No. 20A34

In the

Supreme Court of the United States

U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,

Applicants,

v.

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, *et al.*,

Respondents.

RESPONSE IN OPPOSITION TO APPLICATION FOR A STAY OF THE PRELIMINARY INJUNCTION ISSUED BY THE U.S. DISTRICT COURT FOR THE DISTRICT OF MARYLAND

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STATEMENT PURSUANT TO SUPREME COURT RULE 29.6

Pursuant to Supreme Court Rule 29.6, the undersigned states that Plaintiffs-Respondents American College of Obstetricians and Gynecologists, Council of University Chairs of Obstetrics and Gynecology, and SisterSong Women of Color Reproductive Justice Collective do not have any parent corporations.

Plaintiff-Respondent New York State Academy of Family Physicians is a chapter of the American Academy of Family Physicians.

No publicly held corporation holds 10 percent or more of any of Plaintiffs-Respondents' stock.

INTRODUCTION

This case asks whether, during the national emergency declared because of the COVID-19 pandemic, Defendants can force patients seeking early abortion care and their health care providers to unnecessarily risk exposure to a life-threatening disease by mandating that patients travel to a health center for the sole purpose of picking up a pill and signing a form. Plaintiffs-Respondents ("Plaintiffs") include membership organizations representing more than 60,000 physicians and the department chairs of obstetrics and gynecology at nearly 150 universities across the United States. Dkt. 11-5, ¶ 3; Dkt. 11-8, ¶ 3; Dkt. 11-11, ¶ 5.[1] Acting to protect their patients and themselves from COVID-19, which has infected more than six million people in the United States and killed nearly 200,000, Plaintiffs sought time-limited relief from a U.S. Food and Drug Administration ("FDA") requirement that makes unnecessary COVID-19 risk a condition of obtaining or prescribing mifepristone, a safe and effective medication used to end an early pregnancy. On July 13, the U.S. District Court for the District of Maryland preliminarily enjoined enforcement of certain aspects of the challenged restriction for the duration of Defendants-Applicants' ("Defendants") COVID-19 Public Health Emergency ("PHE"). *See* Appendix ("App.") 1a-82a, 92a-94a. On August 13, a unanimous Fourth Circuit panel denied Defendants' motion for a stay of the injunction pending appeal. *Id.* at 85a-86a.

[1] All references to the "Dkt." are citations to Case No. TDC-20-1320 in the U.S. District Court for the District of Maryland. All references to the "4th Cir. Dkt." are citations to Case No. 20-1824 in the U.S. Court of Appeals for the Fourth Circuit.

Defendants now ask this Court to step in while this case is before the court of appeals and strip the nation's health care providers—including Plaintiffs American College of Obstetricians and Gynecologists ("ACOG") and Council of University Chairs of Obstetrics and Gynecology ("CUCOG"), supported by *amici* including American Medical Association ("AMA")—of the urgent relief they need to protect their own safety and that of their patients, staff, and families during the pandemic. Defendants have not met the "especially heavy burden" they bear on such an overriding stay petition. *Edwards v. Hope Med. Grp. for Women*, 512 U.S. 1301, 1302 (1994) (Scalia, J., in chambers) (quotation marks and citation omitted).

Recognizing the importance of avoiding travel and interpersonal contact during the PHE, Defendants have taken "extraordinary actions" to reduce viral transmission by suspending in-person requirements for drugs, including potentially lethal controlled substances like opioids, and urging the use of telemedicine "whenever possible." App. 43a-44a. However, when it comes to medication abortion, the FDA forces patients to travel to a hospital, clinic, or medical office just to pick up the medication and sign a form (the "Requirements")—even though the agency does not require any in-person examination, any in-person counseling, or that the patient swallow the pill while in the office. Of more than 20,000 FDA-approved drugs, mifepristone is the *only* one that patients must pick up in person in a clinical setting but are permitted to self-administer elsewhere, unsupervised. App. 5a; Dkt. 11-3, ¶ 58. Because of Defendants' Requirements, patients who have been previously evaluated and counseled by a clinician at a prior in-person visit or telemedicine

appointment are forced to travel to a health center during the pandemic *just* to be handed a pill and sign a form—and these patients, their doctors, and other essential workers are all needlessly exposed to greater risk of contracting COVID-19 for this ministerial function.

The district court entered a preliminary injunction because it found that Plaintiffs were likely to succeed on their claim that requiring unnecessary in-person visits to obtain mifepristone during the pandemic imposes an undue burden on the right to abortion, and that, absent an injunction, Plaintiffs and their patients would suffer irreparable harm. The district court's holding that, during the PHE, the Requirements' "burdens alone" constitute a substantial obstacle, App. 49a-50a, 61a-62a, is sufficient to support the injunction. There is simply no evidence in the record on which this Court could find that the district court acted in error, much less clear error: Defendants offered not a single declaration to rebut Plaintiffs' extensive expert testimony that the Requirements impose serious and unnecessary COVID-19 risk. Indeed, it was to avoid precisely this risk that Defendants suspended mandatory in-person visits for so many other drugs during the PHE. *See* App. 10a, 43a-44a. Nor do Defendants dispute that pregnancy itself renders people especially vulnerable to COVID-19, or that the vast majority of those affected by Defendants' Requirements are low-income and people of color, who face disproportionately high risk of both exposure to and severe illness and death from COVID-19. *Id.* at 46a-47a.

While not necessary to sustain the injunction, Defendants also fall far short of establishing that the district court committed clear error in what Defendants concede

was an "alternative" holding, Defs.' Appl. Stay Inj. ("Stay Pet.") 8: that the Requirements do not advance any safety benefit and indeed endanger patients, a finding endorsed by the nation's preeminent medical associations, *see generally* Br. of American Medical Association et al. as Amici Curiae Supporting Resp'ts (Sept. 8, 2020) ("AMA et al. Amicus Br."), and therefore that the Requirements' serious burdens substantially outweigh their benefits. App. 51a, 59a.

Defendants assert only two justifications for maintaining the Requirements in the pandemic, and neither withstands review. *First*, Defendants speculate that the Requirements provide "*an opportunity* for in-person counseling" at the time of dispensing, App. 54a (emphasis added), which "*might be* more effective . . . at communicating risks," Stay Pet. 22 (emphasis added). However, Defendants do not dispute the court's finding that "telemedicine is now in widespread use, including as an effective means to provid[e] counseling relating to medication abortion," App. 55a, nor explain why, if in-person dispensing is necessary, Stay Pet. 21, Defendants impose this requirement on mifepristone—for which serious complications are, in the FDA's words, "exceedingly rare"—but not on virtually any other drugs, including highly addictive and potentially lethal opioids like fentanyl, App. 5a, 59a.[2]

Second, Defendants argue that the Requirements "*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," Stay Pet. 21 (emphasis added); *id.* at 6, 23,

[2] U.S. Food & Drug Admin., *Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS)* 7 (last modified Aug. 2017), https://www.accessdata.fda.gov/drugsatfda_docs/rems/TIRF_2017-09-07_Full.pdf (authorizing pharmacies to dispense fentanyl).

33. This ignores that the injunction does not permit dispensing by local pharmacies, App. 58a, 80a; it only allows FDA-certified prescribers to dispense mifepristone by mail or delivery rather than in person, *id.* at 93a. And, far from ensuring timely access, the court found that the Requirements delay access to care due to office closures and by forcing patients to raise funds for and arrange unnecessary travel and childcare during a pandemic and "severe economic crisis." *Id.* at 49a-50a.

Defendants' request for a stay of this fact-bound, time-limited preliminary injunction rests on two novel legal theories, both incorrect. Defendants first argue that the government is free to unduly burden access to medication abortion because patients could have a surgical abortion instead—even though the latter also involves travel, requires more human contact, and poses greater COVID-19 risk. *See* Stay Pet. 3, 10, 13-19. But four decades of this Court's precedent squarely foreclose Defendants' argument that the government has free rein to restrict medication abortion, the most common method of early abortion care, because patients could instead travel for a *more* invasive surgical procedure that would *magnify* their risks of contracting COVID-19, as long as patients are ultimately able to get an abortion.

Defendants' second argument—that *Planned Parenthood of Southeastern Pennsylvania v. Casey* prohibits courts from considering the interplay between a legal requirement and the real-life circumstances in which it operates, Stay Pet. 15-17—is contradicted by virtually every decision of this Court evaluating restrictions on abortion access. The notion that the risks and harm resulting from Defendants' imposition of the Requirements during the pandemic are somehow "incidental" or out

of Defendants' hands, *see id.*—despite their having created the Requirements, waived in-person requirements for other drugs, but refused to do so here—defies reason.

Defendants' objections to the nationwide scope of the relief also do not support a stay. *See id.* at 26-32. Here, the Organizational Plaintiffs sue on behalf of their tens of thousands of members across all 50 states, App. 73a, in the sole lawsuit of its kind. The court properly found that the administrative complexities of enforcing anything less than a bright-line rule would impede Plaintiffs' ability to obtain full relief. *See id.* at 76a-78a. And, even if the Court were to credit Defendants' objection to the extension of relief to similarly situated nonparties, that would justify at most only a partial stay, leaving in place protection for the plaintiff organizations' 60,000-plus members and their patients. *See id.* at 73a.

