IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

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

Plaintiffs,

vs.

UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants.

Case No. 8:20-cv-1320-TDC

DEFENDANTS' MOTION TO STAY PRELIMINARY INJUNCTION PENDING APPEAL

Pursuant to Federal Rule of Civil Procedure 62, Defendants respectfully request that this Court stay pending appeal: 1) its Order, Dkt. 91, granting in part and denying in part Plaintiffs' Motion for a Preliminary Injunction; and 2) its Preliminary Injunction, Dkt. 92, which enjoins Defendants from enforcing in-person dispensing and signature requirements ("in-person requirements") during the COVID-19 pandemic for a medication abortion drug that is associated with serious risks. At a minimum, the Court should issue a stay limiting the effect of its injunction to redress only the irreparable harms demonstrated by Plaintiffs. The reasons for this Motion are set forth in the accompanying Memorandum in Support (Attachment 1).

Dated: July 24, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of July 2020, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Hilary K. Perkins
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DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO STAY PRELIMINARY INJUNCTION PENDING APPEAL

Defendants respectfully request that this Court stay pending appeal: 1) its Order, Dkt. 91, granting in part and denying in part Plaintiffs' Motion for a Preliminary Injunction; and 2) its Preliminary Injunction, Dkt. 92, which enjoins Defendants from enforcing in-person dispensing and signature[1] requirements ("in-person requirements") during the COVID-19 pandemic for a medication abortion drug that is associated with serious risks. Defendants have satisfied the factors necessary for a stay. Defendants are likely to succeed on the merits because Plaintiffs lack third-party standing and have failed to show that the in-person requirements pose a substantial obstacle to abortion for their members' patients during the pandemic. Defendants will also suffer irreparable harm in the absence of a stay because they will be unable to enforce requirements that FDA has determined, based on its experience and scientific expertise, are necessary to ensure safe use of Mifeprex.[2] This Court should therefore stay the preliminary injunction pending resolution of Defendants' appeal. At a minimum, the Court should issue a stay limiting the effect of its injunction to redress only the irreparable harms demonstrated by Plaintiffs.

BACKGROUND

As Defendants explained in their Opposition to Plaintiffs' Motion for a Preliminary Injunction, *see* Defs.' Opp. to Pls.' Mot. For Prelim. Inj. at 3-4 (Dkt. 62) ("Defs.' Opp."), FDA may require a Risk Evaluation and Mitigation Strategy (REMS) for a drug if the agency determines that a REMS "is necessary to ensure that the benefits of the drug outweigh the risks of the drug." *See* 21 U.S.C. § 355-1(a). A REMS may include certain Elements to Assure Safe

[1] Although both parties' briefs focused on the in-person dispensing requirement, the Court found that "the Patient Agreement Form can be read as requiring that the prescriber and patient be in the same location when this paperwork is completed." Mem. Op. at 6.

[2] The use of "Mifeprex" in this motion refers to the brand-name and generic versions of the drug.

Use (ETASU), such as the requirement challenged here that a drug be dispensed by a certified provider only in certain healthcare settings. *See* 21 U.S.C. § 355-1(f)(A). The drug's sponsor may later seek to modify the REMS through submission of a supplemental new drug application (sNDA). *See* 21 U.S.C. § 355-1(g)(4). FDA does not approve modifications to a drug's REMS absent an adequate rationale, including data to support the proposed changes. *See* Defs.' Opp. at 4.

In 2000, FDA approved Mifeprex for use in conjunction with another drug (misoprostol) to terminate intrauterine pregnancy through the seventh week of pregnancy. *See id.*; Defs.' Opp. Ex. 11 at 0223 (Dkt. 62-3). To mitigate the serious risks associated with Mifeprex, which include incomplete abortion or serious bleeding requiring surgical intervention in up to seven percent of patients who take the drug, FDA placed certain restrictions on Mifeprex, including the in-person requirements challenged here. *See* Defs.' Opp. at 4; Defs.' Opp. Ex. 11 at 0228; Defs.' Opp. Ex. 12 at 0016 (Dkt. 62-4). In 2013, FDA conducted a full review of the Mifeprex REMS and reaffirmed that the REMS, including the in-person requirements, "provides the foundation to ensure the implementation of safe use conditions with Mifeprex use." Defs.' Opp. at 4-5; Defs.' Opp. Ex. 14 at 0344 (Dkt. 62-6). With respect to the in-person dispensing requirement, FDA concluded that it remains necessary to ensure that: (1) at the time of dispensing, the patient has the opportunity to receive counseling about the risk of serious patient complications associated with Mifeprex and what to do should they arise; and (2) the patient does not delay picking up the prescription—or the prescription is not delayed in the mail—before initiating an abortion, which could increase risks of serious bleeding or infection that might require surgical intervention. *See* Defs.' Opp. at 5-6, 24; Defs.' Opp. Ex. 14 at 0356-57.

