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 DEFENDANTS-APPLICANTS' SUPPLEMENTAL BRIEF IN SUPPORT OF APPLICATION FOR A STAY

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The United States is now facing "the most deadly phase" of the COVID-19 pandemic, Suppl. App. 5a (quoting the White House Coronavirus Task Force Coordinator), with "uniformly dire" conditions nationwide, *id.* at 30a. Nevertheless, Defendants-Applicants ("Defendants") ask this Court to take the extraordinary step of staying a preliminary injunction that protects patients and health care providers from life-threatening COVID-19 risks. Their application should be denied.

Five months ago, Plaintiffs-Respondents ("Plaintiffs")—whose members include more than 60,000 physicians in all 50 states and the department chairs of obstetrics and gynecology at nearly 150 universities nationwide, Dkt. 11-5, ¶ 3; Dkt. 11-8, ¶ 3; Dkt. 11-11, ¶ 5[1]—secured a preliminary injunction temporarily blocking the government from enforcing its requirement that abortion patients travel to a health center during the pandemic for the sole purpose of picking up a pill and signing a form (the "In-Person Requirements" or "Requirements"). In October, this Court left that preliminary injunction in place while directing the parties to build a "more comprehensive record" in the district court, including as to whether any "relevant circumstances had changed." *Food & Drug Admin. v. Am. Coll. of Obstetricians & Gynecologists*, No. 20A34, slip. op. at 1, 2020 WL 5951467 (U.S. Oct. 8, 2020) [hereinafter "October Order"] (mem.). Through the lens of that supplemental record, Defendants' failure to meet their heavy burden is even more plain.

The district court made extensive findings detailing how Defendants' In-Person Requirements continue to subject patients to needless and grave health risks

[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.

that "ha[ve] only gotten worse" nationwide since July. Suppl. App. 15a. At the same time, the court found that—months after the injunction took effect—"Defendants have offered *no* evidence that their temporary inability to enforce the In-Person Requirements has injured them or, for that matter, harmed a patient." *Id.* at 29a (emphasis added). Since mifepristone patients were already free to have their evaluation and counseling done via telemedicine and to swallow the mifepristone tablet at the time and place of their choice, *see* App. 4a–7a, temporarily enjoining the in-person pick-up requirement averts serious viral risks with no countervailing cost.

Indeed, the court noted that Defendants have maintained their nationwide suspensions of in-person requirements for other drugs during the pandemic, including permitting patients throughout the country to forgo "otherwise mandatory in-person evaluations" and counseling before obtaining opioids like fentanyl, which cause so many overdose deaths each year that they are the subject of their own official national emergency. Suppl. App. 17a; Dkt. 142-4, ¶¶ 13–17.[2] Given the breadth of Plaintiffs' membership, the uniformly deteriorating conditions, and Defendants' nationwide actions to prevent unnecessary travel even for far *less* safe drugs, the court concluded that the scope of relief remained proper. Suppl. App. 30a–32a.

Defendants' brief ignores all but two pages of the district court's recent decision, presumably because the record evidence overwhelmingly counsels against a stay. *See generally* Defs.' Suppl. Br. Supp. Appl. Stay ("Defs.' Suppl. Br."). Their

[2] *See also Renewal of Determination That a Public Health Emergency Exists*, U.S. Dep't of Health & Human Servs. (July 6, 2020), https://www.phe.gov/emergency/news/healthactions/ phe/Pages/opioid-6jul2020.aspx (Defendant Azar renewing for the tenth time "the October 26, 2017 determination . . . that a public health emergency exists nationwide as a result of the consequences of the opioid crisis").

argument that contextless, cherry-picked data from two states disproves the burdens on patients, *see id.* at 2, 4–7 (citing Suppl. App. 27a–28a), is hardly relevant to, much less defeats, the district court's core finding that the In-Person Requirements present a substantial obstacle by subjecting medication abortion patients to heightened risk of contracting a deadly disease, Suppl. App. 15a (citing App. 44a-45a).

In early October, when the Court sent this matter back to the district court, some might have hoped the pandemic was easing. But the risks and burdens reflected in the record have since worsened so profoundly that Defendants have abandoned in this Court their claim below that "changed circumstances" justify a stay. Dkt. 141-1, 1. All the arguments Plaintiffs previously raised (and incorporate by reference here) are only bolstered by the supplemental record. There is even less basis to support a stay today than there was in October, when this Court initially declined to grant one.