The public interest weighs heavily against a full *or* partial stay. The injunction protects not only the right to abortion but the health and lives of patients, essential workers, their families, and communities, as COVID-19 continues to rage across the nation. Defendants cannot show that they face any harm if this Court denies the stay, particularly given that all other FDA regulations on mifepristone—including that prescribers must be specially certified and review with their patients an FDA-approved counseling form—remain in place and can be fully performed without in-person delivery of the pill itself.

Finally, this Court should be especially reluctant to interfere where, as here, granting a stay would likely amount to a final resolution. *See Nat'l Socialist Party of Am. v. Village of Skokie*, 434 U.S. 1327, 1328 (1977) (Stevens, J., in chambers)

(denying stay application that "would be tantamount to a decision on the merits in favor of the applicants"). Defendants have not even sought an expedited appeal in the Fourth Circuit, which would afford them relief if the court of appeals reverses. But if this Court grants a stay, for all practical purposes the case may be finally resolved in Defendants' favor—without Defendants ever having prevailed on the merits.

STATEMENT

Mifepristone Regimen and Safety

Medication abortion, the most common form of early abortion care, *see* AMA et al. Amicus Br. 4, involves taking two prescription pills: mifepristone, followed 24 to 48 hours later by misoprostol, App. 2a. Together, they cause a patient to undergo a pregnancy termination in a manner similar to an early miscarriage. *Id.* at 2a-3a; Dkt. 11-3, ¶ 27. Millions of people have used this regimen, Dkt. 11-3, ¶ 37, which the FDA has approved through the first 10 weeks of pregnancy, App. 6a.

A clinician may assess a patient's eligibility for medication abortion through an in-person examination, or through telemedicine (for patients with regular periods and no risk factors). App. 6a-7a; Dkt. 11-3, ¶ 30. The FDA does not require the patient to undergo a physical examination or any form of testing; it leaves the determination of where and how to assess the patient to the clinician's judgment. App. 6a-7a. During the pandemic, Plaintiff ACOG has issued expert guidance recommending that clinicians perform these assessments remotely for medically eligible patients to mitigate COVID-19 spread. Dkt. 11-3, ¶ 30.

The FDA has acknowledged that mifepristone's safety is "well established by

both research and experience." *Id.* at ¶ 41. Defendants' suggestion that mifepristone "carries serious risks for up to seven percent of patients," Stay Pet. 7, inflates the risks by a factor of 70: as the FDA reported in 2016, "'[m]ajor adverse events . . . are exceedingly rare, generally far below 0.1% for any individual adverse event.'" App. 59a; *see also* AMA et al. Amicus Br. 5-8 (discussing safety of mifepristone).

The FDA's Regulation of Mifepristone

The Requirements and other restrictions on mifepristone are imposed under the FDA's Risk Evaluation and Mitigation Strategies ("REMS") authority, which permits restrictions beyond a drug's labeling for the sole purpose of mitigating clinical risks. 21 U.S.C. § 355-1(a)(1). Defendants have authority to impose penalties for REMS violations against the drug manufacturer and/or individual clinicians. App. 3a, 20a-21a; Dkt. 75.

The most burdensome type of REMS are "Elements to Assure Safe Use" ("ETASU"), *see* 21 U.S.C. § 355-1(f)(3), of which mifepristone has three:

- **ETASU A**: only specially certified clinicians (or those acting under their supervision) may prescribe mifepristone;
- **ETASU C**: mifepristone must be dispensed only in hospitals, clinics, or medical offices under the supervision of a certified prescriber; and
- **ETASU D**: the prescriber and patient must review and sign a form containing information about mifepristone, and the prescriber must give the patient a copy. This counseling need not happen in person: prescribers may conduct all counseling via telemedicine in advance and then merely

obtain a signature when the patient picks up their medication at the clinician's office. App. 56a. All information in this form is also included in a Medication Guide that accompanies the mifepristone pill. *Id.* at 7a.

In 2016, the FDA updated the mifepristone REMS, including removing language stating that patients must take mifepristone at their prescriber's office. *Id.* at 53a. The agency identified "safety" as one of the benefits of allowing patients to take the medication at the time and place of their choosing. Dkt. 62-11, 0589. However, the FDA retained the Requirements described above with "only the following statement as explanation . . . . : 'This ensures that [mifepristone] can only be dispensed by or under the direct supervision of a certified prescriber.'" App. 53a.

Of more than 20,000 FDA-approved drugs, mifepristone and its brand name analogue (Mifeprex®) are among just 17 medications that the FDA requires patients to obtain in a hospital, clinic, or medical office. Mifepristone is the *only* drug the FDA requires to be picked up in person at a clinic but permits patients to take anywhere, unsupervised; all of the few other drugs that must be dispensed by a clinician must also be administered under clinical supervision. App. 5a; Dkt. 11-3, ¶ 58.

Defendants' Actions in Response to the Pandemic

"COVID-19 is a highly contagious and life-threatening respiratory disease caused by the SARS-CoV-2 novel coronavirus that is transmitted through respiratory transmission, including droplet and possibly aerosolized transmission, and the touching of contaminated surfaces." App. 8a. As of July 13, the Centers for Disease Control and Prevention ("CDC"), an HHS sub-agency, reported over three million

U.S. cases and 130,000 deaths, with new daily cases repeatedly surpassing 44,000 in the weeks preceding the injunction. *Id.* As of September 7—just eight weeks later—the number of cases has doubled, and the number of deaths now exceeds 188,000.[3]

Since Defendant Azar declared a COVID-19 PHE, Defendants have taken "extraordinary actions" to mitigate "the health risks associated with patient travel to medical facilities during the pandemic," including by waiving mandatory in-person requirements for drugs in deference to clinicians' medical judgment. App. 9a, 43a-44a. Defendant Azar worked with the U.S. Drug Enforcement Administration to suspend in-person evaluation requirements for controlled substances including opioids, "even though it would mean" such drugs "would be released into the community with fewer safeguards."[4] *Id.* at 10a, 43a-44a. Under this suspension, clinicians are permitted to forgo the mandatory in-person visit for controlled substances as long as "[t]he prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice."[5] In addition, the FDA announced it would not enforce any REMS ETASU requirements mandating laboratory testing or magnetic resonance imaging ("MRI") studies before prescribing

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[3] U.S. Ctrs. for Disease Control & Prevention, *United States COVID-19 Cases and Death By State*, https://covid.cdc.gov/covid-data-tracker/?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fcases-updates%2Fcases-in-us.html#cases (last visited September 7, 2020) (reporting more than 6.2 million cases).

[4] Defendant Azar lifted this requirement during the PHE even though "[o]ne of the highest priorities of the FDA is advancing efforts to address the crisis of misuse and abuse of opioid drugs harming families. Opioids are claiming lives at a staggering rate, and overdoses from prescription opioids are reducing life expectancy in the United States." U.S. Food & Drug Admin., *Opioid Medications* (last updated Aug. 4, 2020), https://www.fda.gov/ drugs/information-drug-class/opioid-medications.

[5] U.S. Dep't of Justice, Drug Enforcement Admin., *COVID-19 Information Page*, https://www.deadiversion.usdoj.gov/ coronavirus.html#TELE (last visited Sept. 7, 2020).

certain drugs that carry serious risks, App. 10a, 43a, as long as "the accommodation is made based on the judgment of a health care professional," Dkt. 11-4, ¶46. And, during the PHE, the FDA is permitting patients to receive prescription-drug samples by mail "for the protection of patients and healthcare providers during the COVID-19 [emergency]." Dkt. 73, 2.[6] More broadly, CDC urges clinicians to use telemedicine "whenever possible" as "the best way to protect patients and staff from COVID-19," and encourages patients to fill prescriptions by mail or delivery. App. 11a-12a.

In March and April 2020, leading medical authorities, including ACOG, "formally requested that [the] FDA agree not to enforce the Requirements during the COVID-19 pandemic." *Id.* at 53a; *see also* Dkt. 1-5; Dkt. 1-6; Dkt. 1-7; Dkt. 1-8. The FDA never responded and "has provided no sign that it has undertaken a formal review of the issue in light of . . . the ongoing pandemic." App. 53a.

The District Court Decision

On May 27, Plaintiffs—including ACOG, a membership organization with tens of thousands of doctors in all fifty states, and CUCOG, a membership organization representing the department chairs of obstetrics and gynecology at nearly 150 universities and hospitals, Dkt. 11-5, ¶ 3; Dkt. 11-8, ¶ 3; Dkt. 11-11, ¶ 5—filed suit and moved for a preliminary injunction limited to the duration of the pandemic, *see* Dkt. 74-1; Dkt. 12. Plaintiffs argued that requiring unnecessary in-person visits during the pandemic to pick up the prescribed medication, when FDA permits all

[6] U.S. Food & Drug Admin., *Temporary Policy on Prescription Drug Marketing Act Requirements for Distribution of Drug Samples During COVID-19 Public Health Emergency* (June 2020), https://www.fda.gov/media/138697/download.

evaluation and counseling to be done through telemedicine and allows patients to self-administer the drugs anywhere without supervision, imposes an undue burden on the right to abortion and violates equal protection. *See id.*

On July 13, the district court granted in part Plaintiffs' motion. The court preliminarily enjoined Defendants from enforcing the REMS during the PHE, "only to the extent that it requires that mifepristone may be dispensed only in clinics, medical offices, or hospitals, rather than by mail or delivery service." App. 93a. The injunction temporarily expands patients' ability to obtain mifepristone in two narrow ways: After assessing a patient either at a prior in-person visit or telemedicine appointment, a certified prescriber can 1) mail or deliver the medication to their patient; or 2) arrange to have the medication shipped directly to the patient from a mail-order pharmacy with whom the prescriber has pre-arranged to stock and mail mifepristone on their behalf. *See id.* at 87a-91a. The injunction does *not* permit clinicians to issue a prescription and then leave patients to their own devices to find a pharmacy that stocks the medication, *see* App. 87a-91a, and in-person dispensing remains available where appropriate for a particular patient, *id.* at 57a. The court enjoined the patient form ETASU "only to the extent" that it requires a clinically unnecessary in-person trip: prescribers are still required to review the information with their patients but no longer need to obtain a physical signature. *Id.* at 92a-94a.