In 2016, FDA conducted another review of the Mifeprex REMS in response to an sNDA submitted by Mifeprex's sponsor. Defs.' Opp. at 5. After a careful review of the sNDA, FDA approved certain changes that the drug sponsor proposed, with some modifications, concluding that the proposed alterations were supported by appropriate data and information. *See id.*; Defs.' Opp. Ex. 15 at 0464-70 (Dkt. 62-7). The drug sponsor did not request—and FDA did not decide—to eliminate or modify the requirement that Mifeprex be dispensed only by a certified prescriber in certain healthcare settings. *See* Defs.' Opp. at 5; Defs.' Opp. Ex. 16 at 0414-15 (Dkt. 62-8). FDA maintained the in-person requirements based on the conclusion that they remained necessary to assure safe use because the drug's safety profile had "not substantially changed." Defs.' Opp. at 5; Defs.' Opp. Ex. 18 at 0681 (Dkt. 62-10).

LEGAL STANDARD

Federal Rule of Civil Procedure 62(d) allows a district court to stay an injunction pending appeal. In deciding whether to grant a stay, the court considers the following four factors: "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure other parties interested in the proceeding; and (4) where the public interest lies." *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987). The government's harm and the public interest merge when the government is a party. *See Nken v. Holder*, 556 U.S. 418, 435 (2009).

ARGUMENT

I. Defendants are Likely to Succeed on the Merits.

A. Plaintiffs Lack Third-Party Standing.

Notwithstanding the Court's recent decision granting the preliminary injunction, Defendants respectfully submit that they are likely to succeed on the merits of their appeal. As Defendants explained, *see* Defs.' Opp. at 9, Plaintiffs failed to meet the ordinary standard for asserting the rights of their third-party patients, which requires showing a close relationship between Plaintiffs and their patients and that the patients are hindered from bringing suit on their own. *See Kowalski v. Tesmer*, 543 U.S. 125, 130 (2004). Yet Plaintiffs alleged only limited interactions with their patients—in fact, the entire point of this suit is to *reduce* Plaintiffs' relationship with their patients—and failed to show that their patients were hindered from vindicating their own rights. *See* Defs.' Opp. at 9. Nor did Plaintiffs show that they are directly regulated by the in-person requirements such that they are entitled to assert their patients' rights. *See id.* at 9-10.

The Court incorrectly concluded that Plaintiffs provided sufficient evidence to satisfy the elements of third-party standing. Mem. Op. at 24 (Dkt. 90). As to the close-relationship element, the Court ruled that Plaintiffs "provided specific evidence of close physician-patient relationships, including between Dr. Paladine and her patients." *Id.* at 26. But evidence of a single physician's relationship with her patients does not establish that the thousands of physicians who are members of the Plaintiff organizations *generally* have close relationships with their own patients who seek a Mifeprex prescription, and may seek to assert not only the rights of long-time patients, but of *all* patients seeking Mifeprex prescriptions.

With respect to hindrance, the Court ruled that "the record provides sufficient facts to illustrate that Plaintiffs' patients are hindered from acting on their own," including the time-sensitivity of securing an abortion, various childcare and transportation challenges, and economic and public health obstacles stemming from the COVID-19 pandemic. Mem. Op. at 29-30. Yet many of these alleged challenges existed prior to the pandemic and did not prevent patients in other cases from vindicating their own rights in recent decades. *See Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2323 n.1 (2016) (Thomas, J., dissenting) (collecting cases). And the challenges faced by patients during the pandemic are also applicable to all litigants, including Plaintiffs.

Moreover, as Defendants explained, *see* Defs.' Opp. at 9, Plaintiffs' suit is not like the cases in which the Supreme Court has relaxed the standard for third-party standing on the ground that the plaintiffs themselves were directly regulated. *See Kowalski*, 543 U.S. at 130. Although, as the Court here noted, "FDA has the statutory authority to pursue an enforcement action against any person who violates 21 U.S.C. § 355(p)," Mem. Op. at 20—which makes it unlawful to "introduce or deliver for introduction into interstate commerce a new drug" while "fail[ing] to maintain compliance" with the ETASU requirements, 21 U.S.C. § 355(p)—Plaintiffs have not alleged that they engage in, or intend to engage in, interstate activity that could conceivably violate 21 U.S.C. § 355(p), *see* Defs.' Corresp. at 1 (Dkt. 75). Nor has FDA ever brought such an enforcement action against a prescribing physician. *See id.*

B. Plaintiffs Have Not Shown That the In-Person Requirements Pose a Substantial Obstacle to a Large Fraction of Women Seeking an Abortion During the COVID-19 Pandemic.

