No. 20-1824, No. 20-1970, No. 20-1784

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, *et al.*,
Plaintiffs-Appellees,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,
Defendants-Appellants,

and

STATE OF INDIANA, *et al.*,
Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND

PLAINTIFFS-APPELLEES' PRINCIPAL AND RESPONSE BRIEF

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INTRODUCTION

This case asks whether, during the COVID-19 emergency, Defendants-Appellants ("Defendants") can force patients seeking abortion and miscarriage care to unnecessarily risk exposure to a life-threatening disease by mandating that they travel to a health center for the sole purpose of picking up a pill and signing a form.

Plaintiffs-Appellees ("Plaintiffs") include leading medical organizations whose members comprise more than 60,000 physicians nationwide and the department chairs of obstetrics and gynecology at nearly 150 universities across the United States. Acting to protect their patients and themselves from COVID-19, which has infected more than 26 million people in the United States and killed nearly half a million,[1] 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 mifepristone, a safe and effective medication used to end an early pregnancy or complete an early miscarriage. Although Defendants suspended similar requirements for many other, far *less* safe, medications during the pandemic, they denied urgent requests from Plaintiffs and other medical experts to do the same for mifepristone. In July, the U.S. District Court for the District of Maryland

[1] *CDC COVID Data Tracker: United States COVID-19 Cases and Deaths by State, U.S. Ctrs. for Disease Control & Prevention*, https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days (last visited Feb. 4, 2021) [hereinafter "*CDC U.S. Cases and Deaths*"].

preliminarily enjoined enforcement of certain aspects of this federal restriction for the duration of Defendants' COVID-19 Public Health Emergency ("PHE").

Plaintiffs challenge Defendants' refusal to temporarily suspend their requirement that mifepristone patients travel to a hospital, clinic, or medical office just to pick up medication and sign a form ("In-Person Requirements" or "Requirements"). There is no medical content to this visit: Defendants do not require any clinical services or counseling when patients pick up their pill, and permit patients to swallow the pill later, unsupervised, at the location of their choice. Of more than 20,000 FDA-approved drugs, mifepristone is the *only* one patients must pick up in a clinical setting yet are free to self-administer elsewhere. During the pandemic, Defendants' Requirements prohibit patients who have already been evaluated and counseled by a clinician via telemedicine or at a prior in-person visit from safely receiving their mifepristone by mail or delivery.

There is no genuine dispute that the In-Person Requirements impose severe viral transmission risks: Defendants have taken "extraordinary actions" to mitigate precisely those same risks by urging the use of telemedicine "wherever possible" and relaxing in-person requirements nationwide for other drugs during the PHE. Joint Appendix ("JA") 1463-64. Indeed, in recognition of the exposure risks posed by travel, Defendants even suspended a requirement that patients meet with a

clinician in person to be evaluated and counseled before obtaining opioids like fentanyl, which are so dangerous they are the subject of their own national PHE.[2]

Defendants can show no error in the district court's well-founded conclusion that their refusal to likewise suspend the mifepristone Requirements—which make needless and life-threatening viral risk a condition of obtaining care—imposes a substantial obstacle to abortion access. Nor did the court abuse its discretion in carefully crafting a remedy tailored to the exigencies of the case, including Plaintiffs' 50-state membership, administrative feasibilities, and fairness to vulnerable patients during this national crisis. The court's sole error was denying relief based on Plaintiffs' equal protection claim, by misapprehending governing precedent and disregarding the evidence squarely establishing the irrationality of Defendants' refusal to temporarily suspend these "unnecessary health regulations," JA1482 (internal quotations and citation omitted), even as they suspended other in-person requirements containing actual medical content.

Finally, the court properly rejected efforts by ten States ("States" or "Denied-Intervenors") to intervene in this case. This litigation solely concerns the federal government's actions that endanger and discriminate against abortion and

[2] *Renewal of Determination That a Public Health Emergency Exists*, U.S. Dep't of Health & Human Servs. (Jan. 7, 2021), https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioids-7Jan2021.aspx.

miscarriage patients during the PHE. The court correctly concluded that Defendants more than adequately represent whatever interest the States may have in enforcement of the Requirements without injecting irrelevant and complicated questions of state law into the litigation.

This Court should affirm the denial of intervention and the grant of the preliminary injunction, while reversing the erroneous equal protection ruling.

JURISDICTIONAL STATEMENT

Plaintiffs invoked the district court's jurisdiction pursuant to 28 U.S.C. §§ 1331, 1346, 2201, 2202. *See* JA35. This Court has jurisdiction under 28 U.S.C. § 1292(a)(1) over Defendants' appeal (July 22, *see* JA1512) and Plaintiffs' appeal (September 10, *see* JA1574) of the district court's July 13 order granting and denying in part Plaintiffs' motion for a preliminary injunction, *see* JA1501-05. This Court has jurisdiction under 28 U.S.C. § 1291 over the States' appeal (July 15, *see* JA1509) of the district court's June 15 denial of intervention, *see* JA1304-05.

It is "well settled" that "only parties to a lawsuit, or those that properly become parties, may appeal an adverse judgment," *Marino v. Ortiz*, 484 U.S. 301, 304 (1988) (per curiam) (citation omitted), and thus the Court lacks jurisdiction over the Denied-Intervenors' protective appeal of the injunction, *see* JA1509, unless the Court finds that intervention was improperly denied, *see, e.g.*, *Farmland Dairies v. Comm'r of N.Y. State Dep't of Agric. & Mkts.*, 847 F.2d 1038, 1044-45 (2nd Cir. 1988).

STATEMENT OF THE ISSUES

1. Whether the district court correctly adhered to two unbroken lines of Supreme Court precedent holding that abortion providers have third-party standing to vindicate their patients' constitutional rights, including where, as here, the providers themselves face penalties under the challenged law.
2. Whether the court correctly held that a requirement that abortion patients expose themselves to COVID-19 risk in order to travel to a health center for the sole purpose of picking up a pill and signing a form likely constitutes an undue burden on the right to abortion during the PHE.
3. Whether the court acted within its discretion in crafting injunctive relief that accounts for Plaintiffs' tens of thousands of members nationwide, the unique administrative challenges of anything less than a categorical rule, and fairness to vulnerable patients during this national emergency.
4. Whether the court erred in denying Plaintiffs' equal protection claim where, to reduce viral transmission risks, Defendants waived in-person safety requirements for other patients but refused to waive the mifepristone Requirements, which indisputably lack any medical content and which the record evidence proved to be unnecessary.
5. Whether the court acted within its discretion in denying intervention to ten States that share Defendants' objective to uphold the constitutionality of the

challenged restrictions and that seek to interject irrelevant issues regarding a multitude of unchallenged state laws.

STATEMENT OF THE CASE

Mifepristone Regimen

Abortion

Medication abortion, the most common form of early abortion care, *see* Br. of AMA et al. as Amici Curiae Supporting Pls.-Appellees (forthcoming) ("AMA et al. Amicus Br."), involves two prescription pills: mifepristone, followed 24 to 48 hours later by misoprostol, JA1422. Together, they cause a patient to undergo a pregnancy termination similar to a miscarriage. JA1422-23, 145. Millions have used this regimen, which is FDA-approved through 10 weeks of pregnancy, JA147-48, 1426.

Clinicians can assess a patient's eligibility for medication abortion through an in-person examination or through telemedicine. JA1426-27, 145-46. 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 evaluate and counsel the patient to the clinician's judgment. JA1426-27. During the pandemic, Plaintiff American College of Obstetricians and Gynecologists ("ACOG"), which represents the vast majority of the nation's OB-GYNs, JA1493-94, issued expert guidance recommending that clinicians perform these assessments remotely for medically eligible patients to mitigate COVID-19 spread, JA146. Other leading medical groups, including the

American Medical Association, agree that eligible patients can obtain all necessary clinical evaluations and counseling remotely. *See* AMA et al. Amicus Br.

FDA acknowledges that mifepristone's safety is "well established by both research and experience." JA1323. The FDA-approved labeling for mifepristone identifies two serious risks: "Serious and Sometimes Fatal Infections or Bleeding," but notes that "[n]o causal relationship between the use of [mifepristone] and misoprostol and [these risks] has been established," and that the same serious adverse events are a risk any time the pregnant uterus is emptied, whether through "miscarriage, surgical abortion, medical abortion, or childbirth." JA75-76, 90. In its "most recent safety review" for mifepristone, FDA found that major adverse events are "'exceedingly rare, generally far below 0.1% for any individual adverse event.'" JA1479 (citation omitted); *see generally* AMA et al. Amicus Br. The small fraction of patients who have a follow-up procedure after using the mifepristone-misoprostol regimen typically do so for reasons that FDA acknowledges are *not* serious adverse events, such as continuing pregnancy. JA87, 150. In any scenario, the follow-up procedure is identical to the procedure used in a surgical abortion or to evacuate the uterus in cases of miscarriage. JA150.

Miscarriage

Mifepristone is also part of the superior treatment regimen for medical management of early pregnancy loss, which involves the same two drugs used in a

medication abortion. JA1423, 148. Mifepristone enhances the efficacy of the misoprostol, making it more likely that a patient suffering a miscarriage will completely expel the pregnancy with medications alone and not need a follow-up in-office procedure to evacuate the uterus. JA1423, 148.

Miscarriage is very common: one in four pregnancies end in miscarriage, with 80 percent of pregnancy loss occurring in the first trimester. JA144. Patients often do not obtain treatment at the same time and place that they receive a miscarriage diagnosis—for instance, because an overwhelmed emergency department refers them elsewhere, or the patient needs more time to process the news. JA161, 263, 275-76, 291. In such cases, patients seeking miscarriage treatment must (1) travel to a health center (either to pick up mifepristone pursuant to the Requirements, or to have an in-office procedure) or (2) use misoprostol (which can be obtained at retail pharmacies or by mail) only, despite its lower effectiveness when taken alone.

FDA's Regulation of Mifepristone

The Requirements and other restrictions on mifepristone are imposed under FDA's Risk Evaluation and Mitigation Strategies ("REMS") authority, which permits restrictions beyond a drug's labeling. 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. JA1423, 1440-41, 1349.

The mifepristone REMS contains three "Elements to Assure Safe Use" ("ETASU," 21 U.S.C. § 355-1(f)(3)(A), (C)-(D)), *see* JA95-102:

- **ETASU A**: only specially certified clinicians 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 at the medication pick-up. JA1476. All information in this form is also included in a Medication Guide that accompanies each mifepristone pill. JA1427.

In 2016, FDA updated the mifepristone REMS, including by removing language directing patients to take the mifepristone at their prescriber's office. JA1424. The agency identified "safety" as a benefit of allowing patients to take the medication at the time and place of their choice. JA760. However, FDA retained the In-Person Requirements 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.'" JA1473 (quoting JA694).

Of more than 20,000 FDA-approved drugs, mifepristone and its brand name analogue (Mifeprex®) are among just 17 medications that FDA requires patients to obtain in a health center. JA1352. Mifepristone is the *only* drug FDA requires patients to pick up in a clinical setting 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, for instance because of a risk of "immediate, life-threatening allergic reaction." JA153-54, 1425.

Defendants' Actions in Response to the Pandemic

In January 2020, Defendant U.S. Department of Health and Human Services ("HHS") declared a nationwide PHE resulting from COVID-19, "a highly contagious and life-threatening respiratory disease caused by the SARS-CoV-2 novel coronavirus." JA1428-29. Defendants have renewed their PHE declaration four times on a nationwide basis.[3] As of July 13, when the preliminary injunction was issued, the Centers for Disease Control and Prevention ("CDC") within HHS reported over three million U.S. cases and 130,000 deaths, with a seven-day moving average of 44,000 new cases and 726 new deaths per day. *Id.*[4] In recent months,

[3] *Renewal of Determination That a Public Health Emergency Exists*, U.S. Dep't of Health & Human Servs. (Jan. 7, 2021), https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-07Jan2021.aspx.

[4] *See also 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,

consistent with the predictions of Plaintiffs' expert epidemiologist Dr. Arthur L. Reingold, the nation has faced a severe resurgence. JA1466. The total number of U.S. cases had increased *eight-fold* since July to more than 26 million, with nearly 450,000 U.S. deaths.[5] As of February 2, the United States had a seven-day moving average of nearly 140,000 new infections, and more than 3,100 deaths, each day.[6]

Recognizing that, during the pandemic, "travel to medical facilities [is] fraught with health risk to [patients], medical professionals, others they encounter during such trips, and the members of their households to whom they return," Defendants have taken extensive actions to minimize such travel. JA1463-65. For instance, the Secretary of HHS, acting with the concurrence of the U.S. Drug Enforcement Administration ("DEA"), suspended in-person evaluation requirements nationwide for controlled substances, including opioids—which "claim[] lives at [such] a staggering rate" that they "are reducing life expectancy in the United States"[7]—"even though it would mean" that these drugs "would be released into the community with fewer safeguards." JA1430, 1463-64. And FDA

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https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases (last visited Feb. 4, 2021) [hereinafter "CDC Data Trends"].

[5] *CDC U.S. Cases and Deaths*, *supra* n.1.

[6] *CDC Data Trends*, *supra* n.4.

[7] *Opioid Medications*, U.S. Food & Drug Admin. (last updated Aug. 4, 2020), https://www.fda.gov/drugs/information-drug-class/opioid-medications.

announced that it would not enforce any REMS ETASU requirements mandating laboratory testing or imaging studies in order to obtain certain drugs that carry serious risks, JA1430, 1463, as long as the accommodation is made based on the judgment of a health care professional, JA202.[8] Indeed, FDA lifted in-person requirements even for unapproved drugs still undergoing clinical trials.[9] More broadly, CDC urges clinicians to use telemedicine "whenever possible" as "the best way to protect patients and staff from COVID-19," and explicitly encourages patients to fill prescriptions by mail or delivery. JA1430-32.