The district court found that Plaintiffs were likely to prevail on their due process claim because Defendants' Requirements "present a serious burden" to patients by forcing them "to decide between forgoing or substantially delaying

abortion care, or risking exposure to COVID-19 for themselves, their children, and family members." *Id.* at 48a. The court's extensive factual findings on burdens relied on Plaintiffs' unrebutted expert testimony,[7] as well as Defendants' own suspension of restrictions on other drugs, which "effectively acknowledged that the COVID-19 pandemic has created a significant burden upon patients and the public that renders travel to medical facilities fraught with health risk to themselves" and "the members of their households to whom they return." App. 42a-45a.

The court found that "abortion patients generally face more significant health risks arising from traveling to a medical facility during the pandemic." *Id.* at 46a. That conclusion rested on multiple undisputed findings. *First*, "CDC has specifically identified pregnancy as a condition that may place an individual at increased risk for severe illness from COVID-19." *Id.* at 47a. *Second*, "60 percent of women who have abortions are people of color"—including 53 percent identifying as Black or Hispanic—who are more likely to have preexisting health conditions and face "as much as three and half times the risk" of serious illness or death from COVID-19. *Id.* at 46a; Dkt. 11-3, ¶¶ 19, 86. *Third*, abortion patients face greater viral exposure risks

[7] Plaintiffs' witnesses included Arthur Reingold, M.D., the Division Head of Epidemiology at the University of California at Berkeley School of Public Health and a former CDC official, who is currently serving on SARS-CoV-2 advisory boards for the University of California system and the city of San Francisco, Dkt. 11-4; Allison Bryant Mantha, M.D., M.P.H., FACOG, an Associate Professor at Harvard Medical School in the department of Obstetrics, Gynecology, and Reproductive Biology, and the Vice Chair of Quality, Equity and Safety for the OB/GYN department at Massachusetts General Hospital, Dkt. 11-3; Eve Espey, M.D., M.P.H., FACOG, the chair of the OB/GYN department at the University of New Mexico School of Medicine, Dkt. 11-8; Heather Paladine, M.D., M.Ed., FAAFP, an Assistant Attending Physician at New York Presbyterian Hospital and Assistant Professor of Medicine at Columbia University Medical Center, Dkt. 11-5; as well as several other highly qualified physicians who provide medication abortion care as part of their clinical practices.

because of their "particularized" transportation and childcare needs. App. 49a, 61a. The court specifically found that 75 percent of abortion patients are low-income; they are less likely to own a car and more likely to have to share "an enclosed [space] with others" to travel to a health care facility; and travel to the nearest abortion provider may take several hours each way and involve multiple gas and rest stops. *Id.* at 46a-47a, 49a; *see also* AMA et al. Amicus Br. 17-18. *Fourth*, 60 percent of abortion patients already have one child, and "may face serious hurdles in finding any childcare during the COVID-19 crisis," or else "have to accept the risk that bringing someone outside the family into their home to care for their child, or sending their child to someone else's home, will expose them and their family to a potentially deadly virus." App. 48a (quotation marks and citations omitted). *Finally*, people of color and low-income people, who comprise the majority of abortion patients, are more likely to live in intergenerational housing where contracting COVID-19 would put family members, including elderly relatives, at risk. *Id.* at 46a.

The district court found further that the Requirements significantly delay or prevent some patients from obtaining care. *Id.* at 49a-50a. This finding relied on unrebutted evidence of medical offices closing during the pandemic for all in-person services and/or operating at reduced capacity, both of which limit the availability of any abortion care requiring an in-person visit. *Id.* at 45a-46a, 49a-50a. The court also relied on expert testimony and specific factual evidence that patients—particularly the 75 percent of abortion patients with incomes at or below 200 percent of the federal poverty level—face "serious hurdles" finding and paying for transportation and

childcare for an in-person visit due to the pandemic and associated economic crisis. *Id.* at 46a-50a; Dkt. 11-3, ¶ 18. The court found that the resulting delays may "increase the risk from medication abortion . . . or cause the patient to miss the opportunity for a medication abortion such that they must seek a more invasive form of abortion," which itself poses greater COVID-19 exposure risks. *Id.* at 49a-50a.

Based on these findings, which were neither rebutted below nor challenged here, the district court concluded that, "in the specific context of the unprecedented COVID-19 pandemic," the "convergence" of these burdens "present[s] a substantial obstacle to a large fraction of the women for whom the In-Person Requirements are relevant." *Id.* at 49a-50a, 62a-63a.

In the alternative, the court held that the Requirements are unconstitutional when considering their "serious burdens" together with their purported benefits. *Id.* at 62a. Defendants submitted no current evidence to demonstrate the need for their Requirements; rather, Defendants' justifications "rely entirely" on the FDA's "dated" 2013 REMS review, which "did not take account of intervening events" in the past seven years, such as the FDA's 2016 determination that patients can safely self-administer mifepristone anywhere, the now-widespread use of telemedicine, and the unprecedented exigencies of the pandemic. *Id.* at 53a-55a. While "giv[ing] FDA's prior determination appropriate deference," the court ruled that "it is particularly important to consider the specific evidence in the record relating to the alleged benefits of the In-Person Requirements in light of present circumstances." *Id.* at 55a.

Defendants maintained that the Requirements further safety by providing an

opportunity for in-person counseling and potentially helping to prevent delay. *See id.* at 54a. The district court found that "under the present circumstances," the Requirements do not advance either interest. *Id.* at 51a-59a. The court found no evidence showing that the Requirements improve patient safety by providing "an opportunity for in-person counseling prior to dispensing." *Id.* at 54a. To begin with, the court found that this asserted counseling justification was ill-fitted to the medication at issue, for which FDA admits complications are "exceedingly rare." *Id.* at 59a. Indeed, Defendant Azar has expressly waived in-person evaluation and counseling requirements for dangerous opioids, effectively conceding the safety and efficacy of counseling using telemedicine. *Id.* at 10a, 43a. Moreover, because FDA permits the patient to ingest the mifepristone hours or days after obtaining it, and because complications are extremely rare and would not occur until hours or days after the patient takes the medication, counseling provided at the time of dispensing would not be "contemporaneous" with any clinical event. Stay Pet. 6; App. 51a, 58a; Dkt. 11-3, ¶¶ 33-35. Defendants offered "no evidence demonstrating that telemedicine counseling sessions are ineffective or insufficient for communicating information about the risks or alternatives to medication abortion." App. 57a.

The district court found three bases for rejecting Defendants' only other proffered justification, namely, that the Requirements could avoid delay in initiating the abortion "that could arise if the drug were dispensed by a party other than the health care provider, such as in cases where patients had difficulty finding a pharmacy that stocks the drug." Stay Pet. 6; *see also* Dkt. 62, 32, 34. *First*, the court

emphasized that the FDA already "specifically does not control when the mifepristone is actually taken," and has not reconsidered this 2013 "delay" rationale for requiring dispensing in a clinical setting since the FDA began permitting patients to self-administer mifepristone, unsupervised, at a date and time of their choosing, outside of the clinical setting. App. 58a-59a. *Second*, the court found that, far from preventing delay, "the In-Person Requirements are in many instances a slower means of providing the drug to the patient" "[u]nder the circumstances of the pandemic, where medical offices are closed or operating in a limited way, and patients face significant hurdles in visiting such offices because of health risks, transportation challenges, and childcare limitations." *Id.* at 57a-58a. The court also noted that Defendants' asserted concern that patients might experience delay if retail pharmacies decline to stock mifepristone was irrelevant, because the injunction does not permit dispensing through retail pharmacies.[8] *Id.* at 57a-59a. *Third*, the court reasoned that under the injunction, "[i]f in-person dispensing is the most efficient" delivery method "for a particular patient, that option will remain available." *Id.* at 57a.

The district court further found that the likely constitutional injury Defendants' Requirements are imposing during the COVID-19 emergency established irreparable harm, *id.* at 68a-70a, and that the balance of equities and public interest tipped decisively in favor of injunctive relief, *id.* at 70a-72a. The court explained that the government "will not be harmed by a preliminary injunction

[8] In a clarification order, the court confirmed that while the injunction encompasses supervised delivery through a mail-order pharmacy that stocks and dispenses mifepristone as the prescriber's agent, it does not permit dispensing through retail pharmacies (*i.e.*, physical stores). App. 87a-91a.

temporarily preventing the enforcement of a regulation that is likely to be unconstitutional under the present circumstances," and that Defendants had not shown that temporarily enjoining the Requirements would harm their interest in patient safety. *Id.* at 70a-71a. The court also noted that a "limited" injunction of the Requirements would leave untouched all other FDA regulations on the prescribing and dispensing of mifepristone, including that it be dispensed only under the supervision of a prescriber certified through the FDA's REMS program. *Id.* at 71a.