The Court also erred in holding that Plaintiffs are likely to succeed on their due process claim that the Mifeprex in-person requirements impose an undue burden on the right to abortion.

As an initial matter, the Court concluded that the Supreme Court's decision in *Whole Woman's Health* allowed it to balance a regulation's burdens and benefits regardless of whether Plaintiffs showed a substantial obstacle. *See* Mem. Op. at 36-38. Under *Casey*, however, an abortion regulation does not impose an undue burden unless it "has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus." *Planned Parenthood of Se. Penn. v. Casey*, 505 U.S. 833, 877 (1992) (joint opinion). All nine Justices in *June Medical* recently emphasized the importance of demonstrating that a law poses a substantial obstacle to abortion access in order to obtain relief. *See June Medical Services, LLC v. Russo*, No. 18-1323, 2020 WL 3492640, at *4, *7, *10, *12, *20 (U.S. June 29, 2020) (plurality op.) (analyzing whether Louisiana law posed a substantial obstacle to abortion access); *id.* at *23-26 (Roberts, C.J., concurring in the judgment) (same); *id.* at *38-39 (Alito, J., joined by Thomas, Gorsuch, and Kavanaugh, JJ., dissenting) (same). And at least five Justices (a majority of the Court) explicitly *rejected* the sort of free-floating cost-benefit test applied by the Court in this case. *See id.* at *23-26 (Roberts, C.J., concurring in the judgment); *id.* at *38-39 (Alito, J., joined by Thomas, Gorsuch, and Kavanaugh, JJ., dissenting); *id.* at *63 (Kavanaugh, J., dissenting).

Notwithstanding the foregoing, the Court here ruled that the Mifeprex in-person requirements pose a substantial obstacle to women seeking abortion because of certain challenges patients face during the pandemic, including office closures and limited capacity at doctor's offices, heightened health risk due to demographics, childcare and transportation challenges, and the economic downturn. Mem. Op. at 49. But "[t]he fact that a law which serves a valid purpose, one not designed to strike at the right itself, has the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate

it." *Casey*, 505 U.S. at 874 (plurality); *see also Greenville Women's Clinic v. Bryant*, 222 F.3d 157, 167-70 (4th Cir. 2000). A one-time trip to obtain Mifeprex at a clinic is at most a minimal burden, and the current COVID-19 pandemic does not transform a one-time trip into a substantial obstacle to abortion access. *Cf. Casey*, 505 U.S. at 886 (plurality) (waiting period requiring "at least two visits to the doctor" not substantial obstacle). As Defendants explained, Defs.' Opp. at 16, the same or similar "risk" of exposure to COVID-19 arises *whenever* a patient travels outside the home, whether to go to the store, the park, or any other location. And CDC guidelines provide numerous steps patients and medical professionals can take to mitigate patient safety concerns in light of COVID-19. *See* Defs.' Opp. at 16-17. Furthermore, FDA is not responsible for removing obstacles to abortion access that are not of its own creation. *See Harris v. McRae*, 448 U.S. 297, 316 (1980) ("[A]lthough government may not place obstacles in the path of a women's exercise of her freedom of choice, it need not remove those not of its own creation.").

Indeed, the in-person requirements cannot constitute an undue burden because they concern only medication abortions using Mifeprex or its generic, which are approved only during the first 10 weeks of pregnancy. After that time, a surgical abortion would obviously require an in-person visit. If an in-person surgical abortion is not an undue burden for women seeking abortions after ten weeks, it cannot be an undue burden for women seeking earlier-term abortions simply because Plaintiffs would prefer another alternative. *See Gonzales v. Carhart*, 550 U.S. 124, 163-165 (2007) (rejecting claim of undue burden from law prohibiting certain abortion procedures where "reasonable alternative procedures" remained available). Indeed, a contrary conclusion would imply that FDA was *constitutionally required* to approve Mifeprex in the first place—which is not the law. *See In re Abbott*, 956 F.3d 696, 720 (5th Cir. 2020) (no

constitutional "right to the abortion method of the woman's (or the physician's) choice"); *cf. Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 713 (D.C. Cir. 2007) (en banc) (rejecting, on rational-basis review, a substantive-due-process challenge to FDA's refusal to approve experimental drugs for terminal patients).