In March and April 2020, Plaintiff ACOG and other leading medical authorities "formally requested that FDA agree not to enforce the Requirements during the COVID-19 pandemic." JA1473, 104-129. FDA neither heeded these requests nor provided any "sign that it has undertaken a formal review of the issue in light of ... the ongoing pandemic." JA1473.

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[8] U.S. Food & Drug Admin., Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency 7 (2020), https://www.fda.gov/media/136317/download [hereinafter "REMS Non-Enforcement Guidance"].

[9] *See* U.S. Food & Drug Admin., FDA Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency 3 (2020, updated 2021), https://www.fda.gov/media/136238/download [hereinafter "Clinical Trials Guidance"] (authorizing trial sponsors to "determine if in-person visits are necessary to fully assure the safety of trial participants" or "whether alternative methods … could be implemented").

Procedural History

On May 27, Plaintiffs—including ACOG, a membership organization representing tens of thousands of doctors in all 50 states and D.C., and the Council of University Chairs of Obstetricians and Gynecologists ("CUCOG"), a membership organization representing the department chairs of obstetrics and gynecology at nearly 150 universities and hospitals nationwide, JA243, 279-80, 300—filed suit and moved for a preliminary injunction, JA1307-48, 130-345. Plaintiffs argued that, by forcing mifepristone patients to incur unnecessary COVID-19 risks while lifting similar requirements for other patients, Defendants' refusal to suspend the Requirements unduly burdens the right to abortion and violates equal protection during the pandemic. JA1307-48, 130-345.

Preliminary Injunction

On July 13, the Honorable Judge Theodore D. Chuang granted in part and denied in part Plaintiffs' motion. The court granted relief based on Plaintiffs' due process claim, enjoining enforcement of the mifepristone REMS during the PHE "to the extent" that it prohibits clinicians from dispensing mifepristone "by mail or delivery service" to patients obtaining medication abortions. JA1504. The court denied relief based on Plaintiffs' equal protection claim, thereby excluding patients seeking treatment for a miscarriage from the injunction's protections.

The injunction temporarily authorized abortion patients to avoid unnecessary COVID-19 risks in two narrow ways: After assessing a patient at a prior in-person or telemedicine appointment, a certified prescriber could 1) mail or deliver the medication to their patient; or 2) arrange to have the medication shipped directly to their patient from a mail-order pharmacy with which the prescriber had pre-arranged to stock and mail mifepristone on their behalf. JA1571-73. The injunction did *not* permit clinicians to issue a prescription and then leave patients to their own devices to find a pharmacy that stocks mifepristone. JA1571-73. In-person dispensing remained available where appropriate for a particular patient. JA1477. The court enjoined the Patient Form ETASU "only to the extent" that it requires an in-person trip: prescribers were still required to review the information with their patients but no longer needed to sign in person. JA1504-05.

Standing: The court's opinion first found it "firmly established" based on Supreme Court precedent "that abortion care physicians have third-party standing to challenge abortion restrictions infringing on their patients' constitutional rights." JA1444; *see also* JA1438-43. The court also found based on "case-specific" evidence that Plaintiffs' patients were suffering injury; that Plaintiffs and their members have close relationships with their patients seeking medication abortion care and that their interests in providing and obtaining abortion care without needless viral risk are aligned; and that the hindrances abortion patients typically face in

bringing a lawsuit are exacerbated in the context of the pandemic and associated economic crisis. JA1444-50. Additionally, the court found that Plaintiffs and their members are directly regulated by the REMS, and that the direct constitutional injury Plaintiffs and their members allege establishes standing on their equal protection claim. JA1441-42, 1451.

Undue Burden: Judge Chuang found that Plaintiffs were likely to prevail on their due process claim because Defendants' Requirements "present a serious burden" by forcing patients "to decide between forgoing or substantially delaying abortion care, or risking exposure to COVID-19 for themselves, their children, and family members." JA1468. The court's extensive factual findings relied on Plaintiffs' unrebutted expert testimony,[10] as well as Defendants' actions regarding other drugs, which "effectively acknowledged" that any travel, "for any purpose … presents a significant risk to patients" during the PHE. JA1464-65.

[10] Plaintiffs' witnesses included Arthur Reingold, M.D., Division Head of Epidemiology at the University of California at Berkeley School of Public Health and former CDC official, who serves on SARS-CoV-2 advisory boards for the University of California system and the city of San Francisco, JA187-240; Allison Bryant Mantha, M.D., M.P.H., FACOG, Associate Professor at Harvard Medical School and Vice Chair of Quality, Equity and Safety for Massachusetts General Hospital's OB-GYN department, JA138-86; Eve Espey, M.D., M.P.H., FACOG, Chair of the OB/GYN department at the University of New Mexico School of Medicine, JA278-84; Heather Paladine, M.D., M.Ed., FAAFP, Assistant Attending Physician at New York Presbyterian Hospital and Assistant Professor of Medicine at Columbia University Medical Center, JA241-54; as well as other highly qualified physicians who provide medication abortion care, JA255-77, 285-92.

Moreover, the court found that abortion patients generally face even "*more* significant health risks arising from traveling to a medical facility during the pandemic." JA1466 (emphasis added). 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." JA1467. *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. JA1466, 143, 160-61. *Third*, abortion patients face greater exposure risks because of their "particularized" transportation needs. JA1469, 1481. Specifically, 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 for health care; and travel to the nearest abortion provider may take hours and involve multiple gas and rest stops. JA1466-67, 1469; *see also* AMA et al. Amicus Br. *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." JA1468 (internal quotations and citations omitted). *Finally*, abortion patients are more likely

to live in intergenerational housing where contracting COVID-19 would put family members at risk. JA1466.

The court further found that the Requirements significantly delay or prevent some patients from obtaining care. JA1469-70. This finding relied on unrebutted evidence of medical offices closing during the pandemic for in-person services and/or operating at reduced capacity, both of which limit the availability of any abortion care requiring an in-person visit. JA1465-66, 1469-70. The court also found that low-income patients face "serious hurdles" finding and paying for transportation and childcare due to the pandemic and economic crisis. JA1466-70, 1443. 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. JA1469-70.

Based on these undisputed findings, the court concluded that, "in the specific context of the unprecedented COVID-19 pandemic," the "convergence" of burdens "present[s] a substantial obstacle to a large fraction of the women for whom the In-Person Requirements are relevant." JA1469-70, 1482-83.

In the alternative, Judge Chuang held that the Requirements are unconstitutional when considering their "serious burdens" together with their purported benefits. JA1482. The court rejected Defendants' argument that the Chief

Justice's concurrence in *June Medical Services, LLC v. Russo*, 140 S. Ct. 2103 (2020), overruled the majority's holding in *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2309 (2016) ("*WWH*"), that an abortion restriction's burdens must be considered together with its benefits. JA1456-58 (citing *A.T. Massey Coal Co. v. Massanari*, 305 F.3d 226, 236 (4th Cir. 2002)). Having already found a due process violation based on the "burdens alone," the court also found that "the evidence shows" the Requirements "to likely be 'unnecessary health regulations' under the present circumstances." JA1482 (quoting *WWH*, 136 S. Ct. at 2309).

Defendants submitted no current evidence to demonstrate the need for their Requirements; rather, Defendants' justifications "rel[ied] entirely" on FDA's "dated" 2013 REMS review, which "did not take account of intervening events," such as FDA's 2016 determination that patients can safely self-administer mifepristone anywhere, the now-widespread use of telemedicine, or the unprecedented exigencies of the pandemic. JA1473-75. 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." JA1475.

Defendants attempted to justify their continued enforcement of the Requirements by arguing that the restrictions further safety in two ways: (1) providing an "*opportunity* for in-person counseling," JA1474, and (2) "avoid[ing]

the *possibility* of delay that *could* arise *if* patients were to obtain the drug from pharmacies on their own," Defs.' Br. 6 (emphases added); JA1474. The district court found that "under the present circumstances," the Requirements do not advance either interest. JA1471-79. To begin with, the Requirements do not mandate in-person counseling, JA1476, and, irrespective of the Requirements, in-person counseling is available if a clinician determines that it would be beneficial or a patient wishes to receive it. Defendants offered "no evidence demonstrating that telemedicine counseling sessions are ineffective or insufficient for communicating information about the risks or alternatives to medication abortion," JA1477; indeed, Defendants authorized opioid prescriptions through telemedicine alone, effectively conceding the safety and efficacy of remote counseling. JA1430, 1463. By contrast, Plaintiffs provided extensive evidence that "telemedicine is now in widespread use, including as an effective means to providing counseling relating to medication abortion" and that "face-to-face counseling can be accomplished with equal effectiveness through telemedicine, especially during the pandemic." JA1475-77.

Moreover, the court found this asserted justification ill-suited to mifepristone given FDA's admissions regarding the medication's strong safety profile. JA 1479. And, because FDA permits the patient to ingest the mifepristone hours or days after obtaining it and any rare complications 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. JA1471, 1478, 147.

The district court found four bases for rejecting Defendants' only other proffered justification: that the Requirements could avoid delay in initiating the abortion "that could arise if patients were to obtain the drug from pharmacies on their own, such as delay caused by difficulty finding a pharmacy that stocks the drug." Defs.' Br. 6; *accord id.* at 42-43, 45; JA485. *First*, the court emphasized that FDA already "specifically does not control when the mifepristone is actually taken," and has not reconsidered this 2013 "delay" rationale since it began permitting patients to self-administer mifepristone, unsupervised, at a date and time of their choice. JA1478-79. *Second*, the court noted that Defendants' asserted concern that retail pharmacies might decline to stock mifepristone was irrelevant because the injunction does not permit dispensing through retail pharmacies.[11] JA1477-79. *Third,* 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." JA1477-78 (emphasis added). *Fourth*, the court reasoned that under the injunction, "[i]f in-person dispensing is the most efficient"

[11] In a clarification order, the court confirmed that while the injunction encompasses supervised delivery through a mail-order pharmacy that pre-stocks and dispenses mifepristone on behalf of the prescriber, it does not permit dispensing through retail pharmacies (*i.e.*, physical stores). JA1571-73.

delivery method "for a *particular* patient, that option will remain available." JA1477. Judge Chuang concluded that Defendants' efforts to "raise the specter of health risks and complications" justifying the Requirements failed, because "the actual operation of the Mifepristone-Misoprostol Regimen illustrates that the In-Person Requirements do not advance general interests of patient safety." JA1471.

Equal Protection: Judge Chuang declined to grant preliminary relief based on Plaintiffs' equal protection claim. Having already held that the Requirements likely violate abortion patients' due process rights, the court said it would limit its equal protection review to patients and clinicians using mifepristone for miscarriage and a rational basis analysis. JA1483-84. Although Judge Chuang acknowledged that Defendants' "waivers of certain in-person requirements [but not the mifepristone Requirements] appear to reflect differential treatment during the pandemic," the court concluded that the record was inadequate to support an equal protection finding under rational basis review. JA1485-88.

Although it is undisputed that the mifepristone Requirements contain no medical content—patients can obtain all evaluation and counseling and take the pill at home, JA1424, 1426-27—and although the district court found that the Requirements are "unnecessary" and "do not advance" either of Defendants' asserted justifications, JA1471 (internal quotations and citation omitted), the court nevertheless surmised that potential "safety" distinctions might exist between

mifepristone and the drugs for which Defendants have waived mandatory in-person evaluation, testing, and/or administration requirements during the PHE that would justify differential treatment, JA1484-87. Perceiving "too many gaps" to determine whether mifepristone patients and clinicians are similarly situated to the comparator groups and whether there is a rational basis for suspending other in-person requirements but not the mifepristone Requirements, the court denied preliminary injunctive relief on Plaintiffs' equal protection claim. JA1488.

Irreparable Harm: The district court found that the likely constitutional injury Defendants' Requirements impose during the COVID-19 emergency established irreparable harm for medication abortion patients, JA1488-90, and that the balance of equities and public interest weighed decisively in favor of injunctive relief, JA1490-92. The court explained that the government "will not be harmed by a preliminary injunction temporarily preventing the enforcement of a regulation that is likely to be unconstitutional under the present circumstances," and that an injunction would not harm Defendants' interest in patient safety. JA1490-91. The court also noted that its "limited" injunction of the In-Person Requirements would leave untouched all other REMS requirements for mifepristone, including that it be dispensed under the supervision of a REMS-certified prescriber. JA1491.

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." JA1491-92 (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." JA1492.

Equitable Relief: In crafting the injunction, the 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 [o]rganizational Plaintiffs is extensive in number and geography." JA1493. For instance, ACOG alone "has more than 60,000 members, including practitioners in all 50 states, the District of Columbia, [and] 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." JA1494. To reach all of Plaintiffs' members, the injunction was necessarily national in scope.

The court found that extending the injunction to the "limited number" of non-member clinicians who are similarly situated to Plaintiffs' members would ensure "uniform, fair, and rational treatment" of "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." JA1494-96 (internal quotations 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," "the costs of addressing the issues relating to enforcement against the remaining healthcare providers far outweigh the benefits of a narrower injunction." JA1493, 1497. Covering similarly situated patients and clinicians would also avoid the need for "duplicative" follow-on lawsuits. JA1496. By contrast, excluding similarly situated patients and clinicians or attempting to limit the geographic scope of the injunction "would create practical, administrative complexities," including by conditioning enforcement of the injunction on "a determination whether the physician is a member of one or more of the [o]rganizational Plaintiffs" as of the relevant date. JA1496-97. And the court concluded 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." JA1497-98.