Finally, the court found that "temporarily enjoining the Requirements plainly promotes 'the public interest in . . . safeguarding public health' because it aligns with [Defendants' own] public health guidance to eliminate unnecessary travel and in-person contact" and is consistent with Defendants' "waivers of in-person requirements relating to other drugs for the specific purpose of protecting public health." *Id.* at 71a-72a (citation omitted). A preliminary injunction would therefore "serve to advance public health during the worst pandemic the world has seen in a century, under which CDC is zealously encouraging social distancing to limit the spread of COVID-19." *Id.*

In crafting the preliminary injunction, the district court noted "[a]t the outset . . . that relief that addresses the harms to all Plaintiffs necessarily will have broad impact because the membership of the Organizational Plaintiffs is extensive in number and geography." *Id.* at 73a. For instance, ACOG alone "has more than 60,000 members, including practitioners in all 50 states, the District of Columbia, Puerto Rico," and its "members comprise 90 percent of the OB/GYN physicians in the United

States." *Id.* CUCOG likewise is a "nationwide organization with 146 members representing the departments of obstetrics and gynecology within or affiliated with medical schools in 48 states, the District of Columbia, and Puerto Rico." *Id.* at 74a.

The court granted an injunction reaching all Plaintiffs' members, which was therefore necessarily national in scope. In addition, the court found that extending the injunction's protections to the "limited number" of non-member clinicians who are similarly situated to the Organizational Plaintiffs' members would ensure "uniform, fair, and rational treatment" of the "vulnerable" abortion patients those clinicians serve, who "disproportionately [face] significant economic and health concerns during the COVID-19 pandemic" as well as "challenges [to] bringing suits on their own behalf based on legitimate privacy concerns" and the "limited time period within which to file suit based on the nature of abortion." *Id.* at 74a-76a (quotation marks and citation omitted). The court reasoned that, "[w]here an injunction covering Plaintiffs already covers 90 percent of OB/GYN physicians in the United States" with members in every state, "the costs of addressing the issues relating to enforcement against the remaining healthcare providers far outweigh the benefits of a narrower injunction." *Id.* at 73a, 77a. Covering similarly situated others would also avoid the need for "duplicative" follow-on lawsuits. *Id.* at 76a. By contrast, excluding similarly situated patients or clinicians or attempting to limit the geographic scope of the injunction "would create practical, administrative complexities," including by conditioning enforcement of the unitary REMS program, which is administered primarily by the drug manufacturers acting as FDA's agent, on "a determination whether the

physician is a member of one or more of the Organizational Plaintiffs" as of the relevant date. *Id.* at 76a-77a. The court noted further that "crafting relief that attempts to account for both the unpredictable changes and nuanced regional differences" in COVID-19 rates "across 50 different states over an extended period of time is simply infeasible." *Id.* at 77a-78a.

The district court limited the injunction to the duration of Defendants' declared COVID-19 PHE—"an objectively identifiable marker that the COVID-19 pandemic continues to have a significant impact on the nation warranting emergency relief, [which] in fact has been a precondition for [Defendants'] emergency waivers of in-person requirements relating to the prescribing and dispensing of drugs based on the COVID-19 pandemic." *Id.* at 78a-79a.

On July 30, the district court denied Defendants' motion to stay the injunction pending appeal based on the reasoning in its earlier opinion. *Id.* at 83a-84a.

Fourth Circuit Proceedings

On August 13, a panel of the Fourth Circuit unanimously denied Defendants' stay motion without opinion. App. 85a-86a. Defendants waited two weeks before seeking an emergency stay in this Court on August 26, and have not moved to expedite their appeal in the Fourth Circuit.

ARGUMENT

Defendants bear a "heavy burden" to justify the "extraordinary" relief of a stay. *Whalen v. Roe*, 423 U.S. 1313, 1316 (1975) (Marshall, J., in chambers). Their burden is "especially heavy" "[b]ecause this matter is pending before the Court of Appeals,

and because the Court of Appeals denied [the] motion for a stay." *Packwood v. Senate Select Comm. on Ethics*, 510 U.S. 1319, 1320 (1994) (Rehnquist, C.J., in chambers); *accord Edwards*, 512 U.S. at 1302 (Scalia, J., in chambers). An overriding stay is "rare and exceptional," granted only "upon the weightiest considerations." *Fargo Women's Health Org. v. Schafer*, 507 U.S. 1013, 1013 (1993) (O'Connor, J., concurring in denial of stay) (denying stay despite view that lower court decisions were "inconsistent" with this Court's precedent) (quotation marks and citations omitted); *Heckler v. Redbud Hosp. Dist.*, 473 U.S. 1308, 1312 (1985) (Rehnquist, J., in chambers) ("[A] stay application to a Circuit Justice on a matter before a court of appeals is rarely granted." (quotation marks and citation omitted)).

Defendants cannot satisfy the requirements for this extraordinary relief, namely: "(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 vote to reverse the judgment below; and (3) a likelihood that irreparable harm will result from the denial of a stay." *Hollingsworth v. Perry*, 558 U.S. 183, 190 (2010). But even if Defendants could meet these criteria—which they cannot—"[t]he conditions that are *necessary* for issuance of a stay are not necessarily *sufficient*." *Barnes v. E-Systems, Inc. Grp. Hosp. Med. & Surgical Ins. Plan*, 501 U.S. 1301, 1304 (1991) (Scalia, J., in chambers). "It is ultimately necessary, in other words, 'to balance the equities'—to explore the relative harms to applicant and respondent, as well as the interests of the public at large." *Id.* at 1305 (quotation marks and citation omitted). Here, the public interest is best served by leaving in place a narrow

injunction that prevents Defendants from subjecting Plaintiffs, their patients, and their families to wholly unnecessary COVID-19 risk as a condition of abortion care.

This Court should be especially hesitant to grant relief here, where—given the realities of timing—the stay Defendants request would very likely afford them ultimate relief without ever prevailing on the merits. Defendants are free to move for expedited review by the court of appeals, and if they prevail there, the injunction would be lifted. They should not be permitted to pretermit ordinary litigation through the grant of a stay that effectively resolves the case without the court of appeals ever having weighed in on the merits. *Nat'l Socialist Party*, 434 U.S. at 1328 (Stevens, J., in chambers) (denying stay application that "would be tantamount to a decision on the merits in favor of the applicants").

I. This Court is Unlikely to Grant Review and Reverse.

Defendants do not make a compelling case for why this Court would review a time-limited preliminary injunction directed narrowly at the harms caused by an abortion restriction under the *sui generis* conditions of a global pandemic. Nor can they show that, even if the Court were to grant review, a majority would reverse.

A. The District Court's Pandemic-Specific Undue Burden Finding Raises No Certiorari-Worthy Questions and Was Not an Abuse of Discretion.

1. The District Court's Substantial Obstacle Finding Does Not Provide a Basis for This Court's Review or Reversal.

The district court's principal conclusion is that Defendants' Requirements, which force patients to travel unnecessarily to a health center during a lethal

pandemic, impose a substantial obstacle on the right to abortion and should be enjoined during the official COVID-19 PHE. That determination is entirely consistent with well-established precedent that the government may not impose a regulation that "has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus," and does not warrant this Court's review. *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 877 (1992) (plurality opinion).

The district court did not err in finding that "taken together, the burdens of the In-Person Requirements, in the specific context of the unprecedented COVID-19 pandemic, impose a 'substantial obstacle in the path of women seeking an abortion,'" and that "this substantial obstacle affects a 'large fraction' . . . of 'those women for whom the provision is an actual rather than an irrelevant restriction." App. 50a, 62a-63a. Noting that "[a] combination of . . . barriers can establish a substantial obstacle," *id.* at 49a (citing *June Med. Servs., LLC v. Russo*, 140 S. Ct. 2103, 2130 (2020); *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2317-18 (2016)), the district court based its conclusion on the "combined" effects of Defendants' Requirements, which force patients to engage in activity "fraught with health risk" as a condition of obtaining abortion care, during a pandemic that had already infected more than three million Americans and killed more than 130,000 at the time of the ruling, and that continues to infect and kill every day. *Id.* at 45a, 49a, 61a.

As long as a "district court's account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it," even if the appellate court "would have weighed the evidence differently" themselves. *Anderson*

v. City of Bessemer City, 470 U.S. 564, 574 (1985); *see also June Med.*, 140 S. Ct. at 2141 (Roberts, C.J., concurring) (district court's factual findings "bind" the Supreme Court unless it is "left with the definite and firm conviction that a mistake has been committed" (quotation marks and citation omitted)). Here, there is absolutely no evidentiary basis for finding that the district court erred. Its substantial obstacle finding relied on *unrebutted* evidence that, given the "highly contagious" nature of COVID-19, App. 8a, 42a, the transportation, childcare, and other interpersonal contact necessitated by an in-person trip to a health center pose serious exposure risks, *see supra* at 13-14. That conclusion is fully supported by Defendants' own "extraordinary actions" during the PHE, including suspending in-person requirements for opioids. *See supra* at 9-11. Indeed, mifepristone is the *only* drug that can be self-administered without supervision, but requires in-person pickup at a clinic during the pandemic. *See supra* at 9. The court made further findings, again based on *unrebutted* evidence, that abortion patients, by virtue of their pregnancy and other factors, are at especially high risk of both exposure to SARS-CoV-2 and severe illness or death from COVID-19. *See supra* at 13-14. Defendants simply have no record evidence with which to contradict the court's conclusion that, "[b]y causing certain patients to decide between forgoing or substantially delaying abortion care, or risking exposure to COVID-19 for themselves, their children, and family members," the Requirements pose a substantial obstacle. App. 48a.