1. Defendants Have Not Met the Threshold Requirement for Extraordinary Relief from This Court.

As a threshold matter, Defendants' renewed application to this Court is premature: Defendants have not requested that the court of appeals grant a stay based on the supplemental record and thus "adequate relief" still may be available to them from that court. Sup. Ct. R. 20.1 (2019) (extraordinary relief under 28 U.S.C. § 1651(a) requires a showing that "adequate relief cannot be obtained . . . from any other court"). This Court's rules require that a stay application "set out with particularity why the relief sought is not available from any other court," Sup. Ct. R. 23.3, yet Defendants do not even attempt to make that showing. *See Williams v. Wilson*, 140 S. Ct 2800, 2801 (2020) (mem.) (declining to grant stay where "the

Government ha[d] not sought review of or a stay of" the district court's most recent order in the court of appeals); *In re United States*, 139 S. Ct. 452, 453 (2018) (denying stay without prejudice where "adequate relief may be available" in the court of appeals); *Conforte v. Comm'r*, 459 U.S. 1309, 1312 n.2 (1983) (Rehnquist, J., in chambers) ("Applicant's failure to seek a stay in the Court of Appeals provides an alternate ground for denial of the stay."); *In re Blodgett*, 502 U.S. 236, 240 (1992) ("[A]s a predicate for extraordinary relief, the State should have asked the Court of Appeals [for relief] before coming here.").

The fact that the prior stay application was held in abeyance does not alter this requirement, as the record on which a stay should or should not be granted is now different, and has not been considered by the court of appeals. There is no reason to believe the court of appeals would not consider that full record were Defendants to seek such relief. The rules regarding stays are designed to obviate unnecessary intervention by this Court, and that purpose would be fully served here by requiring Defendants to seek relief first in the court of appeals. For this reason alone, this Court should deny Defendants' stay application—or, at a minimum, continue to hold it in abeyance while Defendants exhaust their opportunities for relief below.

2. The Supplemental Record Only Bolsters the District Court's Finding of a Likelihood of Success on the Merits.

The district court's July 13 opinion granting the preliminary injunction rested "primarily" on its finding that, in the context of the COVID-19 pandemic, Defendants' In-Person Requirements impose "'a significant burden upon patients'" with "'travel to medical facilities fraught with health risk to [those patients], medical professionals,

others they encounter during such trips, and the members of their households to whom they return.'" Suppl. App. 15a (quoting App. 44a–45a). When that record was first considered by this Court, the Court declined to grant a stay but requested further factual development. *See* October Order, slip. op. at 1. This fall, in accordance with the Court's order, the parties submitted supplemental evidence in the district court principally focused on whether there have been any "changes in the severity of the problems caused by the COVID-19 pandemic" since July such that a stay, dissolution, or modification of the preliminary injunction is warranted. *Id.*, slip. op. at 2 (Alito, J., dissenting); *see also* Suppl. App. 13a; Dkt. 141-1, 1.

Plaintiffs' evidence included declarations from four leading national experts in public health, epidemiology, and economics, regarding the dire state of the pandemic, the increased risks and burdens associated with traveling for health care, and why the injunction remains essential to protect abortion patients from serious and needless exposure risks.[3] Defendants relied exclusively on declarations from officials in several states "describing changes to public health restrictions and guidance in

[3] Specifically, Plaintiffs submitted expert declarations from: (1) Arthur L. Reingold, M.D., a former CDC official and the Division Head of Epidemiology at the University of California, Berkeley School of Public Health, who currently chairs Governor Newsom's California COVID-19 Scientific Safety Review Workgroup, Dkt. 142-1; (2) Mary Travis Bassett, M.D., M.P.H., the Director of Harvard University's François-Xavier Bagnoud Center for Health and Human Rights, who served as Commissioner of New York City's Department of Health and Mental Hygiene from 2014–2018, Dkt. 142-2; (3) Ameet Sarpatwari, Ph.D., J.D., a pharmacoepidemiologist, public health expert, and Assistant Professor of Medicine and Health Policy at Harvard University who currently serves as the Principal Investigator on a multi-year collaborative study with the United States Food & Drug Administration ("FDA") to assess how FDA's Risk Evaluation and Mitigation Strategies ("REMS") programs have impacted physician and patient burden, drug utilization, safety monitoring, and health outcomes, Dkt. 142-4; and (4) Trevon D. Logan, Ph.D., a Professor of Economics at The Ohio State University and Research Associate of the National Bureau of Economics Research, who previously served as the President of the National Economics Association, Dkt. 142-5.