Judge Chuang 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." JA1498-99.

Stay Proceedings

Defendants appealed the preliminary injunction order and sought a stay of the injunction pending appeal, which the district court denied. JA1550-51. On August 13, a panel of this Court unanimously denied Defendants' stay motion without opinion. No. 20-1824, Dkt. 30. Defendants then filed an application in the Supreme Court for a stay of the injunction pending appeal. On October 8, the Supreme Court issued an order leaving the preliminary injunction in place but "hold[ing] the Government's application in abeyance to permit the District Court to promptly consider a motion by the Government to dissolve, modify, or stay the injunction, including on the ground that relevant circumstances have changed." *FDA v. Am. Coll. of Obstetricians & Gynecologists*, No. 20A34, slip. op., at 1, 2020 WL 5951467 (U.S. Oct. 8, 2020) (mem.) [hereinafter "October Order"].

Defendants filed such a motion in the district court, arguing that the "risks and burdens" associated with travel during the pandemic have all been "eliminated or mitigated." No. TDC-20-1320, Dkt. 141-1, at 21. Judge Chuang denied that motion on December 9, finding that Defendants' Requirements continue to impose grave health risks that "ha[ve] only gotten worse," with "uniformly dire" conditions nationwide. No. TDC-20-1320, Dkt. 144, at 15, 30. The court also 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 29 (emphasis added).

Defendants returned to the Supreme Court, which granted the stay application on January 12. *FDA v. Am. Coll. of Obstetricians & Gynecologists*, No. 20A34, slip. op., at 1 (U.S. Jan. 12, 2021) (mem.) [hereinafter "Stay Decision"].

Denial of Intervention

On June 15, Judge Chuang rejected the States' motion to intervene. JA1287-1305. The court found that the States were not entitled to mandatory intervention because their asserted interest in enforcing their own abortion laws—which "are independent of the federal scheme" and "not ... conditioned on FDA's ongoing enforcement of its guidelines" for mifepristone, JA1293—did not establish a "direct and substantial" interest in the case that would be "practical[ly] impair[ed]" if intervention were denied, JA1296 (quoting *Feller v. Brock*, 802 F.2d 722, 730 (4th Cir. 1986)). *See* JA1291-97. The court also found that Defendants and the States "share the 'same ultimate objective' for the FDA regulations to be upheld as constitutional," JA1298 (quoting *Stuart v. Huff*, 706 F.3d 345, 352 (4th Cir. 2013)); additional citation omitted), and that the States' "speculation" that they may not be "aligned" with Defendants' "litigation strategy" did not suffice to rebut the presumption that the U.S. government, which had "already filed its brief with

exhibits vigorously opposing [Plaintiffs'] Motion for Preliminary Injunction," would adequately represent the States' interests, JA1298-1300.

Judge Chuang also denied permissive intervention, finding that the States' participation as parties "would require the Court to grapple with issues of the laws of ten different states, none of which are in this circuit," in a case narrowly challenging FDA restrictions during the pandemic. JA1300-02. Judge Chuang noted that "the number of would-be intervenors with their own unique issues is more than triple" the number of proposed intervenors that raised concerns over "complicat[ions]" and "resources" in *Stuart v. Huff*. JA1301 (citing 706 F.3d at 350). The court reasoned that any additional information the States wished to present could be "adequately and most appropriately conveyed through an amicus brief," just like those already filed by numerous States and medical organizations supporting Plaintiffs. JA1302; *see also* No. TDC-20-1320, Dkt. 42, 43. The court denied the States' Motion to Reconsider. JA1506-08.

In addition to appealing from the denial of intervention, the States purport to appeal the preliminary injunction order despite their non-party status. JA1509.

SUMMARY OF ARGUMENT

The district court entered a preliminary injunction because it properly found that Plaintiffs had standing to vindicate their patients' rights; that mandating an unnecessary in-person visit during the pandemic likely imposes an undue burden on

the right to abortion; and that, absent an injunction, Plaintiffs, their members, and their patients will suffer irreparable harm.

Defendants can show no error in the court's thorough standing analysis or its conclusion, based on decades of Supreme Court precedent and undisputed "case-specific" evidence, that Plaintiffs and their physician-members are proper and effective advocates for their abortion patients' due process rights.

With respect to undue burden, the court's conclusion that the Requirements' "burdens alone" pose a substantial obstacle during the PHE is sufficient to support its finding that Plaintiffs are likely to succeed on the merits of their due process claim. JA1481-82. Unable to dispute the district court's findings, based on extensive and unrebutted evidence, that the Requirements impose serious viral transmission risks and particular harm to the majority of abortion patients who are low-income and people of color, Defendants advance two novel legal theories. Both are incorrect.

Defendants first argue that the government may 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* Defs.' Br. 16-17, 24-28. But four decades of Supreme Court precedent squarely foreclose Defendants' argument that the government has free rein to restrict the most common method of early abortion care, because patients could

instead travel for a *more* invasive surgical procedure that would *heighten* their risk of contracting COVID-19, as long as patients are ultimately able to get an abortion.

Defendants' second argument—that *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833 (1992), and *Harris v. McCrae*, 448 U.S. 297 (1980), prohibit courts from considering the interplay between a legal requirement and the real-life circumstances in which it operates, Defs.' Br. 28-31—is contradicted by virtually every Supreme Court decision evaluating restrictions on abortion. The notion that the risks and harm resulting from Defendants' imposition of the Requirements during the PHE are somehow "incidental" or out of Defendants' hands, *id.*—despite their having created the Requirements and despite waiving in-person requirements for other drugs, but refusing to do so here—defies reason.

Defendants also fall far short of establishing error in the court's "alternative" holding, Defs.' Br. 10, 33, that the Requirements advance no benefit and indeed endanger patients, and therefore that the serious burdens they impose during the PHE substantially outweigh their benefits. As the court found, Defendants' two justifications—both purely speculative, both drawn exclusively from an "outdated" 2013 analysis, and neither revisited during the pandemic—are contradicted by logic and unrebutted evidence.

Defendants' objections to the nationwide scope of relief are equally unavailing. Defendants argue that the court exceeded "Article III's constraints" and

the limits of its "equitable powers" in extending protections during a lethal pandemic to similarly situated patients whose clinicians happen not to be card-carrying members of the Plaintiff organizations, Defs.' Br. 45, 47; *see also id.* at 44, 48-50. But this Court has long held that "relief to similarly situated parties is sometimes appropriate," as even Defendants concede, Defs.' Br. 49-50 (citing *Roe v. Dep't of Def.*, 947 F.3d 207, 232-33 (4th Cir. 2020))—including to provide "uniform, fair, [and] rational treatment" for all vulnerable people suffering under a categorical rule, *Roe*, 947 F.3d at 233-34. The court acted well within its discretion in crafting a remedy consistent with Plaintiffs' vast membership and "practical, administrative complexities" arising from anything short of categorical relief. JA1496.

However, the court erred in denying injunctive relief based on Plaintiffs' equal protection claim. The court's analysis of whether mifepristone patients and clinicians are similarly situated to others during the pandemic defied binding precedent and ignored unrebutted evidence that mifepristone patients and prescribers are similar with respect to the interest animating Defendants' waivers: minimizing the risk of viral spread. And the court disregarded the voluminous evidence—and its own findings—establishing the irrationality of Defendants' refusal to suspend these "unnecessary health regulations," JA1482 (internal quotations and citation omitted), despite waiving other in-person requirements containing actual medical content.

Finally, Judge Chuang properly found that the ten States seeking to intervene in a case challenging only federal policies were not entitled to intervention. The States argue that they have a direct and substantial interest in this litigation because a ruling addressing the constitutionality of FDA's Requirements could "cast doubt" on independent state laws that are "modeled after, influenced by, logically related to, or otherwise interact with" this federal restriction. States' Br. 23. But this far-reaching theory cannot be squared with this Court's requirement that a movant seeking mandatory intervention must "stand to gain or lose by the *direct legal operation* of the court's judgment on [the] complaint." *Teague v. Bakker*, 931 F.2d 259, 261 (4th Cir. 1991) (emphasis added). Nor have the Denied-Intervenors made *any* showing, much less the requisite "strong showing," that the federal government cannot adequately represent their shared interest in defending the Requirements. *Stuart*, 706 F.3d at 351-52. The district court appropriately exercised its discretion in determining both that the States had not met the threshold for mandatory intervention, and that *tripling* the number of parties so that the States could purport to defend numerous distinct state laws not challenged here would only cause complication and delay. Instead, the Denied-Intervenors properly participated as amici—just like nearly two dozen other States and *all* of the nation's leading medical associations, who argued as amici that the Requirements impose needless risk and should be suspended during the PHE.

STANDARD OF REVIEW

The grant or denial of a preliminary injunction or of mandatory or permissive intervention are reviewed "for an abuse of discretion," which "is a deferential standard." *Roe*, 947 F.3d at 219 (citations omitted); *Dewhurst v. Century Aluminum Co.*, 649 F.3d 287, 290 (4th Cir. 2011) (citation omitted); *Stuart*, 706 F.3d at 349. Factual findings are reviewed for clear error and legal conclusions de novo. *Mountain Valley Pipeline, LLC v. W. Pocahontas Props. Ltd. P'ship*, 918 F.3d 353, 366 (4th Cir. 2019).

ARGUMENT

I. The District Court Did Not Abuse Its Discretion in Granting the Preliminary Injunction.

To obtain a preliminary injunction, a party must establish: (1) likelihood of success on the merits; (2) likelihood of irreparable harm; (3) that the balance of equities tips in its favor; and (4) that an injunction is in the public interest. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The district court correctly determined that Plaintiffs satisfied each of these conditions.

A. Plaintiffs Have Standing.

Just last year, the Supreme Court reaffirmed that it "ha[s] long permitted abortion providers to invoke the rights of their actual or potential patients in challenges to abortion-related regulations." *June*, 140 S. Ct. at 2118 (plurality); *see also id.* at 2139 n.4 (Roberts, C.J., concurring and joining plurality's standing

reasoning). These "well-established precedents foreclose" Defendants' standing arguments. *Id.* at 2120.

"Generally, a plaintiff may assert the constitutional rights of a third party if the plaintiff has [a] 'close relationship' to [that] party and if there exists some 'hindrance to the third party's ability to protect his or her own interests.'" JA1442 (quoting *Powers v. Ohio*, 499 U.S. 400, 411 (1991)). Closeness for these purposes focuses on shared interests and the likelihood of effective advocacy, not the length of the relationship. *See, e.g.*, *Campbell v. Louisiana*, 523 U.S. 392, 397-98 (1998). As the Supreme Court has explained, abortion patients' rights are "inextricably bound up with" the activity the clinician aims to pursue, and the "closeness of the relationship" for standing purposes is "patent." *Singleton v. Wulff*, 428 U.S. 106, 114-17 (1976). Similarly, all pregnant patients seeking abortion face obstacles of, *inter alia*, imminent mootness and privacy. *Id.* at 117. Thus, the Court has long held that "it is generally appropriate to allow a physician to assert the rights of women patients against governmental interference with" abortion, *id.* at 118, or even the rights of "potential patients," *June*, 140 S. Ct. at 2118 (plurality).

While four decades of unbroken Supreme Court precedent were sufficient to support the court's standing determination, Judge Chuang also found based on "case-specific evidence" that Plaintiffs had established closeness and hindrance. JA1444. The court found that "Plaintiffs have provided specific evidence of close physician-

patient relationships," and that providers and patients "share the common interest of [ensuring] access to a medication abortion [for] eligible patients in a timely manner while avoiding health risks during the COVID-19 pandemic arising from in-person visits," whereas Defendants did not present "any evidence showing ... divergent, or even non-parallel, interests." JA1446-48.[12] And the court found based on overwhelming evidence that patients seeking time-sensitive medication abortion face vastly increased hindrances now, since they are predominantly low-income parents facing "specific dangers and challenges" during the pandemic. JA 1449-50.

In addition to permitting third-party standing when the closeness and hinderance prongs are satisfied, the Court has "permitted plaintiffs to assert third-party rights in cases where the enforcement of the challenged restriction *against the litigant* would result indirectly in the violation of third parties' rights." *June*, 140 S. Ct. at 2118-19 (plurality) (internal quotations and citation omitted). Here, the district court properly found that the REMS directly regulates clinicians and subjects

[12] Defendants' argument that Judge Chuang erred in focusing the standing analysis principally on one of Plaintiff NYSAFP's physician members is meritless. *See* Defs.' Br. 20-21. "The Supreme Court has made it clear that 'the presence of one party with standing is sufficient to satisfy Article III's case-or-controversy requirement,'" *Bostic v. Schaefer*, 760 F.3d 352, 370 (4th Cir. 2014), and that a single member with standing in their own right is sufficient to establish associational standing, *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 563 (1992). Moreover, the district court's discussion of that physician was simply illustrative; Plaintiffs submitted similar evidence from members of the other organizational Plaintiffs, as well as Dr. MacNaughton, an individual Plaintiff. JA285-92.