The court also did not err in concluding that the Requirements delay patients' access to abortion under the conditions of the pandemic and economic crisis, thereby

increasing health risks and forcing patients to obtain more invasive procedures. *See supra* at 14-15; *see June Med.*, 140 S. Ct. at 2140 (Roberts, C.J., concurring) (favorably citing district court finding that patients seeking abortion care under challenged law would face "longer waiting times for appointments, increased crowding and increased associated health risk" (quotation marks and citation omitted)). Again, no evidence even calls into question, much less contradicts, the district court's conclusion that these factors render the Requirements "dangerous during the pandemic." App. 49a.[9]

Having failed to rebut any of this evidence, Defendants ask this Court to simply ignore it, advancing two profoundly flawed legal arguments. *See* Stay Pet. 10, 12-19. Defendants first argue that the serious health risks they are forcing medication abortion patients to incur are constitutionally immaterial because patients could obtain a surgical abortion instead. *See id.* at 3, 12-15, 18-19. But Defendants' theory that the alternative option of a surgical abortion somehow defeats Plaintiffs' claim makes no sense: The constitutional violation in this case arises from the FDA's mandate that patients incur grave COVID-19 risk by engaging in unnecessary travel and physical proximity to other people as a condition of obtaining

[9] With tens of thousands of new infections daily and a national COVID-19 case count exceeding six million, U.S. Ctrs. for Disease Control & Prevention, *United States COVID-19 Cases and Deaths By State*, *supra* n.3, Defendants' *amici* callously assert that the "burdens of in-person services at this point are non-existent." Br. of Indiana et al. as Amici Curiae Supporting Applicants 14 (Aug. 28, 2020). Defendants' *amici*'s nonchalance in the face of the fact that a *million* Americans contracted a life-threatening virus in just 22 days this August, *see* AMA et al. Amicus Br. 14-15, is not only gravely out of step with Defendants' actions to reduce in-person medical care for the duration of the PHE, *see* App 43a-45a, but also contradicted by the public health guidance of authorities like AMA, which underscore the urgency of avoiding all unnecessary in-person contact as an essential condition to reduce contagion and allow states to partially reopen. *See generally* AMA et al. Amicus Br.; *see also* Br. of New York et al. as Amici Curiae Supporting Respondents (Sept. 8, 2020) ("New York et al. Amicus Br.").

abortion care, when they could safely obtain the pill by mail. It is no defense for mandating this unnecessary risk of COVID-19 infection to say that instead of receiving medication safely at home, such patients could instead travel to a health center for a more invasive procedure, involving greater risk of COVID-19 infection. *See* App. 50a, 69a; Dkt. 11-3, ¶ 102; AMA et al. Amicus Br. 17.

The isolated phrases from *Gonzales v. Carhart*, 550 U.S. 124 (2007), on which Defendants rely cannot rescue this argument. *See* Stay Pet. 10, 13-15, 18-19. To the contrary, four decades of case law, including *Gonzales*, foreclose Defendants' argument that the government is free to make needless COVID-19 risk a condition of obtaining the most common method of early abortion care, simply because another abortion method posing greater COVID-19 risk exists. *See id.* Indeed, as Defendants acknowledge, this extreme argument would permit them even to *ban* medication abortion altogether. *See id.* at 14 (arguing that the FDA could have refused to approve mifepristone in 2000). That is not the law, as this Court's precedent makes clear.

Gonzales concerned a ban on a rarely used procedure for second-trimester abortions. The plaintiffs brought several claims, including that (1) the ban imposed an undue burden because it reached not only this little-used procedure, but also the "most common" second-trimester abortion method, *see Gonzales*, 550 U.S. at 147; *see also id.* at 135; *Stenberg v. Carhart*, 530 U.S. 914, 934 (2000) (describing "relative rarity" of same abortion method); and (2) that the ban was facially invalid because it lacked a health exception, *see Gonzales*, 550 U.S. at 143-44, 161. The *Gonzales* Court rejected the undue burden claim because it found that the law did not, in fact, prohibit

the "usual" second-trimester method, *id.* at 135; *see also id.* at 150-54, 164-65 (distinguishing federal ban as "different from" law invalidated in *Planned Parenthood of Central Missouri v. Danforth*, 428 U.S. 52 (1976), which banned the "then-dominant second-trimester abortion method"). And the Court held that facial invalidation was improper on the health exception claim because there was "documented medical disagreement" as to whether the banned procedure *ever* provided health advantages and, therefore, whether banning that rare procedure "would *ever* impose significant health risks" on patients—much less do so in a large fraction of relevant cases. *Id.* at 162; *see also id.* at 161, 163-65 (emphasis added). In so holding, the Court stressed that this conclusion was supported by the fact that the method used in the majority of second-trimester abortions and considered "generally the safest method of abortion during the second trimester" remained available. *Id.* at 164 (quotation marks and citation omitted).

But it is one thing to say, under the unique circumstances presented in *Gonzales*, that the government can bar a rare method of abortion when the most common and safe method remains available, and there is "documented medical disagreement" as to whether the banned method *ever* offers a safety benefit. *Id.* at 162. It is another altogether to say that the government can freely burden the method that accounts for 60 percent of early abortion care, *see* AMA et al. Amicus Br. 4, where the alternative Defendants propose is forcing patients to endure the even more substantial risks posed by not only traveling to a health center but also obtaining a medical procedure that involves more time in the facility, more extended human

contact, and thus greater exposure risk.[10] Indeed, far from supporting Defendants' legal argument, *Gonzales* and its predecessors squarely contradict it. *See Gonzales*, 550 U.S. at 150-54; *Stenberg*, 530 U.S. at 931-932, 936-37, 945-56 (invalidating law banning "most commonly used" second-trimester method)); *Danforth*, 428 U.S. at 77-79 (striking ban on "most commonly used" second-trimester method).

Moreover, even putting aside the fact that medication abortion is the most common method of obtaining an early abortion, Defendants' extraordinary argument that the government has carte blanche to subject abortion patients to life-threatening medical risks and delays, so long as patients can eventually obtain an abortion, is unsupported by either facts or law. *See* Stay Pet. 15 (criticizing district court holding 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'"); *id.* at 16-17. As a factual matter, Defendants' premise that a surgical procedure is a "readily available" alternative during the pandemic is entirely unfounded. *Compare* Stay Pet. 3, 12, *with* App. 45a-50a (discussing challenges abortion patients face obtaining any in-person care during the pandemic); AMA et al. Amicus Br. 14 (discussing evidence of patients being unable to obtain reproductive health care during pandemic). Even under normal circumstances, a substantial

[10] Additionally, *Gonzales* involved a method that Congress had prohibited altogether because it found it posed unique "ethical and moral" concerns, 550 U.S. at 158, whereas here the FDA has not only *approved* mifepristone, but has determined that it is "important to the health of women." Dkt. 62-3, 0226. Defendants do not, and could not, argue that social or moral considerations relating to abortion justify the Requirements, as the REMS statute under which the FDA promulgates these restrictions limits the FDA to imposing only strategies designed to mitigate clinical "adverse events" associated with a drug, 21 U.S.C. 355-1(a)(1)(E); *see also* Dkt. 1-4, 9 (FDA counseling form discussing only clinical information about mifepristone).

percentage of health centers that provide abortion care offer only medication abortions and do not perform surgical abortions. AMA et al. Amicus Br. 4. & n.5. During the pandemic, the district court specifically found that medical office closures and reduced capacity impede patients' ability to obtain *any* in-person abortion care, and that poor women, who comprise a majority of abortion patients, face particularly severe challenges arranging transportation and childcare for health care in the current economic crisis. App. 45a-50a. In addition, in suspending other in-person requirements during the PHE, Defendants themselves highlighted the "difficult[y]" patients may face obtaining in-office medical services (such as MRIs or laboratory testing) "because patients may need to avoid public places and patients suspected of having COVID-19 may be self-isolating and/or subject to quarantine." Dkt. 11-4, ¶ 46.