their states during the COVID-19 pandemic." Suppl. App. 3a.[4] Defendants did not submit a single declaration from any FDA, U.S. Department of Health and Human Services ("HHS"), or other federal official. *Id.* at 16a, 28a. Nor did they submit any evidence relating to the injunction's impact on patient safety. *Id.* at 29a.

Based on the supplemental evidence and data from the U.S. Centers for Disease Control and Prevention ("CDC"), the court found that, far from improving, the "health risk" imposed by the In-Person Requirements "has only gotten worse." *Id.* at 15a. The court explained that, since the preliminary injunction was issued, "the number of COVID-19 cases in the United States has increased four-fold, from over three million to more than 14.5 million, and the number of deaths from COVID-19 have more than doubled, from 130,000 to more than 280,000." *Id.* at 15a–16a. On July 13, the CDC's national seven-day moving average of new cases per day was approximately 44,000; as of December 5, it was 188,504, *id.* at 16a; and it has risen still further in just the past two weeks, to 239,604 as of December 20.[5] The court emphasized that "[t]his increase is not limited to any one part of the nation. In 49 states and the District of Columbia, the seven-day moving average of daily new cases is higher now than in July." *Id.* One would have to close one's eyes and ears not to know that the risks of contracting COVID-19 are at the highest they have ever been.

Presumably for that reason, as the district court noted, "although the CDC, the

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[4] Defendants' declarants work for the States of Alabama, Idaho, Indiana, Kentucky, Mississippi, Nebraska, and Oklahoma. Dkt. 141-4 to 141-11.

[5] *Trends in Number of COVID-19 Cases and Deaths in the US Reported to CDC, By State/Territory*, U.S. Ctrs. for Disease Control & Prevention, https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases (last visited Dec. 21, 2020) [hereinafter "CDC COVID Data Tracker"].

National Institutes of Health ("NIH"), and the FDA are all components of HHS, Defendants have offered no expert opinions, from a scientist at one of these agencies or elsewhere in the federal government, to contradict the facts and conclusions provided by" Plaintiffs' public health experts regarding the severe and ongoing viral risks. *Id.* To the contrary, while Defendants' motion was pending, "Dr. Deborah Birx, Coordinator of the White House Coronavirus Task Force, issued a report stating that the nation is 'entering the most concerning and most deadly phase of this pandemic.'" *Id.* at 5a. Recent CDC data confirms the accuracy of this assessment. As of December 20, the United States's seven-day moving average of new COVID-19 deaths per day was 2,654—nearly *triple* the seven-day moving average for deaths per day on August 26 (940), when Defendants first sought a stay in this Court, and approaching *quadruple* the average number of daily deaths on July 13 (726).[6]

Moreover, the district court found that the "ongoing health risks from exposure to COVID-19 are even more pronounced" for abortion patients, who "are disproportionately low-income and women of color." Suppl. App. 17a. Indeed, the court found that Black and Hispanic people between the ages of 25 and 34 are more than *700 percent* more likely to die from COVID-19 than white people in the same age range. *Id.* Here, too, Defendants offered nothing to contradict these facts.

The court rejected Defendants' speculation, unsupported by any expert testimony, that "[t]he precautionary measures that Americans are now aware of and have access to have mitigated the risks of travel such that an individual trip does not

[6] CDC COVID Data Tracker, *supra* n. 5.

increase the risk of contracting COVID-19 beyond that individual's baseline risk." Dkt. 141-1, 7. For example, the court found that public transportation, which abortion patients are disproportionately likely to need to get to a health center, *see* App. 14a, "still presents significant risks of infection," Suppl. App. 27a.[7] And the court found that the record rebutted Defendants' equally unsupported speculation that increased "use of masks" means that traveling to a health center does not increase a person's risk of contracting COVID-19, noting "the reality . . . that masks and mask mandates have not prevented the present spikes in COVID-19 cases across the country." *Id.* at 18a. For instance, Indiana "has had a mask mandate at least since September 2020," but "its seven-day moving average of new cases gr[e]w from 529 cases per day on July 13, 2020, . . . to 6,573 on December 5"—an increase of more than *one thousand percent*. *Id.* at 19a; *accord id.* at 10a. Another declarant state, Kentucky, instituted a mask mandate on July 10, when its seven-day daily case average was 327; by December 5, Kentucky averaged 3,411 new cases each day. *Id.* at 18a.