Plaintiffs and their members to "imminent injury." JA1439-42.[13] FDA concedes that it can enforce the Requirements against clinicians directly, and that clinicians face penalties for violations—at minimum, loss of ability to prescribe mifepristone; at maximum, criminal sanctions. JA1440-42, 1349-50. On this basis, too, the district court correctly found standing. JA1442.[14]

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[13] The Denied-Intervenors' argument that the Plaintiff associations cannot vindicate the rights of their members' patients, States' Br. 35-37, is without merit. *Pa. Psychiatric Soc'y v. Green Spring Servs., Inc.*, 280 F.3d 278, 293 (3d Cir. 2002) (finding psychiatric society can rely upon associational standing *and* members' ability to assert the rights of members' patients). The cases the States cite provide no support for their position, States' Br. 36: *Warth v. Seldin* holds that an association has standing based solely on its members' injury "[e]ven in the absence of injury to itself," 422 U.S. 490, 511 (1975); *Northeast Ohio Coal. for the Homeless v. Blackwell* concludes that a charity cannot establish standing based on injury to the populations it serves in the absence of any "reference at all to injury to the [organization's] members," 467 F.3d 999, 1010 (6th Cir. 2006); and *Hunt v. Washington State Apple Advertising Comm'n* illustrates that associational standing allows organizations with extensive memberships, as here, to stand in their members' shoes and collectively bring those members before the Court to seek relief against government policies. 432 U.S. 333, 343 (1977).

[14] While Defendants do not contest traceability or redressability, the States argue that because the drug manufacturers play a role in enforcing FDA's requirements, there is some standing defect. States' Br. 31-35. These arguments fail. "[F]or an injury to be fairly traceable ... the defendant's actions need not be 'the very last step in the chain of causation.'" *Am. Acad. of Pediatrics v. FDA,* 379 F. Supp. 3d 461, 478-79 (D. Md. 2019) (citations omitted) (tracing injury to "FDA's actions" even though "the manufacturers theoretically could have chosen to ... remove their products from the market in response" to FDA guidance); *accord Bennett v. Spear*, 520 U.S. 154, 168-69 (1997). And the States' theory that the manufacturers could refuse to allow mifepristone to be distributed by mail ignores both that any clinician acting pursuant to an injunction is still in "full compliance" with their legal

B. Defendants' Requirements Likely Pose an Undue Burden During the PHE.

1. Mandating Travel and Interpersonal Contact During a Lethal Pandemic is a Substantial Obstacle.

The government may not impose regulations with "the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus." *Casey*, 505 U.S. at 877 (plurality). Here, correctly noting that "[a] combination of ... barriers can establish a substantial obstacle," JA1469 (citing *June*, 140 S. Ct. at 2130; *WWH*, 136 S. Ct. at 2317-18), the court found that Defendants' Requirements impose numerous burdens "in the specific context of the unprecedented COVID-19 pandemic" which, "taken together," present a substantial obstacle. JA1470, 1482-83.

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" itself. *Anderson v. City of Bessemer City, N.C.*, 470 U.S. 564, 574 (1985). Here, the evidence is entirely one-sided. Judge Chuang's substantial obstacle finding relied on *unrebutted* and indisputable evidence that the transportation, childcare, and other interpersonal contact necessitated by Defendants' Requirements are "fraught with health risk"

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obligations, States' Br. 32, and that redressability is "not [an] onerous" requirement, *Deal v. Mercer Cty. Bd. of Educ.*, 911 F.3d 183, 189 (4th Cir. 2018).

both for patients and for "the members of their households to whom they return." JA1464-65. That finding is fully supported by Defendants' own "extraordinary actions" during the PHE, including suspending in-person requirements for opioids and many other drugs. *See supra* at 11-12. The court made further findings, again based on *unrebutted* evidence, that abortion patients are at especially high risk of both exposure to SARS-CoV-2 and severe illness or death from COVID-19. *See supra* at 16-17. Defendants 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 substantially burden patients. JA1468. And Defendants' protestation that the In-Person Requirements necessitate a "one-time trip" that is not "substantially riskier than a trip anywhere else," Defs.' Br. 2, 17, 27, 39, is incompatible with their decision to waive other in person requirements—and in any event cannot justify a *government mandate* that patients incur life-threatening risks as a condition of obtaining constitutionally protected medical care.

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 17; *June*, 140 S. Ct. at 2140 (Roberts, C.J., concurring) (favorably citing

district court finding that challenged law would cause "longer waiting times for appointments, increased crowding and increased associated health risk" (internal quotations and citation omitted)). No evidence even calls into question, much less contradicts, the court's conclusion that these factors render the Requirements "dangerous during the pandemic." JA1469.

Having failed to rebut any of this evidence, Defendants ask this Court simply to ignore it, advancing two profoundly flawed legal arguments. *See* Defs.' Br. 24-31. 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 2-3, 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 FDA's mandate that patients incur grave COVID-19 risk by engaging in unnecessary travel and proximity to other people as a condition of obtaining abortion care when they could safely obtain the pill by mail. It is no defense 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* JA1479, 1489, 166; AMA et al. Amicus Br.[15]

[15] Moreover, Defendants' reliance on the "availability of surgical abortions," Defs.' Br. 25, *accord id.* at 17, 26-27, cannot be squared with their assertion that the Requirements are somehow justified because a tiny fraction of patients may

The isolated phrases from *Gonzales v. Carhart* on which Defendants rely cannot rescue this argument. *See* Defs.' Br. 24-25, 26-27 (citing 550 U.S. 124 (2007)). 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 because another abortion method, posing greater COVID-19 risk, exists. Indeed, as Defendants acknowledge, this extreme argument would permit them even to *ban* medication abortion altogether. *See id.* at 26 (arguing that FDA could have refused to approve mifepristone in 2000 regardless of whether the medication met the agency's standards for approval). That is not the law.

Gonzales concerned a ban on a rarely used procedure for second-trimester abortions. The plaintiffs made 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, *Gonzales*, 550 U.S. at 147; *see also id.* at 135; *Stenberg v. Carhart*, 530 U.S. 914, 934 (2000) (describing "relative

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eventually "require surgical intervention" after completing the mifepristone-misoprostol regimen, Defs.' Br. 6; *accord id*. at 5-6. It is undisputed that the very same procedure is used both in a surgical abortion *and* as the "surgical intervention" in the few cases when a medication abortion patient needs follow-up care. *See supra* at 7. Defendants cannot decry this procedure as evidence of mifepristone's risks while at the same time holding it up as an alternative that grants the government free rein to burden mifepristone access.

rarity" of banned abortion method); and (2) that the ban was facially invalid because it lacked a health exception, *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 Mo. 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" for any patient—much less do so in a large fraction of relevant cases. *Id.* at 162 (emphasis added); *see also id.* at 161, 163-65. 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 (internal quotations and citation omitted).

It is one thing to say, under the unique circumstances of *Gonzales*, that the government can bar a rare abortion method when the most common, 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 the government can force patients to face undeniable risk of exposure to a deadly virus to obtain the method of abortion that accounts for 60 percent of early care, *see* AMA et al. Amicus Br., and where the alternative Defendants propose is that patients not only travel to a health center, but also have a procedure involving more time in the facility and more extended contact, and thus even greater COVID-19 risks.[16]

Moreover, 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* Defs.' Br. 25. As a factual matter, Defendants' premise that a surgical procedure is a "readily available" alternative during the pandemic is unfounded. *Compare id.* at 24, *with* JA1465-70 (discussing challenges abortion patients face obtaining any in-person care during the pandemic); JA1465-70 (discussing office closures and reduced capacity for *any* in-person abortion care during the pandemic, and the severe challenges abortion patients face arranging transportation and childcare in the current economic crisis); AMA et al. Amicus Br. (discussing evidence of patients being unable to obtain reproductive health care during the pandemic, and that a substantial percentage of abortion providers offer only

[16] Additionally, *Gonzales* involved a method that Congress *prohibited* because it found it posed unique "ethical and moral" concerns, 550 U.S. at 158, whereas here FDA has not only *approved* mifepristone, but has determined that it is "important to the health of women." JA445.

medication, not surgical, abortions). Indeed, Defendants themselves have highlighted the "difficult[y]" patients may face obtaining in-office services during the PHE "because patients may need to avoid public places and patients suspected of having COVID-19 may be self-isolating and/or subject to quarantine." JA202.

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, Defs.' Br. 25, cannot be squared with Supreme Court precedent, which has emphasized a range of burdens short of complete bars in invalidating abortion restrictions. *June*, 140 S. Ct. at 2130 (plurality) (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) (internal quotations 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" (internal quotations and citations omitted)); *WWH*, 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 ultimately are able to 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 already killed nearly half a million Americans in a year. *See supra* at 11.

Defendants' second argument is equally unavailing. Characterizing the restrictions challenged here as "incidental," Defendants maintain that the court was forbidden from considering how their Requirements impact patients during the pandemic because Defendants did not *cause* the pandemic. Defs.' Br. 28-31. But Supreme Court precedent, which routinely examines the real-world effects of abortion regulations given existing circumstances, flatly refutes that argument.

When, as here, the government imposes restrictions on abortion access, courts must consider 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*, the Supreme 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)—circumstances that are no more an "obstacle[] of [the government's] creation" than COVID-19. Defs.' Br. 29 (quoting

Harris, 448 U.S. at 316). In *June*, the Court examined the effect of the challenged law in light of patients' poverty. 140 S. Ct. at 2130 (plurality) (emphasizing that the burdens "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" (internal quotations and citation omitted)). The same was true in *WWH*, which assessed the particular burdens on "poor, rural, or disadvantaged women." 136 S. Ct. at 2302 (internal quotations and citation omitted). Similarly, 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 between abortion providers, are critical considerations in an undue burden challenge. *See, e.g.*, *June*, 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).[17] The Requirements are indisputably

[17] The election-specific cases the States cite are entirely inapposite. States' Br. 47. In *Tully v. Okeson*, the plaintiffs' claims "hinge[d] on one question: what is 'the right to vote'?," 977 F.3d 608, 611 (7th Cir. 2020). *New Georgia Project v. Raffensperger*

a restriction on abortion access which Defendants 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 court's well-founded holding that the government's actions impose a substantial obstacle "in the specific context of the unprecedented COVID-19 pandemic." JA1470.

Finally, Defendants fail to show that Judge Chuang abused his discretion in concluding that the Requirements likely posed such an obstacle for a large fraction of patients for whom it "'is an actual rather than an irrelevant restriction.'" JA1458 (quoting *WWH*, 136 S. Ct. at 2320), 1460-61, 1466-67, 1482-83. The relevant denominator is not all "patients seeking a medication abortion," Defs.' Br. 41—just as the denominator in *Casey* was not all patients required to notify their spouses, 505 U.S. at 893, 895. Instead, the court properly found that the relevant class is medication abortion patients "during the COVID-19 pandemic for whom an in-person visit is not medically necessary" (*i.e.*, who are otherwise eligible to receive

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concerned whether the State must extend the deadline for receiving absentee ballots despite its "strong" election-related interests, where the Court found that voters could "simply take reasonable steps and exert some effort to ensure that their ballots are submitted on time." 976 F.3d 1278, 1282 (11th Cir. 2020). And in *Texas League of United Latin American Citizens v. Hughs,* the Fifth Circuit found that limiting the number of ballot drop boxes did not unconstitutionally burden voting rights where voters could cast their ballot without *any* travel by putting it in the mail. 978 F.3d 136, 145 (5th Cir. 2020). Unlike the courts' findings in *Raffensperger* and *Hughs*, there is no reasonable alternative for patients here.

medication abortion without an-in person visit)—just as the relevant class in *Casey* was limited to "[1] married women seeking abortions [2] who do not wish to notify their husbands of their intentions and [3] who do not qualify for one of the statutory exceptions." JA1461 (citing 505 U.S. at 893, 895). Defendants point to no evidence undermining the court's finding that a large fraction of such patients will face a substantial obstacle during this national emergency, particularly where the demographics of abortion patients mean that a majority are at heightened risk for both exposure and serious illness. *See* JA1482-83. Nor does the large fraction test require a precise quantification. Defs.' Br. 41. Indeed, in *WWH*, the Court affirmed the district court's large fraction finding, 136 S. Ct. at 2320, even though in granting a permanent injunction the lower court declared it "impossible to divine exactly how many women in Texas may be affected," *Whole Woman's Health v. Lakey*, 46 F. Supp. 3d 673, 683 (W.D. Tex. 2014); *see also Casey*, 505 U.S. at 895 (no quantification of patients harmed by spousal notification requirement).[18]

[18] The fact that, in the course of rejecting Defendants' argument for application of the "no-set-of-circumstances" test from *United States v. Salerno*, 481 U.S. 739 (1987), the district court accurately observed that Plaintiffs seek to enjoin the requirements only "as applied" to the circumstances and duration of the COVID-19 pandemic, does nothing to help Defendants' cause. Defs.' Br. 40-41; JA1453-55. The court correctly found that Plaintiffs satisfied the large fraction test for facial relief, and Defendants have not revived their unsupportable argument regarding *Salerno*. *See, e.g.*, *Casey*, 505 U.S. at 895 (applying "large fraction" test); *Whole Woman's Health*, 136 S. Ct. at 2320 (same); *Planned Parenthood, Sioux Falls Clinic*

2. The Court's Alternative Holding Considering Both Burdens and Benefits Together Provides No Basis for Reversal.

The court likewise did not err in its 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 substantial obstacles the Requirements impose during the PHE outweigh their non-existent benefits, JA1471, 1482 (quoting *WWH*, 136 S. Ct. at 2309).