As a legal matter, Defendants' theory that the Constitution permits the government to unnecessarily expose patients to the risk of contracting a deadly disease as long as they are ultimately able to have an abortion, cannot be squared with this Court's precedent, which has emphasized a range of burdens short of complete bars in invalidating abortion restrictions. *June Med.*, 140 S. Ct. at 2130 (plurality opinion) (noting challenged law would cause "delays in obtaining an abortion" that "may make it impossible for [patients] *to choose a noninvasive medication abortion*" (emphasis added)); *id.* at 2129 ("Those women not altogether prevented from obtaining an abortion would face other burdens."); *id.* at 2114, 2116 (characterizing as "essential" district court finding that even "[t]hose who *can* [obtain an abortion] will face substantial obstacles in exercising their constitutional right to

choose abortion" because of reduced availability (emphasis added) (quotation marks and citation omitted)); *id.* at 2140 (Roberts, C.J., concurring) (noting law would cause "longer waiting times for appointments, increased crowding and increased associated health risk" (quotation marks and citations omitted)); *Whole Woman's Health*, 136 S. Ct. at 2313, 2318 (considering burdens such as "increased crowding" with patients "less likely to get . . . individualized attention, serious conversation, and emotional support"). Thus, there is no support for Defendants' contention that, so long as patients are able to eventually get an abortion, the government is free to subject them to any amount of unnecessary medical risk as a condition of obtaining that care, including needless risk of contracting a disease that has killed nearly 200,000 Americans in less than six months. *See supra* at 10.

Defendants' second argument is equally unavailing. Characterizing the restrictions challenged here as "incidental," Defendants maintain that the court was forbidden from considering how Defendants' Requirements impact patients during the pandemic because Defendants themselves did not *cause* the pandemic. Stay Pet. 15-17 (citing *Casey*, 505 U.S. at 874; *Harris v. McRae*, 448 U.S. 297, 316 (1980)). But this Court's precedent, which routinely examines the real-world effects of abortion regulations given existing circumstances, flatly refutes that argument too.

When, as here, the government imposes restrictions on abortion access, this Court has always considered whether that regulation has "the . . . effect of placing a substantial obstacle in the path of" patients seeking abortion care given the real-world conditions in which the restrictions operate. *Casey*, 505 U.S. at 877 (plurality

opinion). For instance, in *Casey*, this Court struck down a spousal notification requirement for abortion patients because of its impact on women who suffer domestic violence, *id.* at 887-94 (majority opinion)—circumstances that are no more an "obstacle[] of [the government's] creation" than COVID-19. Stay Pet. 16-17 (quoting *Harris*, 448 U.S. at 316). In *June Medical*, the Court examined the effect of the challenged law in light of poverty among abortion patients in Louisiana. 140 S. Ct. at 2130 (plurality opinion) (emphasizing that "the burdens of [the law] . . . would fall disproportionately on poor women, who are least able to absorb them"); *id.* at 2140 (Roberts, C.J., concurring) (highlighting finding "that Louisiana women already have difficulty affording or arranging for transportation and childcare on the days of their clinic visits" and that "[i]ncreased travel distance would exacerbate this difficulty" (quotation marks and citation omitted)). The same was true in *Whole Woman's Health*, which assessed the particular burdens on "poor, rural, or disadvantaged women." 136 S. Ct. at 2302 (quotation marks and citation omitted). In *Hodgson v. Minnesota,* the Court stressed that mandatory two-parent notification requirement for pregnant minors seeking abortion was "positively harmful" and "counterproductive" to pregnant minors in the "thousands of dysfunctional families affected by the statute." 497 U.S. 417, 450–51 (1990).

Indeed, it is often the case that factors not of the government's making, including the distances to the nearest abortion provider, are critical considerations in an undue burden challenge. *See, e.g.*, *June Med.*, 140 S. Ct. at 2140 (Roberts, C.J., concurring) (considering as part of undue burden finding the 320 mile distance

between northern Louisiana and New Orleans). The Requirements are indisputably a restriction on abortion access, which Defendants have affirmatively imposed and, in contrast to their treatment of other drugs, insisted on maintaining even during the pandemic. Defendants cannot establish any error, factual or legal, in the district court's well-founded finding that the government's actions impose an undue burden "in the specific context of the unprecedented COVID-19 pandemic." App. 50a.

Because this Court is unlikely to grant review of, let alone reverse, the district court's holding that the burdens Defendants' Requirements impose during the PHE constitute a substantial obstacle, the stay must be denied.

2. The District Court's Alternative Holding Considering Both Burdens and Benefits Together Does Not Provide a Basis for This Court's Review or Reversal.

The district court's alternative holding that the Requirements "do not advance general interests of patient safety and thus constitute 'unnecessary health regulations'" under "present circumstances," and that the lack of health-related benefits are outweighed by the serious burdens the Requirements impose, App. 51a, 62a (quoting *Whole Woman's Health*, 136 S. Ct. at 2309 (quoting *Casey*, 505 U.S. at 877)), also does not warrant certiorari or reversal.

As an initial and dispositive matter, the district court found an undue burden on two independent legal bases—as Defendants acknowledge. Stay Pet. 7-8. Thus, there is no need for this Court even to review this alternative holding. And, in assessing whether it is likely to grant certiorari, this Court has no indication whether the Fourth Circuit will even reach the district court's benefits-burdens analysis, much

less agree with it. Blind speculation regarding how the Fourth Circuit might rule on an issue not necessary to the injunction sought to be stayed does not establish "a reasonable probability" that four Justices will eventually grant certiorari. *Hollingsworth*, 558 U.S. at 190; *see also O'Connell v. Kirchner*, 513 U.S. 1138, 1138 (1995) (O'Connor, J., dissenting from denial of stay) (stay denied where "[a]t this juncture," the Court could "only speculate about the Illinois Supreme Court's rationale" and whether decision rested on state or federal grounds). That the burdens-vs-benefits analysis is unnecessary to the injunction should alone end the question.

In addition, Defendants err in arguing that the extensive evidence that the Requirements are medically unnecessary is constitutionally irrelevant. *See* Stay Pet. 19-21. As Chief Justice Roberts noted, courts "discuss[] the benefits of [a] regulation[]" in evaluating the law's constitutionality, *June Med.*, 140 S. Ct. at 2138 (Roberts, J., concurring); *id.* at 2130-32 (plurality opinion discussing lack of benefits); at a minimum, restrictions must be "reasonably related" to a legitimate interest to survive, *id.* at 2138 & n.2 (Roberts, C.J., concurring) (quotation marks and citation omitted) (describing *Casey*'s "threshold requirement"). Regardless of how the court framed its benefits discussion, it was appropriate to consider—and reject—Defendants' asserted justifications.

Defendants fall far short of establishing any error, let alone clear error, *see* Fed. R. Civ. Proc. 52(a)(6), in the district court's finding that the Requirements do not advance patient safety, App. 51a-59a. In attempting to justify the Requirements, Defendants "rel[ied] entirely" on the FDA's 2013 REMS Review. App. 53a; *see* Dkt.

62-6. They introduced *no current evidence* to rebut Plaintiffs' expert testimony and the consensus opinion of national medical authorities that the FDA's singular restrictions on mifepristone provided no medical benefit even before the pandemic and decidedly should not be enforced during the PHE, when Defendants have suspended in-person requirements even for opioids. *See* AMA et al. Amicus Br. 7 (citing 2018 AMA resolution); Dkt. 12, 7 n.4 (citing 2016 positions of ACOG and American Public Health Association). Based on a careful evidentiary review, the district court found that neither of FDA's 2013 rationales supports Defendants' retention of the Requirements in the pandemic. App. 53a.[11]

Defendants first speculate that requiring an in-person pill pick-up and physical signature "*could help* patients understand possible serious complications and what to do if they experienced an adverse event." Stay Pet. 21 (emphasis added). But, to the extent the REMS was designed to ensure mifepristone patients receive adequate information, there is an independent requirement—*not challenged by Plaintiffs*—that prescribers "[r]eview the Patient Agreement Form with the patient and fully explain the risks of the mifepristone treatment regimen," and "[a]nswer any questions the patient may have prior to receiving mifepristone." Dkt. 1-4, 7.

[11] Defendants' assumption that the district court must have concluded that the Requirements were "'reasonably related' to a 'legitimate purpose' before the current public-health crisis" because the court "enjoin[ed] their enforcement only through the pandemic's duration," Stay Pet. 25, defies bedrock principles of justiciability. Plaintiffs only *asked* the district court to enjoin the Requirements during the COVID-19 pandemic because of the specific burdens they impose in that context, and it was perfectly appropriate for the district court to tailor its relief to those specific burdens. *Lewis v. Cont'l Bank Corp.*, 494 U.S. 472, 477 (1990) (Federal courts are "confine[d]… to resolving real and substantial controversies admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 241 (1937))).

Defendants do not require that this counseling regarding risks take place in person; they permit it to occur via telemedicine. App. 56a. Therefore, Defendants can muster only a chain of hypotheticals in support of their asserted counseling rationale. They claim that the Requirements provide "*an opportunity* for in-person counseling" at the time of dispensing, *id.* at 54a, which "*might be* more effective because *it might be* closer in time to when the patient takes the drug or more effective at communicating risks," Stay Pet. 22. Defendants do not identify a single piece of data or technical analysis underlying this speculation. *Id.* Moreover, it strains credulity that an in-person dispensing requirement is necessary to ensure patients understand the medical risks associated with a medication, Stay Pet. 21, when (1) risks can equally be communicated through telemedicine counseling; (2) FDA admits that serious complications from mifepristone are "exceedingly rare, generally far below 0.1%"; and (3) FDA requires in-person dispensing for *no* other drug that can be self-administered anywhere without clinical supervision. App. 5a, 59a.