The court concluded that the record evidence also did not support Defendants' logical fallacy that forcing abortion patients to travel to a health center during the pandemic cannot pose a substantial obstacle because "certain states [have] relaxed public health restrictions since the spring of 2020." *Id.* at 19a. Rather, the court found (and Defendants' own declarants admitted) that these local reopening decisions "reflected judgments balancing economic needs, personal liberty, and other factors with public health risk." *Id.* at 22a; *see also* Dkt. 141-4, ¶ 12; Dkt. 141-6, ¶ 3; Dkt.

[7] Notably, more than one in three abortion patients nationwide must travel at least 25 miles to get to the nearest provider. Dkt. 11-3, ¶22.

141-9, ¶ 16. The court detailed the spiking rates of daily infections, hospitalizations, and deaths in the states that submitted declarations, Suppl. App. 9a–10a, observing "particularly significant increases in most of those numbers" in recent weeks. *Id.* at 9a. Based on unrebutted record evidence, the court concluded that "the reopenings have likely contributed to the dramatic increases in cases." *Id.* at 22a; *accord id.* at 10a. The states themselves have evidently drawn the same conclusion. As the district court noted, the recent resurgences have prompted "all of these states . . . to reverse course . . . impos[ing] or reimpos[ing] certain public health restrictions relating to the opening or operation of businesses and facilities." *Id.* at 20a. For example, while Defendants' motion was pending, the Governor of Oklahoma issued an emergency order "that telemedicine 'be used to maximum potential' and be allowed 'for non-established' patients in response to COVID-19." *Id.* at 21a.

The court also found that the population of patients seeking medication abortion care continues to disproportionately face other "specific challenges" relating to "economic conditions and access to medical facilities, childcare, and transportation" during the pandemic. *Id.* at 24a. These factors only multiply the risks and burdens these patients face, bolstering the court's conclusion that the In-Person Requirements continue to pose a substantial obstacle. *Id.* at 24a–27a; App. 47a–50a. For instance, the court found that "childcare remains a significant challenge, particularly for low-wage workers," largely due to ongoing "volatility in school schedules." Suppl. App. 26a. The court observed that "[m]any school districts across the United States either did not resume in-person classes or did so only as part of a hybrid model," and that

the recent resurgence has prompted "numerous large school districts . . . to postpone plans to reopen for in-person classes or to reverse course and suspend in-person classes in favor of remote learning." *Id.* at 25a–26a.

Finally, the court found that the evidence did not support "Defendants' claim that progress on medical treatments and vaccines for COVID-19 establishes changed circumstances sufficient to warrant a stay or dissolution." *Id.* at 22a. The court reasoned that, "while the progress on vaccines and medical treatments for COVID-19 are cause for optimism and may advance the day that the Preliminary Injunction will no longer be warranted, the impact of these advances to date has not meaningfully altered the current health risks and obstacles to women seeking medication abortions." *Id.* at 23a. Far from it: the recent vaccine roll-out has coincided with the highest infection and death rates since the pandemic began, with no signs of abating.[8]

Rightly judging that they could not credibly rehash for this Court their arguments that the risks and burdens of traveling during the pandemic have been "eliminated or mitigated," Dkt. 141-1, 21; *accord id.* at 5, 7, 19, Defendants instead devote their supplemental brief to an argument they addressed only in passing in the district court, *see id.* at 13–14: that small increases in the absolute numbers of abortions in two states during a few months in 2020, as compared with 2019, disprove