As an initial matter, Defendants misconstrue *Marks v. United States*, *see* Defs.' Br. 33-35 (citing 430 U.S. 188 (1977)), in arguing that the single-justice concurrence in *June* implicitly overruled *WWH*'s explicit holding that "[t]he rule announced in *Casey* ... requires that courts consider the burdens a law imposes on abortion access together with the benefits those laws confer," 136 S. Ct. at 2309. *Marks* provides that "[w]hen a fragmented Court decides a case and no single rationale explaining the result enjoys the assent of five Justices, the holding of the Court may be viewed as that position taken by those Members who concurred in the judgments on the narrowest grounds." 430 U.S. at 193 (internal quotations and citations omitted). Defendants' argument that the district court erred in balancing the burdens and benefits because four dissenters and a single concurring Justice rejected

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v. Miller, 63 F.3d 1452, 1458 (8th Cir. 1995) ("We believe the Court effectively overruled *Salerno* for facial challenges to abortion statutes.").

that test in *June* is flatly contradicted both by *Marks* itself and by this Court's precedent. *Marks*, 430 U.S. at 193 (focusing only on the justices that "concurred in the judgment[]"); *Massanari*, 305 F.3d at 236 (instructing courts applying *Marks* to consider the "common denominator" only among Justices "who support the judgment" (internal quotations and citation omitted)). As Judge Chuang explained, *June*'s holding is "limited to the reasoning that represents a 'common denominator'" between the concurrence and the plurality—and "the plurality did not agree with the Chief Justice's criticism of the balancing test," nor did "the Chief Justice predicate[] the decision on an overruling of [*WWH*]." JA1456-57. Rather, the Chief Justice was clear that *WWH* endures. *June*, 140 S. Ct. at 2133 (Roberts, C.J., concurring) ("The question today ... is not whether [*WWH*] was right or wrong but whether to adhere to it in deciding the present case.").

The *Marks* rule does not yield a controlling opinion in every case, because "'one opinion can be meaningfully regarded as narrower ... only when one opinion is a logical subset of other, broader opinions.'" *United States v. Cundiff*, 555 F.3d 200, 209 (6th Cir. 2009) (quoting *King v. Palmer*, 950 F.2d 771, 781 (D.C. Cir. 1991) (en banc)), *cert. denied*, 558 U.S. 818 (2009); *see also, e.g., Cardenas v. United States*, 826 F.3d 1164, 1171 (9th Cir. 2016). In *June*, the plurality and concurrence agreed on stare decisis and the continued validity of *WWH*, deference to district court findings, third-party standing, and to strike down the Louisiana law.

140 S. Ct at 2112-13, 2118-21, 2132-33 (plurality); *id*. at 2133-34, 2139 n.4, 2141-42 (Roberts, C.J., concurring). But they employed two different tests to find the Louisiana law unconstitutional: the plurality reaffirmed that the burdens must outweigh the benefits, while Chief Justice Roberts would look first at whether the restriction was reasonably related to a legitimate state interest and, next, whether the law imposed a substantial obstacle—regardless of the level of benefit. *Compare* 140 S. Ct. at 2132 (plurality), *with id*. at 2141-42 (Roberts, C.J., concurring). A restriction that imposes a substantial obstacle would fail the Chief Justice's test even if it survives *WWH*'s balancing based on significant countervailing benefits. Because the concurrence's proposed test is not a "logical subset" of the plurality's balancing, *King*, 950 F.2d at 781 (Silberman, J., concurring), it does not control.

The court correctly determined that it remained bound by *WWH*, and thus properly considered the lack of any safety benefit as part of its alternative undue-burden analysis. *See* JA1456-59; *see also, e.g.*, *Agostini v. Felton*, 521 U.S. 203, 237 (1997) (lower courts remain bound by Supreme Court precedent "which directly controls" even if it rests on reasons subsequently rejected by the Court (citing *Rodriguez de Quijas v. Shearson/Am. Exp., Inc.*, 490 U.S. 477, 484 (1989)).

Moreover, even under the *June* concurrence, abortion restrictions must be "reasonably related" to a legitimate interest to survive. 140 S. Ct. at 2138 & n.2 (Roberts, C.J., concurring) (internal quotations and citation omitted) (describing

Casey's "threshold requirement"); *id.* at 2138 (Roberts, C.J., concurring) (courts "discuss[] the benefits of [a] regulation[]" in evaluating the law's constitutionality). Thus, regardless of how the district court framed its benefits discussion, Defendants cannot establish either legal or factual error in the court's alternative finding that the Requirements do not advance patient safety. JA1471-79.

In attempting to justify the Requirements, Defendants "rel[ied] entirely" on FDA's 2013 REMS Review: they introduced *no current evidence* as to any interest served by refusing to suspend the REMS. JA1473, 485-86. And they failed to rebut Plaintiffs' expert testimony and the consensus opinion of national medical authorities that the Requirements provided no medical benefit even before the pandemic and decidedly should not be enforced during the PHE. *See* AMA et al. Amicus Br.; JA315 (citing 2016 positions of ACOG and American Public Health Association). Based on a careful evidentiary review, Judge Chuang found that neither of FDA's 2013 rationales supports Defendants' retention of the Requirements during the pandemic. JA1473.

First, Defendants 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." Defs.' Br. 35 (emphasis added). But the mifepristone REMS does not require any in-person counseling: Defendants already permit prescribers to review the mandatory counseling form with

their patient and answer any questions via telemedicine. JA1476. Therefore, Defendants can muster only a chain of hypotheticals in support of their asserted counseling rationale. They claim the Requirements provide "*an opportunity* for in-person counseling" at the time of dispensing, Defs.' Br. 11, 17 (emphasis added), 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," *id.* at 36 (emphases added). Defendants cannot identify a single piece of data or technical analysis underlying this series of speculative assertions. *Id.*

Moreover, Defendants' argument that an "opportunity" for in-person counseling is necessary to ensure patients understand the medical risks associated with a medication, *id.* at 35, is wholly implausible when Defendants have determined that even the risks of opioids can be appropriately communicated through telemedicine, *see supra* at 11-12, and when FDA requires in-person dispensing for *no* other drug that patients are permitted to self-administer unsupervised, JA1425, 1478-79. Based on unrebutted expert testimony, Judge Chuang found that "telemedicine is now in widespread use, including as an effective means to provid[e] counseling relating to medication abortion," JA1475, and Defendants could not "offer[] [any] evidence demonstrating that telemedicine counseling sessions are ineffective or insufficient for communicating information about the risks or alternatives to medication abortion," JA1477; *see also* AMA et al. Amicus Br.

The court likewise did not err in rejecting Defendants' assertion, JA1477-79, that the Requirements "avoid[] the *possibility* of delay that *could* arise *if* patients were to obtain the drug from pharmacies on their own, such as delay caused by difficulty finding a pharmacy that stocks the drug." Defs.' Br. 6 (emphases added); *accord id.* at 35. Defendants' stated concern about patients left "on their own" to "find[] a pharmacy that stocks the drug," *id.* at 6, is a red herring: the injunction permits dispensing only by mail or delivery from the provider, or supervised delivery from a mail-order pharmacy that has pre-arranged to stock the drug on the prescriber's behalf, JA1571-73. And as the court noted, FDA already "specifically does not control when the mifepristone is actually taken." JA1478.

Moreover, the court properly found that "under the present circumstances," in-person dispensing is "in many instances a slower means of providing the drug," JA1477-78, in light of office closures, reduced capacity for in-person appointments, and the challenges patients face in securing funds and arranging childcare during the PHE, JA1465-70. And, critically, the injunction merely expands patients' options: "[i]f in-person dispensing is the most efficient" delivery method "for a particular patient, that option will remain available." JA1477. There is nothing in the record on which this Court could conclude that any of these findings were in error.

C. The Balance of Hardships and Public Interest Favor Plaintiffs.

Judge Chuang properly determined that the balance of hardships and public interest strongly favored granting the nation's medical providers' request to mitigate life-threatening risks during the PHE. JA1490-92; *see* AMA et al. Amicus Br.

Defendants could not identify a shred of evidence supporting their meager claim that the Requirements "might" advance patient safety, and that temporarily enjoining them (as Defendants have suspended other in-person requirements during the PHE) would therefore cause harm. Defs.' Br. 36.[19] Instead, Defendants argue that the district court should have simply deferred to FDA's 2013 rationales—in other words, assume automatic harm. JA1491; *see* Defs.' Br. 39-40, 42 (citing *S. Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613, 1613-14 (2020) (Roberts, C.J., concurring in denial of application for injunctive relief)). But the facts of this case are the inverse of those in *South Bay*. There, the Supreme Court declined to enjoin California's executive order restricting gatherings during the COVID-19

[19] As for the Denied-Intervenors, their parade of horrors bears no relation to reality. Far from putting mifepristone "in unknown hands[,] leav[ing] patients without an accurate understanding of their risk," States' Br. 44, the injunction leaves in place all other mifepristone REMS requirements, *see* JA1491, 1499-1500—not to mention the professional guidelines and ethical principles that otherwise ensure clinicians provide proper counseling and obtain informed consent, *see* JA693-94 (FDA memorandum noting that "comprehensive counseling" and "informed consent" is "standard of care" for both medication and surgical abortion separate and apart from FDA's REMS requirements).

pandemic where "local officials [were] actively shaping their response to changing facts [and risks] on the ground." 140 S. Ct. at 1614 (Roberts, C.J., concurring in denial of application for injunctive relief). Here, Defendants ask this Court to defer to pre-existing rules imposed years *before* the pandemic that indisputably increase viral exposure risks for patients seeking constitutionally protected medical care, and to Defendants' *failure* to respond to the exigencies of the public health emergency, despite requests from leading medical experts to do so. *See* JA1462-65, 1473 (finding that "[FDA] has provided no sign that it has undertaken a formal review of the issue in light of ... the ongoing pandemic").

Moreover, as the Supreme Court recently held in *Roman Catholic Diocese of Brooklyn v. Cuomo*, blind deference to the government's unsupported speculations about harm is unwarranted, particularly when constitutional rights are at issue, *even* during a pandemic and even where (unlike here) the government acted in direct response to the pandemic. 141 S. Ct. 63, 68 (2020) (per curiam).[20] Defendants fail

[20] The Chief Justice concurred in granting Defendants' stay application based on the principle that courts "owe significant deference" to "government responses to the pandemic." Stay Decision, slip. op., at 1-2 (Roberts, C.J., concurring in grant of stay). But that general proposition is not in question here, where it is undisputed that Defendants refused to suspend the In-Person Requirements despite never having reviewed their impact during the pandemic. JA1473.

More broadly, this Court's evaluation of Defendants' appeal on the merits is not pre-ordained by the Supreme Court's preliminary determination to grant a stay. *See, e.g.*, *Sierra Club v. Trump*, 963 F.3d 874, 887 (9th Cir. 2020) (ruling for Plaintiffs despite Supreme Court's suggestion in Order granting stay application that

to show any error in the court's determination—consistent with Defendants' own actions, the unrebutted expert testimony, and the consensus of the nation's leading medical organizations, and in the absence of *any* pandemic-related analysis of the Requirements—that the public interest is served by mitigating irreparable constitutional injury and medical risk during the PHE. *See* JA1464, 1488-92.[21]

D. The Remedy Is Properly Tailored to the Case-Specific Exigencies.

District courts have "wide discretion to fashion appropriate injunctive relief" based "on the equities of a given case," and this Court will alter an injunction only for an abuse of discretion. *Roe*, 947 F.3d at 231 (citing *Trump v. Int'l Refugee Assistance Project*, 137 S. Ct. 2080, 2087 (2017) ("*IRAP*")) (internal quotations and

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Plaintiffs likely lacked a cause of action), *cert. granted*, 141 S. Ct. 618 (2020); *Dodds v. U.S. Dep't of Educ.*, 845 F.3d 217, 221 (6th Cir. 2016) (Supreme Court grant of stay "does nothing more than show a possibility of relief"). This is particularly so where the majority offered no opinion on the stay application to guide this Court's merits review. Stay Decision, slip. op. at 1; *cf. Columbia Union Coll. v. Clarke*, 159 F.3d 151, 174 (4th Cir. 1998) (Wilkinson, C.J., dissenting) ("It is not [an appellate court's] role to read the jurisprudential tea leaves.").

[21] The Denied-Intervenors' argument that patients should have been forced to suffer indefinitely during the pandemic while Plaintiffs further "exhausted" administrative remedies finds no support in law or Defendants' own brief. States' Br. 37-38. It is "well-established" that "when constitutional questions are in issue, the availability of judicial review is presumed." *Califano v. Sanders*, 430 U.S. 99, 109 (1977). Moreover, even when exhaustion applies, "courts 'have the discretion to decline to apply [it] ... where the plaintiff demonstrates that it would be irreparably harmed by delay ... or that the exhaustion effort would be futile." *Ass'n of Am. Physicians & Surgeons, Inc. v. FDA*, 539 F. Supp. 2d 4, 23 (D.D.C. 2008). As Defendants have explained, they "often do not raise the exhaustion defense when," as here, "such circumstances are present." *Id.* at 24.

citations omitted). Defendants have shown none. Rather, the district court properly "'mold[ed] its decree to meet the exigencies of the particular case,'" *IRAP*, 137 S. Ct. at 2087 (citation omitted), imposing an automatic expiration date tied to Defendants' own emergency declaration and meticulously justifying the injunction's terms in light of Plaintiffs' injuries, administrative feasibilities, and fairness to vulnerable patients, JA1492-1500; *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' 50-state membership and the "unpredictable" "'resurgences of COVID-19' across the United States," JA1497, Defendants argue principally that the court erred in extending relief to persons "similarly situated" to Plaintiffs, their members, and their patients, *see* Defs.' Br. 44-50.[22] This Court has already rejected Defendants' argument, *see id.* at 44-47, that "extending relief to those who are similarly situated

[22] Defendants assert in passing that the district court failed to "explain why plaintiffs were entitled to relief for all their members, 'including in locales with very low infection rates and limited COVID-19 restrictions.'" Defs.' Br. 48 (quoting October Order, 2020 WL 5951467, at *2 (Alito, J., dissenting)). This is false: the court explained in detail why "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." JA1497-98. For instance, Judge Chuang noted that Oklahoma saw a spike in cases after asserting that it "had not been significantly affected" by the pandemic. JA1497.

to the litigants is categorically beyond the equitable power of district courts," *Roe*, 947 F.3d at 232. As even Defendants concede, *Roe* held that "relief to similarly situated parties is sometimes appropriate." Defs.' Br. 49-50 (citing 947 F.3d at 232-33).[23] Defendants' arguments about "Article III's constraints" and the limits of the district court's "equitable powers," *id.* at 45-47, cannot be squared with precedent. JA1494-97 (citing, *inter alia*, *IRAP*, 137 S. Ct. at 2088 (leaving in place nationwide injunction protecting plaintiffs and those "similarly situated" to them); *Roe*, 947 F.3d at 207, 232; *Lord & Taylor, LLC v. White Flint, L.P.*, 780 F.3d 211, 217 (4th Cir. 2015); *Richmond Tenants Org., Inc. v. Kemp*, 956 F.2d 1300, 1302 (4th Cir. 1992)); *see also Trump v. E. Bay Sanctuary Covenant*, 139 S. Ct. 782 (2018) (mem.) (denying stay of nationwide order enjoining any enforcement of immigration rule restricting asylum eligibility based on entry point).