In fact, based on unrebutted expert testimony and Defendants' own actions, the district court found that "telemedicine is now in widespread use, including as an effective means to providing counseling relating to medication abortion," *id.* at 55a; AMA et al. Amicus Br. 8, and that Defendants were unable to "offer[] [any] evidence demonstrating that telemedicine counseling sessions are ineffective or insufficient for communicating information about the risks or alternatives to medication abortion," *id.* at 57a. Defendants' belated attempt to brush aside these findings as based merely on "several declarations," Stay Pet. 22, rings hollow in the face of their failure to

submit any declarations whatsoever; their full-throated endorsement elsewhere of telemedicine as "the best way to protect patients and staff from COVID-19," App. 44a, 53a-55a; their suspension of in-person evaluation requirements for controlled substances, allowing clinicians to prescribe opioids and counsel patients about potential complications and what to do in the case of an adverse event entirely through telemedicine, *see supra* at 10, 16; and statements from Plaintiffs' *amici* AMA and other leading medical groups, as well as 22 states and the District of Columbia, regarding the widespread use, high quality, and critical role of telemedicine during the pandemic, *see generally* AMA et al. Amicus Br.; New York et al. Amicus Br.

The court likewise did not err in rejecting Defendants' baseless assertion, App. 57a-59a, that the Requirements "*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," Stay Pet. 21 (emphasis added); *see id.* at 6, 23, 33. Defendants' stated concern about "local pharmacies . . . not stock[ing] the drug" is a red herring: the injunction permits dispensing only by mail, delivery, or supervised delivery from a mail-order pharmacy that has pre-arranged to stock the drug on the prescriber's behalf. *Id.* at 21; App. 87a-93a. And as the court noted, the FDA already "specifically does not control when the mifepristone is actually taken," and has not reconsidered this rationale since it began permitting patients to swallow the mifepristone pill at a time, date, and location of their choosing. App. 58a.[12]

[12] Defendants portray the FDA's 2016 decision to permit patients to administer mifepristone at the location of their choice as a reluctant compromise of patient safety to ensure that patients are in a convenient place when they pass the pregnancy. *See* Stay Pet. 23 ("the agency tolerated the delay"). But it is not mifepristone, but misoprostol—the *second* drug in the medication abortion regimen, taken

Moreover, the court properly found that "under the present circumstances of the COVID-19 pandemic, a rigid In-Person Dispensing Requirement does not actually serve the purpose of preventing delays in the initiation of the [medication abortion]." *Id.* To the contrary, a requirement that mifepristone be handed to patients onsite at a clinical setting is "in many instances a slower means of providing the drug." *Id.* at 57a-58a. This finding rested on unrebutted evidence of medical office closures and reduced appointment availability for in-person services during the pandemic, and unrebutted evidence that abortion patients are delayed in obtaining mifepristone while they secure funds and arrange for transportation and childcare during a pandemic and economic crisis. *See supra* at 14-15. Further, the injunction only creates new options for patients and clinicians; it does not mandate a particular delivery method. App. 57a. "If in-person dispensing is the most efficient" delivery method "for a particular patient, that option will remain available." *Id.*

Defendants argue that courts are not permitted to "second-guess" decisions of public health officials, and suggest that this deference should extend to outdated rationales set forth in 2013 long before any pandemic existed. Stay Pet. 25-26, 32 (citing *South Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613, 1613-14 (2020)). Defendants' reliance on *South Bay*, in which this Court declined to enjoin California's executive order restricting religious (and other) gatherings during the COVID-19 pandemic, turns that case on its head. There, as Chief Justice Roberts

24 to 48 hours after mifepristone—which causes the bleeding and cramping that expels the pregnancy, App. 2a-3a, 7a. Defendants also fail to mention that "safety" was one of the benefits the FDA cited in authorizing patients to self-administer mifepristone outside of a clinical setting. Dkt. 62-11, 0589.

explained, this Court refused to overrule the government's efforts to mitigate viral spread where "local officials [were] actively shaping their response to changing facts [and risks] on the ground," and where the policy imposed similar restrictions on secular and religious gatherings. 140 S. Ct. at 1614 (Roberts, C.J., concurring in denial of application for injunctive relief). Here, by contrast, Defendants ask this Court to defer to pre-existing rules imposed years before the pandemic that indisputably increase risk to patients seeking constitutionally protected medical care, and to Defendants' *failure* to respond to the exigencies of the public health emergency. *See* App. 42a-45a, 53a (finding that "FDA has provided no sign that it has undertaken a formal review of the issue in light of . . . the ongoing pandemic.").[13] The court properly found that the public interest is served by mitigating irreparable constitutional injury and medical risk, consistent with Defendants' COVID-19 guidelines and "extraordinary actions" to reduce viral risks by waiving *other* in-person requirements. *See id.* at 44a, 68a-72a.[14]

Defendants have not shown any of the district court's findings to be clearly

[13] Indeed, there is no evidence that the FDA even *considered* lifting their Requirements for mifepristone during the pandemic. The FDA's guidance document suspending enforcement of REMS laboratory testing and imaging studies requirements during the PHE states only that the non-enforcement policy "does not address other REMS requirements, such as those for in-person *administration*"—and says nothing about mifepristone, which singularly requires in-person dispensing with *no* corresponding in-person administration requirement. U.S. Food & Drug Admin., Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency (Mar. 2020), https://www.fda.gov/media/136317/download (emphasis added).

[14] Defendants' *amici* take Plaintiff ACOG to task for having argued that state orders banning abortions during the pandemic were unconstitutional. *See* Indiana et al. Amicus Br. 9-10. But arguing that a person should be able to exercise their constitutionally protected decision about whether to have a child even under circumstances that involve COVID-19-related risk is in no way inconsistent with arguing that a person should not be forced to undertake wholly unnecessary risks as a condition of exercising their right.

erroneous, much less that the court abused its discretion in concluding that the Requirements constitute "[u]nnecessary health regulations" under current circumstances. *Casey*, 505 U.S. at 878 (plurality opinion). For this reason, too, the court's alternative holding provides no basis for a stay of the injunction.

B. The Scope of the Remedy Raises No Certiorari-Worthy Issues and Is Not an Abuse of Discretion.

1. This *Sui Generis* Preliminary Injunction Is Not Illustrative of Any Recurring Issues.

Defendants contend that the injunction here "illustrate[s]" a purported recurring problem of district courts imposing nationwide injunctions in cases brought by local plaintiffs, and that a future certiorari petition will "squarely present" an asserted broad controversy about nationwide injunctions. Stay Pet. 3, 11; *see also id.* at 12, 26-32. But Defendants' own arguments highlight the salient differences between the time-limited injunction in this case, involving a plaintiff whose tens of thousands of members are dispersed throughout the country, and the other injunctions to which Defendants object. Here, because the parties represented were nationwide, the remedy had to be nationwide. This case is a distinctly poor vehicle for addressing any of Defendants' broad-brush objections to nationwide injunctions.

The preliminary injunction differs in at least four ways from those Defendants portray as problematic. *First*, this injunction's geographic scope does not extend more broadly than the litigants before the court, who sue on behalf of more than 60,000 clinicians across all 50 states, the District of Columbia, and Puerto Rico, and the vast

majority of all OB/GYN physicians in the country. App. 73a.[15]

Second, the plaintiff organizations rely on associational standing—a well-established vehicle for bringing a large number of affected parties before the courts. *See, e.g., Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000) ("association has standing to bring suit on behalf of its members when its members would otherwise have standing to sue in their own right"); *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 342 (1977) ("voluntary membership organization" and "trade association" are prototypical examples of groups that can sue on behalf of members). This is not a case that "circumvent[s] the procedural rules." Stay Pet. 28-29.

Third, this is the sole lawsuit of its kind. The exigent circumstances of the COVID-19 pandemic triggered this litigation, prompting multiple Plaintiffs to join forces to sue together when it became clear that the FDA would not voluntarily suspend the Requirements. No other suits in other jurisdictions seek to temporarily lift the Requirements. Defendants' concerns about "a single district judge" nullifying "the decisions of all other lower courts," or an "asymmetr[y]"" that requires the government to prevail in multiple parallel suits while the plaintiff side needs only prevail in one, *id.* at 29, have no applicability here.

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[15] Nor would it have been appropriate to attempt to tether the injunction to geographic variations in COVID-19 rates, when "the impacts of the pandemic have fluctuated even during the pendency of" Plaintiffs' preliminary injunction motion. App. 77a-78a. With COVID-19 rates "changing daily" and Plaintiffs' expert epidemiologist "already proven to be correct" in predicting "resurgences of COVID-19' across the United States during 2020, including new hot spot[s]," there was no abuse in discretion in the district court's determination that "craft[ing] a remedy that attempts to account for both the unpredictable changes and nuanced regional differences across 50 different states over an extended period of time is simply infeasible." *Id.* (quotation marks and citation omitted).

Fourth, this preliminary injunction is time-limited, and will expire once Defendants' declared COVID-19 health emergency ends.[16] The injunction's automatic expiration not only makes it an unsuitable vehicle for this Court's consideration of general injunction issues, but will likely render the matter moot before this Court has an opportunity to review it on certiorari (though after the court of appeals has had an opportunity to resolve the merits). *See Local No. 8-6, Oil, Chem. & Atomic Workers Int'l Union, AFL-CIO v. Missouri*, 361 U.S. 363, 367-68 (1960) (the Court cannot opine on moot questions once raised by an injunction that has already expired by its own terms). Indeed, as Defendants did not move for an expedited appeal in the Fourth Circuit, and that briefing is scheduled to extend through the end of 2020, *see* 4th Cir. Dkt. 32, it seems unlikely that Defendants would be in a position to seek certiorari in time for review during this Court's 2020 term, and one hopes the pandemic will be well behind us by the 2021 term.