[8] *CDC COVID Data Tracker: United States Forecasting (Weekly Cases)*, U.S. Ctrs. for Disease Control & Prevention, https://covid.cdc.gov/covid-data-tracker/#forecasting_weeklycases (last visited Dec. 21, 2020); *CDC COVID Data Tracker: United States Forecasting (Weekly Deaths)*, U.S. Ctrs. for Disease Control & Prevention, https://covid.cdc.gov/covid-data-tracker/#forecasting_weeklydeaths (last visited Dec. 21, 2020); *'The weapon that will end the war': Vaccinations begin across virus-ravaged America*, N.Y. Times, https://www.nytimes.com/live/2020/12/14/world/covid-19-coronavirus/the-weapon-that-will-end-the-war-vaccinations-begin-across-virus-ravaged-america (last updated Dec. 18, 2020).

the district court's extensive findings that forcing patients to risk exposure to COVID-19 just to pick up a pill they are free to take at home imposes a substantial obstacle on the right to abortion. Defs.' Suppl. Br. 2, 4–7. But the district court correctly found Defendants' isolated abortion numbers beside the point. *See* Suppl. App. 27a–28a. Defendants' argument ignores the viral risks at the heart of this litigation, lacks any scientific rigor, and cannot carry their heavy burden to justify a stay.

As an initial matter, Defendants' sole focus on abortion numbers skirts the central issue in this case: that the In-Person Requirements make heightened risk of contracting a deadly disease a condition of obtaining a medication abortion. As Plaintiffs have explained, this Court's precedent does not permit the government to predicate a patient's access to abortion on serious and needless health risk to them and their families. Pls.' Resp. Opp'n Appl. Stay Prelim. Inj. ("Pls.' Opp'n Br.") 29–30.

But even looking at the question of whether some patients are ultimately able to obtain an abortion despite these government-mandated viral risks, Defendants' argument is woefully inadequate. Whether a policy imposes a substantial obstacle is not determined simply by counting how many people obtained an abortion over a given period without inquiring into any of the surrounding circumstances. Indeed, the suggestion that this Court can draw conclusions about patients' ability to access abortion care based on data comparing only two (partial) years, *see* Defs.' Suppl. Br. 2, 5, from "only two states," Suppl. App. 27a, with no attempt to control for the myriad confounding variables, defies rudimentary principles of statistical analysis. For instance, Defendants read constitutional significance into the fact that there were 3.7

percent more abortions reported in Indiana between March and September 2020 than during the same period for 2019—yet conveniently ignore that the number of abortions in 2020 was five percent *lower* than for the same period in 2018.[9] And Defendants do not even attempt to explain the dramatic month-to-month variation in Indiana's abortion numbers during the pandemic: *e.g.*, in July, up 14 percent relative to 2019; in August, down 19 percent relative to 2019. *See* Dkt. 141-7, 5.

As every student of statistics learns on day one, correlation is not causation. Yet Defendants make no effort to rule out the many other explanations for their data. For example, as the district court found, Defendants entirely ignore—and certainly do not control for—the fact that "demand for abortion services is likely increasing" because of disruptions in contraceptive access, "sudden" unemployment, and other pandemic-related "struggl[es]" that have made unwanted pregnancy more likely and parenting less tenable for some. App. 15a, 45a–46a; *accord* Suppl. App. 27a–28a; *see also* Dkt. 11-3, ¶¶ 20–21 (expert testimony from Allison Bryant Mantha, M.D., M.P.H., FACOG); Dkt. 142-5, ¶¶ 20, 37 (expert testimony from Trevon D. Logan, Ph.D.). Nor do Defendants discuss whether and how disruptions in abortion services during the pandemic in neighboring states like South Dakota and Ohio may have increased the number of abortions in Nebraska and Indiana this year.[10]

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[9] *See* Ind. State Dep't of Health, *Terminated Pregnancy Report 2018*, at Table 2 (2019), https://www.in.gov/isdh/files/2018%20Indiana%20Terminated%20Pregnancy%20Report.pdf. Plaintiffs note that 2020 data on abortions in these states are not yet publicly available and are solely within the possession of Defendants and their declarants.