Defendants' broad-brush objections to nationwide injunctions bear little resemblance to the circumstances of this case. Here, Plaintiffs' members are located

[23] Defendants attempt to rely on this Court's divided panel ruling in *CASA de Md., Inc. v. Trump*. Defs.' Br. 46-47, 49 (citing 971 F.3d 220 (4th Cir. 2020) ("*CASA*"), *rehearing en banc granted*, 981 F.3d 311 (4th Cir. 2020) (mem.)). But the *CASA* panel majority's discussion of nationwide injunctions was dicta, 971 F.3d at 263 ("[T]he district court compounded its error of granting relief with its choice of remedy."); *id.* at 283 (King, J., dissenting) ("[T]he majority's attack [on nationwide injunctions] is dicta."), and that opinion has been vacated by the grant of rehearing. As Defendants implicitly concede, *Roe* remains good law. *See* Defs.' Br. 49-50 (attempting to distinguish *Roe*).

in all 50 states and include the vast majority of the nation's OB/GYNs. JA1493-94; s*ee Va. Soc'y for Hum. Life v. Fed. Election Comm'n*, 263 F.3d 379, 393 (4th Cir. 2001) (characterizing nationwide injunction issued in *Richmond*, 956 F.2d at 1302, as "appropriate" because "the plaintiffs were tenants from across the country"), *overruled on other grounds by The Real Truth About Abortion, Inc. v. Fed. Election Comm'n*, 681 F.3d 544 (4th Cir. 2012). Plaintiffs were not required to certify a class, as Defendants claim, *see* Defs.' Br. 44, 48; they rely on associational standing, a well-established vehicle for bringing a large number of potentially affected parties before the courts and securing legal protection even for members who may choose not to utilize it. *See supra* at n.13. Paralleling *Roe*, Plaintiffs aim to relieve vulnerable patients from categorical requirements that apply regardless of a patient's individual circumstances. JA1495-96. And Judge Chuang explained at length how the equities warrant categorical relief to provide "uniform, fair, [and] rational treatment" for vulnerable patients during an "unprecedented global pandemic." JA1496-98 (quoting *Roe*, 947 F.3d at 233-34), 1462. "In awarding a preliminary injunction a court must … 'conside[r] ... the overall public interest,'" *IRAP*, 137 S. Ct. at 2087 (quoting *Winter*, 555 U.S. at 26), and the court did just that here. Defendants cannot establish that this equitable determination was improper.

The preliminary injunction also avoids "practical, administrative complexities" that would impede complete relief of Plaintiffs' and their patients'

injuries during this national emergency. JA1496. The court properly recognized that it needed an injunction that it could enforce and that FDA and the drug manufacturers acting as its agents could plausibly implement immediately. JA1496-97. The court determined that it could not feasibly impose an injunction involving day-to-day membership checks, which would hamstring manufacturers, clinicians, patients, and FDA itself—and less effectively redress Plaintiffs' injuries. JA1497. And the court reasoned that the costs of attempting to carve out the minority of mifepristone prescribers who are not members of one of the Plaintiff organizations on the day they prescribe the medication were unwarranted "[w]here an injunction covering Plaintiffs already covers 90 percent of" the nation's OB/GYNs. JA1497.[24]

At the same time, the court emphasized the time-limited and circumscribed nature of its action, JA1498-1500, and took pains to make clear that prescribers would still be subject to all other REMS requirements, JA1499-1500, 1571-73. The court arrived at an equitable result "no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Califano v. Yamasaki*, 442

[24] Indeed, if the preliminary injunction were narrowed and certified prescribers who are not members of the Plaintiff organizations had to bring follow-on suits to gain protection, all could sue in the District of Maryland, where FDA is headquartered, unnecessarily burdening that court simply to secure duplicative injunctions. *See* JA1496.

U.S. 682, 702 (1979). Defendants have not shown any abuse of discretion in the preliminary injunction's well-tailored scope.

II. Plaintiffs Demonstrated a Likelihood of Success on Their Equal Protection Claim.

Plaintiffs' equal protection claim challenges Defendants' discriminatory refusal to extend to mifepristone patients and clinicians the same non-enforcement policies they adopted to protect other patients and clinicians from the deadly risks of COVID-19. To establish an equal protection violation, Plaintiffs "must first demonstrate that [they] ha[ve] been treated differently from others with whom [they are] similarly situated and that the unequal treatment was the result of intentional or purposeful discrimination." *Kolbe v. Hogan*, 849 F.3d 114, 146 (4th Cir. 2017) (en banc) (internal quotations and citation omitted). "[T]he court proceeds to determine whether the disparity in treatment can be justified under the requisite level of scrutiny." *Id.* The district court erred at both steps of this inquiry—failing to apply the correct legal standard to identify similarly situated comparators at step one, and ignoring at step two its own findings establishing that Defendants lacked any rational basis for continuing to subject mifepristone patients and clinicians to COVID-19 risks while taking extraordinary actions to protect others from those same risks.

Under established precedent, plaintiffs are similarly situated to differently treated comparators when they are similar with respect to the legitimate interests justifying the challenged action, *Van Der Linde Hous., Inc. v. Rivanna Solid Waste*

Auth., 507 F.3d 290, 293 (4th Cir. 2007)—here, the interest in minimizing viral exposure that drove the government to lift in-person requirements for other drugs during the pandemic. By instead focusing its inquiry on possible differences unrelated to Defendants' interests in protecting against viral spread, the district court failed to apply the governing legal standard at step one of the analysis.

Nor do the potential distinctions on which the court relied provide any basis for the differential treatment at step two. The district court assumed that differences in drug profile, patient population, and regulatory context might justify differential treatment based on patient safety. But this assumption is belied by the court's own findings that the mifepristone Requirements have no medical content and do not advance any interest in patient safety, JA1471, and cannot be reconciled with Defendants' actions waiving other in-person requirements that involve actual medical services to assure patient safety during the pandemic.

A. Mifepristone Patients and Providers Are Similarly Situated to Others for Whom Defendants Have Waived In-Person Requirements.

For equal protection purposes, courts determine "what is 'different' and what is 'the same'" by looking to "the nature of the problem perceived." *Plyler v. Doe*, 457 U.S. 202, 216 (1982); *id.* at 229 (finding "undocumented children [were] basically indistinguishable from legally resident alien children" in terms of government's interest in controlling the quality and cost of public education (internal

quotations and citation omitted)). Persons are similarly situated when they are "similar in all aspects relevant to attaining the legitimate objectives of [the applicable government action]." *Van Der Linde Hous., Inc.*, 507 F.3d at 293.[25] Here, Plaintiffs challenged Defendants' exclusion of mifepristone patients and clinicians from its broad policy of reducing health care travel during the PHE—including by waiving mandatory in-person evaluation requirements for controlled substances and mandatory REMS testing requirements—in order to minimize viral spread. JA1462-65; *supra* at 11-12. This objective of limiting viral exposure—"the problem perceived," *Plyler*, 457 U.S. at 216 —is the relevant interest and should have been the focus of the court's similarly-situated inquiry. But instead of looking to that interest, the court focused on potential differences in statutory context, patient populations, and medication use that are irrelevant to the objective of limiting COVID-19 spread and the similarly situated inquiry. *See* JA 1485–87. Even if any such differences could provide a basis to retain the Requirements—which they do

[25] *See also, e.g., Kolbe*, 849 F.3d at 147 (looking to relevant interest underlying assault weapon ban—preventing criminal and accidental use—in determining that former police officers with extensive firearms and safety training were not similarly situated to members of the general public); *Williams v. Hansen*, 326 F.3d 569, 576 (4th Cir. 2003) (in challenge to police department's internal investigation, asking whether plaintiff-officers were "similarly situated with respect to the object of [the department's] inquiry"); *Merrifield v. Lockyer*, 547 F.3d 978, 991 (9th Cir. 2008) (where interest underlying licensing scheme was focused on risk of pesticide exposure, asking whether pest controllers subject to the scheme and those exempted from it were equally likely to encounter pesticides).

not, *see infra* at 65-71—they cannot defeat a step-one finding that mifepristone patients and clinicians are similarly situated to others for whom Defendants waived in-person requirements in order to mitigate viral spread.

The Supreme Court's decision in *City of Cleburne v. Cleburne Living Center, Inc.*, 473 U.S. 432 (1985), illustrates this error. In *Cleburne*, the Supreme Court invalidated an ordinance that purported to be aimed at regulating density by requiring permits for a group home for mentally disabled individuals but not for other facilities with similarly dense occupancy. *Id.* at 447-50. In striking down the ordinance, the Court cited numerous relevant comparators that were similarly situated in terms of density—including lodging houses, fraternity and sorority houses, hospitals, nursing homes, and private clubs. *Id.* at 447. Each differed from the group home in key respects: they served different populations, addressed different needs, and provided different services. Under the standard the district court erroneously applied here, these differences among the *Cleburne* comparators would have rendered them differently situated and the equal protection analysis would have ended. Instead, despite these distinguishing features, the Supreme Court treated these facilities as relevant comparators for its equal protection analysis because they were similarly situated in the *relevant* respect: the city's interest in regulating density. *See id.* at 448-49 (differences in populations served were "largely irrelevant" where the comparators were similarly situated in terms of density

interest). In failing to focus on the relevant question here—whether the comparators are similarly situated in terms of Defendants' interest in mitigating the risk of viral exposure—the district court misapplied the governing law.

Once properly focused, the record is clear that mifepristone patients and providers are similarly situated with respect to viral exposure risks. As the district court concluded, Defendants' actions in lifting in-person requirements for other medications "exhibit[ed] a clear recognition by the federal government, including [Defendants] HHS and FDA," that "during the pandemic, travel to hospitals, clinics, and medical offices for any purpose is particularly burdensome for Americans who need health care" and is "fraught with health risk to [patients] themselves, medical professionals, others they encounter during such trips, and the members of their household to whom they return." JA1464–65; *see also supra* at 11-12. And the court properly found that mifepristone patients likewise "risk contracting a highly dangerous disease" whenever they "venture out of their residence" for care. JA1462. Given that in-person travel poses identical exposure risks for mifepristone patients and clinicians as for others for whom in-person requirements have been waived, the court erred in failing to conclude that they are similarly situated.

Nor is there any doubt that Defendants intentionally treated mifepristone patients and clinicians differently. *See Kolbe*, 849 F.3d at 146.[26] After taking swift action last March to expand the use of telemedicine and relax in-person requirements for numerous other drugs during the PHE, Defendants received multiple requests from hundreds of leading medical and public health experts asking them to do the same for mifepristone. *See* JA103–29; JA1473. Yet Defendants refused, insisting on mandating avoidable in-person interactions for mifepristone patients and clinicians even while maintaining and expanding waivers for other patients and providers throughout the past year. *See supra* at 11-12.[27]

B. Defendants' Differential Treatment Cannot Survive Any Level of Scrutiny.

As Plaintiffs argued below, JA1484, because Defendants' actions—which treat all mifepristone providers and patients, whether for miscarriage or abortion, differently than those for whom in-person requirements have been waived—

[26] The States' attempt to characterize Plaintiffs' argument as a disparate impact claim is baseless. States' Br. 51 (arguing that equal protection protects "people," not drugs). A REMS operates only by imposing restrictions on how *clinicians* can prescribe a medication and how *patients* can access it. *See* 21 U.S.C. § 355-1(f)(3)(A) (imposing requirements on "health care providers who prescribe the drug"); *id.* § 355-1(f)(3)(C)–(D) (restricting how and where patients receive it).

[27] *See, e.g.*, Clinical Trials Guidance, *supra* n.9 (updated Jan. 2021); U.S. Food & Drug Admin., Temporary Policy on Prescription Drug Marketing Act Requirements for Distribution of Drug Samples During COVID-19 Public Health Emergency 5 (June 2020), https://www.fda.gov/media/138697/download (permitting manufacturers to distribute drug samples directly to patients' homes).