2. This Injunction Falls Squarely Within the District Court's Equitable Discretion.

Defendants also fail to identify any abuse of discretion by the district court in fashioning temporary relief for the likely constitutional violations it found. "Crafting a preliminary injunction is an exercise of discretion and judgment, often dependent as much on the equities of a given case as the substance of the legal issues it presents." *Trump v. Int'l Refugee Assistance Project ("IRAP")*, 137 S. Ct. 2080, 2087

[16] The PHE, which must be renewed every 90 days, currently extends through late October 2020. Alex M. Azar, II, Sec'y of Health & Human Servs., Renewal of Determination That a Public Health Emergency Exists (July 23, 2020), https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-23June2020.aspx.

(2017) (per curiam). A court balances the equities, including the public interest, and "'mold[s] its decree to meet the exigencies of the particular case.'" *Id.* (quoting 11A Charles Alan Wright, Arthur R. Miller, & Mary Kay Kane, Federal Practice and Procedure § 2947, at 115 (3d ed. 2013)). The district court did just that, imposing the automatic expiration date despite Plaintiffs' requests for a more open-ended duration, and meticulously justifying the injunction's terms in light of Plaintiffs' injuries, administrative feasibilities, and fairness to vulnerable patients. *See* App. 72a-80a; *see Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944) ("mercy and practicality," as well as "[f]lexibility rather than rigidity," characterize the courts' equity powers).

Unable to contest the geographic scope of the injunction in light of Plaintiffs' extensive presence in all 50 states, App. 73a, Defendants argue principally that this Court is likely to grant review and reverse because the district court extended relief to "similarly situated" persons who are not members of the Organizational Plaintiffs. Even if the Court were to agree, this would at most support narrowing the injunction to Plaintiffs and their members (who include 90 percent of the nation's OB/GYNs), and would in no way support the wholesale stay Defendants seek. *See* Stay Pet. 4-5.

In any event, the district court properly concluded that an injunction protecting those "similarly situated" to the 60,000-plus clinicians and their patients represented in this lawsuit is constitutionally permissible in unique and narrow circumstances, as here, where equity demands it. App. 74a (citing *IRAP*, 137 S. Ct. at 2087 (partially denying stay application, leaving in place nationwide injunction protecting plaintiffs and those "similarly situated" to them)); *see also Trump v.*

Hawaii, 138 S. Ct. 34 (2017) (mem.) (partially denying stay application as to same nationwide injunction, following further clarification from district court as to impacted categories of refugees); *Trump v. E. Bay Sanctuary Covenant*, 139 S. Ct. 782 (2018) (mem.) (denying stay of nationwide temporary restraining order enjoining any enforcement of immigration rule restricting asylum eligibility based on entry point). The district court's "uniform, fair, [and] rational treatment" of patients and clinicians impacted by its partial, temporary injunction of the mifepristone REMS was well within the court's equitable discretion, App. 75a. "In awarding a preliminary injunction a court must also 'conside[r] . . . the overall public interest.'" *IRAP*, 137 S. Ct. at 2087 (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 26 (2008)). Particularly where the record reflects that successfully curbing the pandemic depends upon a nationwide reduction in viral transmission, *see* App. 42a, 71a-72a, Defendants cannot establish that the district court's equitable determination warrants certiorari, much less reversal.

Moreover, the injunction takes its contours from both the nationwide scope of the Plaintiffs represented by their associations, and the FDA's regulatory structure, which enlists drug manufacturers to enforce REMS program requirements through a uniform nationwide scheme. *See generally* Dkt. 1-4 (REMS document describing implementation and enforcement system). Any "similarly situated" clinicians encompassed by the relief here are necessarily certified mifepristone prescribers—clinicians whom the FDA already regulates through other (unchallenged) components of the mifepristone REMS program, and whose actions are part of the FDA's

assessment of whether the drug manufacturer should face penalties (such as seizure of the drug product, *see* 21 U.S.C. §§ 334, 352(y); *see also id.* § 355(p)(1)(b)) for permitting any violations by any REMS-certified prescribers.

The district court's uniform, bright-line injunction, therefore, avoids "practical, administrative complexities" that would impede complete and immediate relief of Plaintiffs' and their patients' injuries in the emergent context of a pandemic. App. 76a. The district court properly recognized that it needed an injunction that the court could enforce and that the FDA and the drug manufacturers acting as its agents could plausibly implement immediately. *See id.* at 76a-77a. The court determined that it could not feasibly impose an injunction involving day-to-day membership checks, and that attempting to do so would hamstring the manufacturers, clinicians, patients subject to the REMS, and the FDA itself—and less effectively redress Plaintiffs' injuries. The court reasoned that the "costs" of attempting to carve out from the unitary, nationwide REMS enforcement scheme the minority of mifepristone prescribers who are not a member of the Organizational Plaintiffs on the day they prescribe the medication were unwarranted "[w]here an injunction covering Plaintiffs already covers 90 percent of OB/GYN physicians in the United States." *Id.* at 77a.[17]

At the same time, the district court emphasized the time-limited and circumscribed nature of its action. *See id.* at 78a-80a. The court took pains to make

[17] Indeed, if the preliminary injunction were narrowed and any certified mifepristone providers who are not members of the Organizational Plaintiffs had to bring follow-on suits to gain protection, all could sue in the District of Maryland, where the FDA is headquartered, and thus requiring such copycat suits would simply burden that court without reason. *See* App. 76a (considering need to avoid "duplicative" litigation).

clear that prescribers would still be subject to all other REMS requirements, including carefully supervising dispensing of mifepristone, and that mifepristone still could not be distributed through retail pharmacies. *Id.* at 79a-80a, 87a-91a. The court equitably arrived at a result "no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979). Contrary to Defendants' arguments, this is an equitable determination committed to the court's discretion, *see IRAP*, 137 S. Ct. at 2087—not a determination for the "political branches," Stay Pet. 31-32. Because Defendants have not shown and cannot show any abuse of discretion in this preliminary injunction's well-tailored scope, it should be neither stayed nor narrowed.

II. Denying the Stay Will Cause Defendants No Harm and Serve the Public Interest.

Finally, Defendants fail to establish that the preliminary injunction will cause either them or the public any harm, while lifting the injunction will expose countless individuals to unnecessary life-threatening risks. The injunction merely affords clinicians who prescribe mifepristone the same discretion Defendants afford virtually every other clinician prescribing virtually every other drug. Defendants' attempt to portray the court's ruling as a special exception for abortion providers, *see* Stay Pet. 22-23, is exactly backwards: of 20,000 FDA-approved drugs, mifepristone is one of just 17 that may not be dispensed by mail or through a pharmacy, and the *only* drug that patients are required to pick up in a clinical setting yet permitted to self-administer elsewhere, App. 5a; Dkt. 11-3, ¶ 58. The FDA has suspended other kinds of in-person requirements necessitating travel during the pandemic with specific

deference to clinicians' medical judgment. *See, e.g.*, Dkt. 11-3, ¶ 46 (FDA non-enforcement policy during COVID-19 PHE of REMS requirements for laboratory testing or imaging studies as long as "the accommodation is made based on the judgment of a health care professional").[18] Defendants have not, and cannot, offer *any* legitimate explanation why only clinicians prescribing a medication used for abortion care—not clinicians prescribing any other, far less safe drug—should be subject to this singular restriction that prevents them from exercising their medical judgment to provide care to their patients in the safest possible manner during the pandemic.

Nor can Defendants show that the preliminary injunction undermines their interest in patient safety, which even Defendants can muster only that the Requirements "might" advance. Stay Pet. 22. As the district court emphasized, *all* other mifepristone REMS requirements remain in place under the injunction: all prescribers still must be REMS-certified; mifepristone still must be dispensed under the supervision of a certified prescriber and may not be dispensed through retail pharmacies; and clinicians still must review with their patients the FDA's special form containing information about the nature and risks of mifepristone. The court's minor modification of the REMS during the official PHE—at the urgent request of

[18] *See also, e.g.*, U.S. Food & Drug Admin., FDA Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Public Health Emergency 6 (2020), https://www.fda.gov/media/136238/download (authorizing sponsors of clinical trial studies to "determine if in-person visits are necessary to fully assure the safety of trial participants"); *COVID-19 Information Page: Telemedicine*, U.S. Dep't of Justice, Drug Enforcement Admin. Diversion Control Div., https://www.deadiversion.usdoj.gov/coronavirus.html#TELE (last visited Sept. 7, 2020) (explaining that Defendant Azar worked with Drug Enforcement Administration to authorize prescriptions of controlled substances without an in-person evaluation during the PHE as long as "[t]he prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice").

the nation's health care providers, and in conformance with Defendants' actions with respect to other drugs—minimizes COVID-19 risk for patients, clinicians, their families, and their neighbors, with utterly no countervailing injury to Defendants.

CONCLUSION

For the foregoing reasons, Defendants' stay application should be denied.

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Respectfully submitted,

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