[10] *See, e.g.*, Arielle Zionts, *South Dakota abortions halted in March due to pandemic*, Rapid City J. (Oct. 2, 2020; updated Nov. 7, 2020), https://rapidcityjournal.com/news/local/ south-dakota-abortions-halted-in-march-due-to-pandemic/article_f06e1f75-d8f6-50f4-b6b6-15f48afcc197.html (sole abortion clinic in South Dakota has not provided any abortions since March); *Preterm-Cleveland v. Att'y Gen. of Ohio*, 456 F. Supp. 3d 917, 934, 939 (S.D. Ohio 2020) (granting preliminary injunction of COVID-19

As these examples demonstrate, Defendants' raw counts from two states, devoid of any context or causal analysis, are neither scientifically valid nor constitutionally meaningful. *See A Woman's Choice-East Side Women's Clinic v. Newman*, 305 F. 3d 684, 692 (7th Cir. 2002) (rejecting undue burden argument based on studies showing a decline in the number of abortions, in part because they "[left] open . . . the reason *why* the effect occurs"); *Karlin v. Foust*, 188 F. 3d 446, 487–88 (7th Cir. 1999) (showing of decline in abortions without "adequately explain[ing] the reason for the decline" failed to prove that the "drop in abortions . . . [was] causally attributable to any unconstitutional effect of [state law]").

Defendants likewise defy logic in attempting to dismiss the life-threatening viral risks to which their In-Person Requirements subject patients as merely "ordinary risks and hardships" of the pandemic for which Defendants cannot be held responsible. Defs.' Reply Supp. Appl. Stay ("Defs.' Reply Br.") 6; *see also id.* at 7; Defs.' Suppl. Br. 3; Defs.' Appl. Stay Inj. ("Stay Pet.") 3, 15–17. Defendants created the In-Person Requirements, waived comparable requirements for other, far less safe drugs (including fentanyl) during the pandemic, and have refused to do so here—thereby *affirmatively preventing* abortion patients from adhering to the recommendations of Defendants' own CDC to avoid viral risk by using telemedicine whenever possible and "mail-order, or other delivery services" for prescription medications.[11] Patients who

executive order prohibiting surgical abortion procedures, but permitting such procedures only "on a case-by-case basis" where the abortion is "medically indicated and cannot be delayed"; also noting that executive order may prompt Ohio patients to "travel out of the state" for care).

[11] U.S. Ctrs. for Disease Control & Prevention, *Doctor Visits and Getting Medications* (Sept. 11, 2020), https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/doctor-visits-medicine.html.

must take transportation, drop their children off with someone outside their household, and engage in other in-person contact in order to obtain mifepristone because of Defendants' Requirements incur additional COVID-19 risk at every step of the way, *see* App. 46a–48a—not through any choice of their own, but pursuant to a federal mandate that, even according to Defendants, at most "might" advance some hypothetical benefit, Stay Pet. 21–22; *see also* Pls.' Opp'n Br. 33–37; *infra* p. 16.

Consider, by analogy, if the government had a rule forbidding grocery stores from delivering to their customers' homes, despite CDC recommendations that people avoid viral risk by having their essentials delivered.[12] Clearly, the heightened COVID-19 risk incurred by any person who must pick up their groceries in person against their wishes, only because of the mandate, would be attributable to the government; that others might *choose* to take on those risks because they prefer to shop in person is irrelevant. *See* Dkt. 142-2, ¶ 42. Likewise, as the district court observed, that individuals may be "*permitted* to venture out during a pandemic to restaurants or businesses does not establish that women should be *mandated* to risk exposure to COVID-19 in order to exercise a constitutional right." Suppl. App. 22a.

Finally, Defendants' argument that the burdens their In-Person Requirements impose during the pandemic are permissible because "surgical methods of abortion remain widely available," makes no sense. Stay Pet. 3; *see also id.* at 13–15; Defs.' Suppl. Br. 2–3; Defs.' Reply Br. 3–5. As Plaintiffs have explained, Defendants cannot defend their decision to subject medication abortion patients to needless COVID-19

[12] *Running Essential Errands*, U.S. Ctrs. for Disease Control & Prevention (Sept. 11, 2020), https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/essential-goods-services.html.

risk by arguing that, instead of obtaining their mifepristone by mail, patients could instead travel to a health center for a procedure requiring *more* in-person contact and posing a *greater* risk of COVID-19 infection. Pls.' Opp'n Br. 25–28.

Defendants' legal arguments were insufficient to carry the day when Defendants sought a stay four months ago: this Court instead sought more factual development on changed circumstances. *See* October Order, slip. op. at 1. That more comprehensive factual record only magnifies the severe burdens that Defendants' Requirements impose during what has since become an even more lethal pandemic.

