for just two years, so it impossible to know whether the two States simply saw an unusually low number of abortions in 2019. Finally, the data does not distinguish between medication and surgical abortions. For all anyone can tell, then, Indiana and Nebraska may have seen a large increase in surgical abortions and a reduction in medication abortions. For

the reasons discussed above, these procedures are not equivalent. Reading the Government's statistically insignificant, cherry-picked data is no more informative than reading tea leaves.

Together, patients' health vulnerabilities, public transportation risks, susceptible older family members at home, and clinic closures and reduced services pose substantial, sometimes insurmountable, obstacles for women seeking medication abortions during the COVID–19 pandemic. See *June Medical*, 591 U. S., at ___–___ (plurality opinion) (slip op., at 31–35); *id.*, at ___–___ (ROBERTS, C. J., concurring in judgment) (slip op., at 11–16); *Hellerstedt*, 579 U. S., at ___–___ (slip op., at 34–36). Under these conditions, the in-person requirements for mifepristone impose an unjustifiable and undue burden on a woman's constitutional right to an abortion.

B

The District Court was therefore correct on the merits. But even if it were not, the Government has not shown that it will suffer any irreparable harm absent a stay of that court's injunction. The Government argues that all injunctions against a government inherently cause irreparable harm, especially for agencies charged with protecting public health, and that courts should look no further. This Court's precedent does not support such a sweeping rule. See, *e.g., Williams*, 442 U. S., at 1312–1314 (considering whether a state public health agency had shown irreparable harm from an injunction requiring the State to fund medically necessary abortions).

The Government points to no meaningful concrete harms. It argues only that the in-person requirements mitigate health risks from mifepristone "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." Application for Stay of Injunction 33. The former concern is undermined by the fact that patients may receive physician counseling remotely. The latter concern makes no sense: The Government proposes to avoid delays by limiting women's options to obtain care quickly. Indeed, the evidence before the District Court shows that the in-person requirements are causing, not preventing, delays in obtaining critical healthcare. Significantly, the FDA's in-person requirements for mifepristone have now been suspended for six months, yet the Government has not identified a single harm experienced by women who have obtained mifepristone by mail or delivery.

C

The concurrence argues that courts should nonetheless defer to the FDA's decision not to lift mifepristone's in-person requirements during the pandemic. I agree that deference is due to reasoned decisions of public health officials grappling with a deadly pandemic. See *South Bay Pentecostal Church* v. *Newsom*, 590 U. S. ___, ___ (2020) (ROBERTS, C. J., concurring in denial of application for injunctive relief) (slip op., at 2); see also *Roman Catholic Diocese of Brooklyn* v. *Cuomo*, 592 U. S. ___, ___ (2020) (SOTOMAYOR, J., dissenting) (slip op., at 2) (citing medical expert declarations supporting challenged responses to the current pandemic). But the record here is bereft of any reasoning. The Government has not submitted a single declaration from an FDA or HHS official explaining why the Government believes women must continue to pick up mifepristone in person, even though it has exempted many other drugs from such a requirement given the health risks of COVID–19. There simply is no reasoned decision here to which this Court can defer. Cf. *Democratic National Committee* v. *Wisconsin State Legislature*, 592 U. S. ___, ___ (2020) (KAGAN, J., dissenting in denial of application to va-

cate stay) (slip op., at 7) (deference not due where the government "has not for a moment considered whether recent COVID conditions demand changes").

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This country's laws have long singled out abortions for more onerous treatment than other medical procedures that carry similar or greater risks. See Greenhouse & Siegel, Casey and the Clinic Closings: When "Protecting Health" Obstructs Choice, 125 Yale L. J. 1428, 1430 (2016). Like many of those laws, maintaining the FDA's in-person requirements for mifepristone during the pandemic not only treats abortion exceptionally, it imposes an unnecessary, irrational, and unjustifiable undue burden on women seeking to exercise their right to choose. One can only hope that the Government will reconsider and exhibit greater care and empathy for women seeking some measure of control over their health and reproductive lives in these unsettling times. See *Gonzales*, 550 U. S., at 172 (Ginsburg, J., dissenting) ("[Women's] ability to realize their full potential . . . is intimately connected to their ability to control their reproductive lives" (internal quotation marks omitted)). For now, I respectfully dissent.