"impinge[] on personal rights protected by the Constitution," they are properly subject to heightened scrutiny. *Cleburne*, 473 U.S. at 440; *see also Shapiro v. Thompson*, 394 U.S. 618, 638 (1969) (classification that merely "touches on" fundamental right is subject to strict scrutiny), *overruled in part on other grounds by Edelman v. Jordan*, 415 U.S. 651 (1974); *Casey*, 505 U.S. at 859 (matters relating to procreation "involv[e] the most intimate and personal choices a person may make in a lifetime, … [choices] central to the liberty protected by the Fourteenth Amendment"). However, Defendants' discriminatory treatment cannot pass muster even under rational basis, the standard the district court applied.

Under rational basis review, courts must set aside government classifications that cannot be rationally explained and therefore impose arbitrary harms on those subjected to them. *See, e.g.*, *U.S. Dep't of Agric. v. Moreno*, 413 U.S. 528, 533 (1973). While the government is not required to draw classifications with "mathematical nicety," *id*. at 538 (internal quotation and citation omitted), neither is this standard "toothless," *Mathews v. Lucas*, 427 U.S. 495, 510 (1976) (citing *Jimenez v. Weinberger*, 417 U.S. 628 (1974)). As the Supreme Court has admonished, "even the standard of rationality ... must find some footing in the realities of the subject addressed by the [government action]." *Heller v. Doe*, 509 U.S. 312, 321 (1993). Here, the district court surmised that differences between mifepristone and other drugs might warrant differential treatment to advance patient

safety during the pandemic. JA1485-87. But when Defendants waived numerous in-person requirements that involve *actual* medical services, *supra* at 11-12, yet refused to lift restrictions on mifepristone that have no medical content and which the district court found serve no medical purpose, JA1471, JA1479, any notion that this differential treatment might be justified on the basis of patient safety finds no such footing. *See Plyler*, 457 U.S. at 228-29 (rejecting justification that lacked "any 'credible supporting evidence'" and where "the available evidence suggests" the asserted rationale is incorrect).[28]

Recognizing the risks posed even by "one trip" to a health center, Defs.' Br. 17, Defendants waived in-person requirements that normally play important roles in advancing patient safety, JA1462. For example, Defendants announced that they would not enforce REMS ETASU requirements mandating laboratory testing or magnetic resonance imaging studies before patients can obtain certain drugs that carry serious risks, JA1430, JA1463; *see also* JA202 (quoting FDA guidance that "undergoing laboratory testing or imaging studies in order to obtain a drug subject

[28] *See also, e.g., Lazy Y Ranch Ltd. v. Behrens*, 546 F.3d 580, 590-91 (9th Cir. 2008) (relying on *Heller*, 509 U.S. at 321, to conclude that "plaintiffs [can] rebut the facts underlying [an asserted] rationale … to show that the challenged classification could not reasonably be viewed to further the asserted purpose."); *Roe v. Shanahan*, 359 F. Supp. 3d 382, 416 (E.D. Va. 2019) (finding no rational basis where defendants offered no "cogent response" to plaintiffs' unrebutted expert evidence), *aff'd*, 947 F.3d 207 (4th Cir. 2020), *as amended* (Jan. 14, 2020).

to such a REMS can put patients and others at risk for transmission of coronavirus"). Defendants waived in-person requirements for drugs still undergoing clinical trials that have *not even been approved* for safe use. *See supra* at 12. And Defendants deemed the consequences of COVID-19 so great, and the risk of viral transmission associated with traveling for health care so high, that they lifted an otherwise-mandatory requirement that patients be evaluated and counseled in person at least once before obtaining highly addictive opioids that carry lethal risk of misuse and abuse. JA1430, JA1463; *see supra* at 11. Indeed, the only in-person requirements that Defendants left in place during the PHE, other than for mifepristone, are for drugs posing such serious risks that FDA prohibits administration except under clinical supervision. *See infra* at 70.

Yet Defendants refused numerous requests to similarly reduce viral exposure risks for patients seeking mifepristone, notwithstanding that the Requirements have no medical content. As the district court found, the mifepristone REMS requires no in-person clinical services or administration; FDA permits mifepristone patients to be evaluated and counseled entirely via telemedicine where medically appropriate in their clinician's judgment and to take the pill at home. JA1473-77. Patients are traveling to a health center *only* to pick up the pill and sign a form.

In light of these findings, the potential differences Judge Chuang identified are irrelevant. *See* JA1485-87. For example, the court reasoned that "Plaintiffs have

submitted insufficient information to allow the court to fairly evaluate whether the requirements relating to obtaining tests and imaging studies are more, less, or equally important for purposes of patient safety." JA1486. But no additional information could change the fact that the mifepristone Requirements involve no medical content, "do not advance general interests of patient safety," and are "unnecessary." JA1471 (internal quotations and citation omitted). By contrast, as FDA acknowledges, ETASU D testing and imaging requirements are actual medical services that FDA has deemed necessary to mitigate specific, serious side effects.[29]

The court similarly speculated that the different statutory schemes under which mifepristone and opioids are regulated might warrant differential treatment. JA1485-86. But this is a distinction without a difference. Defendants do not dispute that they have authority to (and did in fact) relax in-person requirements imposed under both the Controlled Substances Act and the REMS statute: where Defendants have the authority to relax in-person mandates to address a public health crisis, the fact that such authority derives from different statutes cannot create a rational basis for singling out one category of patients and providers and unnecessarily subjecting them to deadly risk. Moreover, the court was plainly wrong to suggest that Defendants did not make the decision to relax the in-person requirement for

[29] *REMS Non-Enforcement Guidance*, *supra* n.8 (suspended requirements include, *e.g.*, "liver enzyme testing and "magnetic resonance imaging").

controlled substances. JA1485-86. As Defendants themselves admitted, it was Defendant HHS Secretary who, acting "*with the concurrence of* the Acting DEA Administrator, designated that the telemedicine exception in ... the Controlled Substances Act applies during the [PHE] to all schedule II–V controlled substances." JA1353 (emphasis added).

Finally, Judge Chuang suggested that Defendants' differential treatment might be justified by their decision to maintain in-person requirements for 13 drugs that must be administered under clinical supervision because of, for example, a "risk of immediate, life-threatening allergic reaction." JA154; *see* JA1486-87. But, *unlike any other ETASU C drug*, mifepristone has no in-person administration requirement, JA1425—because FDA concluded that the interests underlying such a requirement do not apply here, JA1473; *see also* JA1475 (FDA finding "no significant difference in either efficacy or safety" between administering mifepristone in a medical setting and allowing patients to swallow the pill at home). That patients receiving these other drugs are still subject to a clinical supervision requirement provides no basis for Defendants' refusal to grant mifepristone patients and clinicians a waiver.

There is simply no safety or other conceivable rational justification for Defendant's differential treatment of mifepristone patients and providers during the PHE. To the contrary, by exposing patients to needless viral risk and delaying their access to medication abortion (which, as Defendants admit, increases the risks

associated with this care, JA1477), Defendants *undermine* rather than advance any risk-mitigation goals. JA1464-65, JA1471. Likewise, the refusal to suspend the mifepristone Requirements impedes rather than advances Defendants' efforts to control the pandemic. "[T]his type of singling out, in connection with a rationale so weak that it undercuts the principle of non-contradiction, fails ... rational basis review." *Merrifield*, 547 F.3d at 991; *see also United States v. Vaello-Madero*, 956 F.3d 12, 30 (1st Cir. 2020) (affirming equal protection claim where "the disparity in the benefits received by the poor, elderly, disabled, and blind in Puerto Rico compared to similarly situated individuals residing elsewhere in the United States [without rationale] speaks for itself"); *Shanahan*, 359 F. Supp. 3d at 415 (finding no rational basis to support differential treatment where "Defendants have not offered any cogent response to plaintiffs' experienced medical experts, all of whom persuasively explain why the effectively categorical rule ... is inconsistent with the state of science and medicine and with the way the military treats other chronic but manageable conditions"); *see also Planned Parenthood of Wis., Inc. v. Van Hollen*, 738 F.3d 786, 790 (7th Cir. 2013) (state's disfavored treatment of abortion based on health risks "when [other, unregulated procedures] are more likely to produce complications" presented "[a]n issue of equal protection of the laws").[30]

[30] The States' reliance on *Harris*, 448 U.S. 297, and *Greenville Women's Clinic v. Bryant*, 222 F.3d 157 (4th Cir. 2000), to support Defendants' differential treatment is misplaced. States' Br. 51-52. The States argue that Defendants may

Plaintiffs have demonstrated a likelihood of success on their equal protection claim, and the district court correctly concluded that the other equitable factors favor injunctive relief. Accordingly, this Court should reverse the district court's equal protection ruling, and remand with directions to grant a preliminary injunction to bar enforcement of the In-Person Requirements for the duration of the PHE regardless of whether mifepristone is prescribed for abortion or miscarriage treatment.

III. The District Court Properly Denied Intervention.

Finally, the court properly determined that the States were not entitled to either mandatory or permissive intervention. JA1290-1303. The States failed to show that they "stand to gain or lose by the direct legal operation of the court's judgment" in this litigation challenging only a federal restriction, *Teague*, 931 F.2d at 261, and have not made *any* showing, much less the requisite "strong showing," *Stuart*, 706 F.3d at 351-52, that Defendants HHS and FDA cannot adequately represent the States' asserted interests in defending the constitutionality of the REMS and "guarding [patients'] health and safety," States' Br. 20, 24. The court

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restrict access to mifepristone however they see fit because the government has unique social and moral interests in regulating abortion. *See* States' Br. 51-52. Neither case stands for that unrestricted freedom, but even more importantly: The imposition of unnecessary viral exposure risks does not advance any social or moral interest. Moreover, FDA's statutory authority for imposing REMS in the first place is expressly limited to clinical issues. *See* 21 U.S.C. § 355-1(a)(1)(E); *see also* JA102 (FDA counseling form discussing only clinical information about mifepristone).

also acted well within its discretion in concluding that tripling the number of parties and interjecting consideration of numerous, varied state laws would unduly complicate and delay proceedings. JA1300-02.

A. The States Are Not Entitled to Mandatory Intervention.

A party seeking mandatory intervention must "demonstrate a 'direct and substantial interest' [that] ... would be impaired if intervention was not allowed ... and establish that the interest is inadequately represented by existing parties." *Richman v. First Woman's Bank*, 104 F.3d 654, 659 (4th Cir. 1997); Fed. R. Civ. P. 24(a)(2). Failure to satisfy any one of these requirements is fatal, *Houston Gen. Ins. Co. v. Moore*, 193 F.3d 838, 839 (4th Cir. 1999), and the States fail on each.

1. The States Lack a Direct and Substantial Interest that Would Be Impaired.

The States' central argument is that an injunction of FDA's Requirements could "introduce[] ambiguity into the meaning and application of ... state laws," jeopardizing their enforcement. States' Br. 20. This argument is meritless.

As an initial matter, it is undisputed that any ruling in this case would "not explicitly 'pass judgment on the constitutionality or enforceability'" of any law in eight of the ten States—all but Indiana and Arkansas—because those eight States have no laws even referencing FDA's requirements for mifepristone. States' Br. 20-23; *accord* JA1293. The Denied-Intervenors nonetheless argue that the "preliminary injunction could affect [those] States' enforcement or cast doubt on the[]

constitutionality" of their independent laws, because they have laws "modeled after, influenced by, logically related to, or [that] otherwise interact with FDA's requirements." States' Br. 22-23. But this attenuated relationship falls far below this Court's standard for mandatory intervention: a movant must demonstrate that it "stand[s] to gain or lose by the *direct legal operation* of [this] court's judgment on [the] complaint." *Teague*, 931 F.2d at 261 (emphasis added). The "potential[]" that a ruling in this case might "cast doubt" on state laws neither challenged here nor explicitly related to FDA's restrictions on mifepristone, States' Br. 23, 30, does not meet that bar. *See* JA1293. Indeed, the States' theory would open the floodgates of intervention, potentially authorizing a state's intrusion into any litigation involving any area of federal law "logically related" to an area of state regulation. *See* JA1296 (noting that "every case has the potential to create new legal precedent or persuasive authority, so the application of mandatory intervention under Rule 24 must be governed by a more exacting limiting principle" (citation omitted)); *see also, e.g.*, *Brewer v. Republic Steel Corp*, 513 F.2d 1222, 1223-24 (6th Cir. 1975) (Ohio Civil Rights Commission lacked interest sufficient to support intervention in private employment discrimination action even where stare decisis effect of federal court ruling might impair Commission's ability to enforce Ohio laws). The absence of any direct connection to this litigation is dispositive.

As for Indiana and Arkansas, the Denied-Intervenors' arguments fare no better. Even the States are uncertain whether Indiana or Arkansas law has any explicit connection to the *In-Person Requirements*, alleging only that "at least one" of these States has laws that "incorporate the REMS explicitly." States' Br. 8. In any event, neither State's reference to FDA gives rise to a direct and substantial interest.

The sole reference to the REMS in Indiana law is a provision stating that, "[i]n accordance with FDA guidelines," the physician performing an abortion must "provide the pregnant woman with a copy of the manufacturer's instruction sheets and require that the pregnant woman sign the manufacturer's patient agreement form." *Id.* at 9 (citing Ind. Code § 16-34-2-1(a)(1)). Indiana now asserts that this narrow language addressing only FDA's ETASU D Patient Form requirement *also* tacitly incorporates FDA's ETASU C in-person dispensing requirement—and that Indiana's independent ban on the use of telemedicine for medication abortion, and requirement for an in-person examination before any medication abortion, would not suffice to prevent any harms the State alleges. States' Br. 21; Ind. Code § 16-34-2-1(a)(1). This argument strains credulity. In any event, Indiana's ability to enforce its own laws is untethered to the injunction, which restricts only *Defendants'* enforcement of FDA's In-Person Requirements. JA1504-05 (terms of the injunction), JA1294-95 (noting that "the Court will not take action that prevents Indiana from enforcing its own laws").