3. Defendants Have Not Met Their Burden to Show Irreparable Harm.

As the district court noted, after months of real-life experience under the injunction, Defendants "offered *no* evidence that their temporary inability to enforce the In-Person Requirements has injured them or, for that matter, harmed a patient." Suppl. App. 29a (emphasis added). Defendants' failure to show any harm, much less irreparable harm, is dispositive. *Ruckelshaus v. Monsanto Co.,* 463 U.S. 1315, 1317 (1983) (Blackmun, J., in chambers) ("[L]ikelihood of success on the merits need not be considered . . . if the applicant fails to show irreparable injury" from stay denial).

Instead of citing any evidence of harm, Defendants note, repeatedly, that the Requirements are "longstanding." *See* Defs.' Suppl. Br. 1, 3, 7; *see also* Stay Pet. 1–4, 13; Defs.' Reply Br. 1, 7, 11. But that hardly establishes that a temporary suspension during a declared Public Health Emergency ("PHE") causes irreparable harm. Even outside the pandemic, Defendants' safety justifications are not supported by any scientific data or technical analysis, *see* Pls.' Opp'n Br. 35; Dkt. 62-6, 0356–57, and

are opposed by leading national medical experts, *see* Br. American Medical Association et al. as Amici Curiae Supp. Pls.' Opp'n Defs.' App. Stay Pending Appeal 6–7 (Sept. 8, 2020). Now, months after medically eligible patients began obtaining their mifepristone prescriptions by mail or delivery to avoid COVID-19 risk, Defendants have not even attempted to show any harm. Nor have they ever responded to the district court's finding that the FDA never reviewed the central factual question in this case: the impact of the Requirements on patient safety *during the COVID-19 pandemic*. App. 53a. Even after this Court directed Defendants to build a "more comprehensive record" to support their stay request, October Order, slip. op. at 1, Defendants could not muster a single declaration from any FDA, HHS, or other federal official to show harm of any kind, much less irreparable harm, Suppl. App. 28a. Rather, *all* of the record evidence demonstrates that Defendants' Requirements serve no beneficial purpose while affirmatively endangering patient health.

Moreover, as this Court explained in *Roman Catholic Diocese of Brooklyn v. Cuomo*, blind deference to the government's unsupported speculations about harm is unwarranted *even* during a pandemic, and particularly when constitutional rights are at issue. No. 20A87, 2020 WL 6948354, at *3 (U.S. Nov. 25, 2020) (per curiam). Similarly, here, Defendants cannot meet their burden to show irreparable harm based solely on unfounded speculation that the Requirements "*could* help avoid *potential* delay" and "*might*" allow for counseling closer in time to when the patient takes the pill, Stay Pet. 21–22 (emphasis added); *see also* Pls.' Opp'n Br. 33–37, when they offered no evidence of any harm after five months under the injunction.

Defendants have provided this Court no basis to conclude that denying a stay Defendants first sought in August, and instead permitting Defendants' appeal of the preliminary injunction to continue in the normal course, will cause any harm.

4. Defendants' Arguments for Narrowing the Injunction Are Meritless.

As the district court reiterated in its December ruling, "the scope of the injunction is primarily based . . . on the actual geographic and professional breadth of the members of the plaintiff organizations, who are located in all 50 states and include more than 90 percent of the [nation's] obstetrician/gynecologists." Suppl. App. 33a–34a. A nationwide injunction was dictated by the need to protect Plaintiffs, their members, and their patients across the country from a nationwide mandate. The preliminary injunction likewise accounts for the "practical, administrative complexities" that could impede complete relief of Plaintiffs', their members' and their patients' injuries, Pls.' Opp'n Br. 44, and ensures fairness to vulnerable, similarly situated patients during this national emergency, App. 76a.

Nevertheless, Defendants argued in their renewed motion that the court should narrow the scope of the injunction because "many [states] have weathered rising and falling COVID-19 rates, but they continue to move forward." Dkt. 141-1, 24. Rejecting this empty argument, the district court explained that "even if at some point since the issuance of the Preliminary Injunction there have been signs that certain states were having success in responding to the COVID-19 pandemic, the current circumstances are uniformly dire across the nation." Suppl. App. 30a. With rates surging nationwide—including in all seven states Defendants featured as examples of improving conditions, *id.* at 9a–10a—the court found "no meaningful

basis by which to distinguish one state or region from others as uniquely free from the health risks" underlying the preliminary injunction, *id.* at 30a.

Moreover, as the court found, Defendants themselves "have effectively acknowledged" the uniform risks nationwide "through their decisions and actions relating to the COVID-19 pandemic, which, from all angles, have been homogenous across all regions of the country." *Id.* For instance, the court noted that Defendants have renewed the official COVID-19 PHE three times, "always maintain[ing] the scope of the declaration at a nationwide level" despite legal authority and recent precedent for PHEs limited to specific states or regions. *Id.* at 30a–31a. And just this month, the FDA updated its guidance allowing drug sponsors to forgo in-person requirements for clinical trials—including for drugs whose safety has not yet been determined, *see* Dkt. 142-4, ¶¶ 22–24—"without any change to the nationwide scope" of the policy. Suppl. App. 31a.[13]

Indeed, as the district court highlighted, Defendant Azar has designated that patients "in all areas of the United States," Dkt. 78, be able to obtain all schedule II controlled substances, including opioids like fentanyl and OxyContin®, through telemedicine during the PHE. Suppl. App. 17a; Dkt. 142-4, ¶¶ 13–17. Defendant Azar deems the viral risks associated with traveling for health care during the PHE sufficiently great to justify suspending, *on a nationwide basis*, a requirement that patients meet with a clinician to be evaluated and counseled in person at least once

[13] U.S. Food & Drug Admin., *FDA Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency* 3 (last updated Dec. 4, 2020), https://www.fda.gov/media/136238/download. The district court's decision refers to the FDA's September update, Suppl. App. 31a; neither update narrowed the nationwide scope.

before obtaining opioid drugs that, according to the FDA, cause such a "staggering" number of overdose deaths each year that they are "reducing life expectancy in the United States" and are the subject of their *own* national PHE. Suppl. App. 17a.[14]

In short, there is nothing in the original or supplemental record to support Defendants' arguments that the preliminary "injunction is overly broad in scope, given that it applies nationwide and for an indefinite duration regardless of the improving conditions in any individual State." October Order, slip. op. at 1. To the contrary, the preliminary injunction is entirely consistent with Defendants' own nationwide actions during the PHE with respect to other drugs;[15] terminates when Defendants themselves end the nationwide COVID-19 PHE, App. 78a–80a; Dkt. 92, ¶ 2; and was a proper exercise of the district court's discretion to ensure relief to Plaintiffs and their members and patients nationwide, *see* Pls.' Opp'n Br. 41–45.

CONCLUSION

For the foregoing reasons as well as those articulated in Plaintiffs' September 8 response brief, Defendants' renewed stay application should be denied.

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[14] *Opioid Medications*, U.S. Food & Drug Admin. (Aug. 4, 2020), https://www.fda.gov/drugs/information-drug-class/opioid-medications; U.S. Dep't of Health & Human Servs., *supra* note 2.

[15] Defendants suggest that their extensive actions to mitigate viral spread by suspending in-person requirements for other drugs nationwide, App. 44a, should not be construed as evidence that the In-Person Requirements impose serious viral risks, because the FDA has maintained a requirement for in-person, clinically supervised dispensing *and administration* of 15 drugs out of the 20,000 it regulates. *See* Defs.' Reply Br. 8 (citing App. 67a); *Fact Sheet: FDA at a Glance*, U.S. Food & Drug Admin., https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance (last visited Dec. 21, 2020). Defendants can find no support in the fact that the FDA has maintained in-person clinical supervision requirements for drugs that, *e.g.*, carry "risk of immediate, life-threatening allergic reaction," Dkt. 11-3, ¶ 60, when Defendants concede that mifepristone is the only drug in the nation that patients must pick up in a clinical setting (during a pandemic, no less) even though they are free to self-administer it, unsupervised, at the time and place of their choosing, Defs.' Reply Br. 8. The district court properly found that Defendants' "extraordinary actions" to prevent patients nationwide from having to travel for medical care underscore that the In-Person Requirements impose a substantial obstacle on patients seeking medication abortion care during the PHE. App. 44a, 49a.

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Respectfully submitted,

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