Enforcement of Arkansas's laws likewise does not turn on any ruling in this case. The States argue that Arkansas law is implicated because it requires clinicians prescribing mifepristone to adhere to the FDA-approved "protocol" outlined in mifepristone's "final printed labeling." States' Br. 22; Ark. Code § 20-16-1504. But even assuming that Arkansas's law requires adherence not only to the *treatment regimen* set out in the mifepristone labeling, but also to the discrete REMS requirements to which the labeling alludes, *see* JA80,[31] the injunction in this case merely prohibits Defendants from enforcing their Requirements during the pandemic. It does not alter Arkansas's enforcement of its own law; indeed, an order barring FDA enforcement would not even change the contents of the FDA-approved "final printed labeling" to which Arkansas law refers. *See* JA1295.

The States' further speculation that an injunction might create "ambiguity," or that a local clinician might "disagree" that the state requirements are "independent," States' Br. 21-22, is insufficient to give rise to a direct and substantial interest. Where the court "need not interpret or even make reference to the state law in order to apply the federal law," and will not take action that prevents the States from enforcing their own laws, there is no direct and substantial interest warranting

[31] *Frequently Asked Questions (FAQs) about REMS* (2018), U.S. Food & Drug Admin., https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/frequently-asked-questions-faqs-about-rems (describing a REMS as "additional interventions beyond FDA-approved labeling").

intervention. *Blake v. Pallan*, 554 F.2d 947, 952 (9th Cir. 1977); *see also, e.g.*, *Wash. Elec. v. Mass. Mun. Wholesale Elec.,* 922 F.2d 92, 97 (2d Cir. 1990) ("An interest that is remote from the subject matter of the proceeding, or that is contingent upon the occurrence of a sequence of events before it becomes colorable, will not satisfy the rule."); *Standard Heating & Air Conditioning Co. v. City of Minneapolis*, 137 F.3d 567, 571 (8th Cir. 1998) (denying intervention where interests were "too speculative to be 'direct, substantial and legally protectable'").

The States' asserted "health and safety" interest is likewise unavailing. States' Br. 24, 25. As Judge Chuang found, "broader policy interests ... cannot serve as a basis for mandatory intervention." JA1296. Though conceding this point, States' Br. 24, the Denied-Intervenors argue that this rule does not apply because they specifically seek to "mitigat[e] serious risks" and "protect[] their citizens from … dangers"—but can cite no case holding that reframing a broad policy interest in slightly narrower terms makes it sufficiently "concrete and substantial" to justify intervention. *Id.*[32] Moreover, the Denied-Intervenors' argument that these safety

[32] The States also speculate that an injunction could result in complications that lead to hospital visits that increase States' Medicaid costs. States' Br. 25. This purely hypothetical argument, incompatible with the district court's findings that the Requirements do not advance patient safety and that the injunction will cause no harm, *see* JA1471, JA1490-91, is particularly meritless given the district court's concrete findings that the Requirements needlessly increase the risk of "predominantly low-income" abortion patients contracting COVID-19, *see* JA1466-

interests are unique to the States as *parens patriae*, *id.* at 25, is patently illogical when Defendants' very mission is to protect the health and safety of all U.S. residents. JA1300 (citing *Wyeth v. Levine*, 555 U.S. 555, 567 (2009) (discussing Congress's enlargement of FDA's powers in order to "protect the public health")). The district court properly found that the States lack any direct and substantial interest directly threatened by the litigation.

2. Defendants Provide Adequate Representation.

Judge Chuang also correctly found that the States' interests are more than adequately represented by Defendants, which include the federal agency tasked with imposing and enforcing the challenged restrictions. JA1297-1300. This finding is dispositive under Rule 24(a)(2). *See also Stuart*, 706 F.3d at 349-50.

The States and Defendants share the same ultimate objective in this litigation: to preserve FDA's Requirements. "When the party seeking intervention has the same ultimate objective as a party to the suit, a presumption arises that its interests are adequately represented, against which the [applicant] must demonstrate adversity of interest, collusion, or nonfeasance." *Virginia v. Westinghouse Elec. Corp.*, 542 F.2d 214, 216 (4th Cir. 1976) (citations omitted). As this Court has made plain, that presumption is strongest where, as here, a government agency represents the

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68, JA1496, and in turn being hospitalized, *see* Br. of N.Y. et al. as Amici Curiae Supporting Pls.-Appellees (forthcoming).

interests of the proposed intervenor. *Stuart*, 706 F.3d at 351. "[I]t is among the most elementary functions of a government to serve in a representative capacity on behalf of its people," so "when a [law] comes under attack, it is difficult to conceive of an entity better situated to defend it than the government." *Id.* In such cases, "the putative intervenor must mount a strong showing of inadequacy" of the government's representation. *Id.* at 351-52.

The States do not come close to meeting that standard. The Denied-Intervenors argue that because their defense of the REMS is a means to protect their own state laws, their objective is "markedly different" from that of Defendants. States' Br. 27. But the States cannot avoid this Court's "strong showing" requirement by asserting an objective irrelevant to the litigation in which they attempt to intervene; the Denied-Intervenors' state laws are not challenged here. As Judge Chuang found, the States' desired outcome in *this* litigation is exactly "the same as Defendants' goal: for the FDA regulations to be upheld as constitutional." JA1298. Because "both the government agency and the would-be intervenors want the statute to be constitutionally sustained," they share the same "ultimate objective," and the States cannot secure mandatory intervention without an "exacting showing of inadequacy." *Stuart*, 706 F.3d at 351-52.

The States fail to make *any* showing to overcome the presumption of adequacy. Their argument that Defendants "are unlikely to tailor their argument to

the objective of preserving state laws," States' Br. 27, establishes only that Defendants will properly tailor their arguments to the federal action actually at issue. *See* JA1299 ("Even if the States' interests in defending FDA's regulations are 'stronger' and more 'specific' than the agency's general interest, such differences 'do not adverse interests make ....'" (quoting *Stuart*, 706 F.3d at 353)). And the States' argument that Defendants do not share the "States' significant, relevant expertise in defending their state laws," States' Br. 27-28, hardly establishes the requisite adversity: even if the States' litigation experience were valuable here, "[d]isagree[ment]" with reasonable litigation tactics is insufficient to "rebut the presumption of adequacy," *Stuart*, 706 F.3d at 353-54 (rejecting a finding of adversity of interest where government defendants chose to "rel[y] on legal arguments at the preliminary injunction stage" whereas the would-be interveners would have "presented factual evidence"); JA1298-99.[33] Nor do the States find any support in their conjecture that adversity might be hiding behind FDA's redactions. States' Br. 28. Were adversity established any time the government redacted privileged information from public records, intervention would be an open door.

[33] Moreover, Defendants are evidently willing to introduce state-specific evidence when they deem it helpful to their defense. *See* Defs.' Renewed Mot. Stay Prelim. Inj. & Indicative Ruling Dissolving Prelim. Inj., No. 8:20-cv-1320-TDC, Dkt. 141-4 to 141-11 (declarations from health officials in seven of the Denied-Intervenor States).

The States point to no evidence to show collusion or nonfeasance, *see id.* at 35, nor can they. Defendants vigorously opposed Plaintiffs' Motion for Preliminary Injunction, including through supplemental briefing, *see* JA413-891, JA1300, JA1356-64. And Defendants relentlessly pursued a stay of the injunction pending appeal, including two stay motions in the district court, one in this Court, and—extraordinarily—*two* stay applications in the Supreme Court. *See supra* at 25-26.

"[A]ppellate deference is customarily appropriate ... in the intervention context [because] it is the trial judge who is best able to determine whether ... a proposed intervenor's interests are being adequately represented by an existing party pursuant to Rule 24(a)(2)." *Stuart*, 706 F.3d at 350. As the district court correctly recognized, the States are more than adequately represented by Defendants, and the States cannot mount the strong showing necessary to prove otherwise. JA1297-1300.

B. The District Court Properly Denied Permissive Intervention.

"[A] decision to deny permissive intervention under Rule 24(b) lies within the sound discretion of the trial court." *Smith v. Pennington*, 352 F.3d 884, 892 (4th Cir. 2003) (internal quotations and citation omitted); *see also Stuart*, 706 F.3d at 350 ("Rule 24's requirements are based on dynamics that develop in the trial court and that the court is accordingly in the best position to evaluate" (citation omitted)). In exercising its discretion, the court "must consider whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights." Fed. R.

Civ. P. 24(b)(3). Here, Judge Chuang correctly found that intervention would prejudice the original parties because the States aim to introduce speculative issues and evidence about a myriad of unchallenged state laws. JA1300-02.[34] And, as in *Stuart*, intervention would "necessarily complicate[]" matters without adding substantive value because "the existing Defendants are zealously pursuing the same ultimate objectives." 706 F.3d at 355; *see also Virginia*, 542 F.2d at 217 (denying intervention by State based in part on "potential unmanageability" of the litigation, noting that "[a]t least thirteen other states are possible litigants"). Instead of "enhanc[ing] the proceedings," States' Br. 28, adding ten additional States as parties, all "differently situated" than Defendants and "differently situated" from one another, would muddle discovery and unnecessarily consume the court's resources, resulting in undue delay. *Stuart*, 706 F.3d at 349-50; JA1301-02.

[34] The States cite a single out-of-circuit district court decision to support their assertion that states are "routinely granted permissive intervention to assist in defending federal [laws]," States' Br. 29 (citing *Alabama v. U.S. Dep't of Com.*, No. 2:18-CV-772-RDP, 2019 WL 4260171, at *3 (N.D. Ala. Sept. 9, 2019)), but the unique circumstances of that case support no such generalization. In *Alabama*, states were permitted to intervene in litigation involving federal Census regulations because of their singular, state-specific interest in the "possible loss of seats in Congress, impairment of their ability to conduct intrastate redistricting in compliance with their own state constitutions and laws, and the risk to hundreds of billions of dollars in public funds." 2019 WL 4260171, at *2. The Denied-Intervenors have no such direct stake in the outcome here. *See supra* at 73-78.

The likelihood of undue delay due to unnecessary discovery is particularly apparent here, where the States sought to introduce testimony from experts discredited by other courts. JA406-07, JA892-949, JA1221-83; *see, e.g.*, *Little Rock Family Planning Servs. v. Rutledge*, 397 F. Supp. 3d 1213, 1268, 1273, 1282, 1300, 1306-07 (E.D. Ark. 2019) (rejecting unsupported testimony by States' proposed witness Donna Harrison regarding safety of abortion and noting that Harrison has not practiced in a clinical setting in two decades); *MKB Mgmt. Corp. v. Burdick*, 855 N.W.2d 31, 68-69 (N.D. 2014) (concluding that Harrison is not credible where her "opinions ... appear to be shaped primarily by the position she is advocating at the moment ... lack scientific support, tend to be based on unsubstantiated concerns, and are generally at odds with solid medical evidence"); *Adams & Boyle, P.C. v. Slatery,* No. 3:15-CV-00705, 2020 WL 6063778, at *40 (M.D. Tenn. Oct. 14, 2020) (finding testimony of State's proposed witness Coleman "not worthy of serious consideration" because "[her] views as a social scientist are heavily influenced, if not entirely overridden, by her personal views," her "opinions lack support and ... her work has serious methodological flaws"); *Planned Parenthood of Ind. & Ky. v. Comm'r*, 273 F. Supp. 3d 1013, 1036 (S.D. Ind. 2017) (refusing to credit Coleman's studies, which "have been almost uniformly rejected by other experts in the field," and noting criticism of "methodological problems" in her work "that bring into question both the results and conclusions") (internal quotations and citations

omitted)); *aff'd*, 896 F.3d 809, 826 (7th Cir. 2019) (rejecting argument by State of Indiana that relied on Coleman's "controversial and much maligned ... study").

Judge Chuang properly exercised his discretion in determining that the interests of these States are adequately represented through their participation as amici, just like the nearly two dozen States, and every leading national medical group, participating as amici in support of Plaintiffs. *See McHenry v. Comm'r*, 677 F.3d 214, 227 (4th Cir. 2012) ("Numerous cases support the proposition that allowing a proposed intervenor to file an amicus brief is an adequate alternative to permissive intervention.") (collecting cases).

CONCLUSION

For the foregoing reasons, this Court should affirm the district court's orders denying intervention and granting in part the preliminary injunction, and reverse the court's denial of preliminary injunctive relief based on equal protection.

REQUEST FOR ARGUMENT

Plaintiffs believe oral argument would assist the Court in deciding the above-captioned appeals. Because the preliminary injunction based on Plaintiffs' due process claim is presently stayed pending the resolution of appeals, Plaintiffs respectfully request that argument be scheduled for the Court's May 2021 session, which is the final session of the Court's 2020-2021 term and more than one month after the resolution of briefing.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Principal and Response Brief complies with the type-volume limitation set forth in this Court's Orders of October 10, 2020, No. 20-1784, Dkt. 24, and January 12, 2021, No. 20-1784, Dkt. 47, because, excluding the parts of the document exempted by Fed. R. App. R. 32(f), it contains 19,997 words. This Brief complies with the typeface and type style requirements of Federal Rule of Appellate Procedure 32 because it has been prepared in a proportionally spaced typeface using Word 14-point Times New Roman.

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CERTIFICATE OF SERVICE

I hereby certify that on February 5, 2021, I filed the foregoing motion with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit by using the appellate CM/ECF system. All participants in the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

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