This Court's holding that a law may be an undue burden if it merely results in patients "seek[ing] a more invasive form of abortion," Mem. Op. at 50, cannot be reconciled with the Supreme Court's holding in *Gonzales*, which makes clear that a regulation "does not construct a substantial obstacle to the abortion right" when—as here—it allows other "commonly used and generally accepted method[s]," 550 U.S. at 165. As the Fourth Circuit has explained, a law is an undue burden only if it "essentially depriv[es] women of the choice to have an abortion." *Bryant*, 222 F.3d at 167. Requiring patients to obtain Mifeprex at a clinic—as has been required for years—does not deprive women of the "ability to make a decision to have an abortion," *id.* at 169-70.

Even assuming (incorrectly) that the right to abortion includes the right to a particular type of procedure—here, medication abortion—Plaintiffs provide no evidence that the Mifeprex in-person requirements have caused patients to forgo a medication abortion altogether or undergo a riskier procedure because of delays during the pandemic. *See, e.g.*, *In re Rutledge*, 956 F.3d 1018, 1032 (8th Cir. 2020) (finding no substantial obstacle to abortion access where there was no evidence that order temporarily suspending non-essential medical procedures prevented patients from obtaining an abortion or required them to undergo a more invasive procedure). And, as Defendants explained, *see* Defs.' Opp. at 18, it is far from clear that enjoining FDA from enforcing the in-person requirements would actually reduce delays in the first place, as some patients would instead wait for the drug to arrive in the mail or for a courier to deliver it. In any

event, the possibility that a law may cause some delay in obtaining an abortion does not mean that it constitutes a substantial obstacle. *See Casey*, 505 U.S. at 886 (plurality) (upholding mandatory 24-hour waiting period, which lower court found would often cause "a delay of much more than a day").

Comparing this case with *Whole Woman's Health* and *June Medical* highlights the lack of a substantial obstacle here. As Defendants explained, *see* Defs.' Suppl. Br. in Opp. to Pls.' Mot. for Prelim. Inj. at 3 (Dkt. 84) ("Defs.' Suppl. Br."), the Texas law in *Whole Woman's Health* would have reduced the number of abortion facilities in the state by half, *see Whole Woman's Health*, 136 S. Ct. at 2312-13, while the Louisiana law in *June Medical* would have "reduce[d] 'the number of clinics to one, or at most two,' and the number of physicians in Louisiana to 'one, or at most two,'" *June Medical*, 2020 WL 3492640, at *27, and—according to the plurality opinion—would have left "thousands of Louisiana women with no practical means of obtaining a safe, legal abortion," *id.* at *19 (plurality op.). In this case, by contrast, there is *no* evidence that the in-person requirements have caused, or would cause, a comparable reduction in the number of Mifeprex clinics or prescribers. Nor is there evidence that the requirements have forced, or would force, patients to undergo a more invasive abortion procedure, much less forgo an abortion altogether. *See* Defs.' Opp. at 19-21. The Court was wrong to conclude that Plaintiffs are likely to show that the in-person requirements pose a substantial obstacle to abortion access.

The Court also erred in assessing the benefits of the Mifeprex in-person requirements and in limiting the amount of deference it gave to FDA's scientific judgment. *See* Mem. Op. at 51. As Defendants explained, *see* Defs.' Suppl. Br. at 4, because Plaintiffs are unlikely to establish that the in-person requirements constitute a substantial obstacle to abortion, the Court need

consider the benefits of the requirements only in determining whether FDA has a "rational basis" to impose the requirements "in furtherance of its legitimate interests" in ensuring patient safety. *Gonzalez v. Carhart*, 550 U.S. 124, 158 (2007); *see June Medical*, 2020 WL 3492640, at *25 (Roberts, C.J., concurring in the judgment). FDA's rationale for the requirements easily satisfies this lenient standard. *See* Defs.' Opp. at 26-30.

The Court, however, erroneously reasoned that in order to survive review, the benefits of the in-person requirements had to outweigh their (alleged) burdens, and that the benefits failed to do so. *See* Mem. Op. at 36-38, 51-59. In so ruling, the Court concluded that the in-person requirements "do not advance general interests of patient safety and thus constitute 'unnecessary health regulations.'" Mem. Op. at 51. The Court reasoned that because there is no in-person administration requirement for Mifeprex, in-person dispensing "does nothing to provide for monitoring of the patient for complications," which may occur "hours or days after the pill is ingested." Mem. Op. at 51-52. The purpose of the in-person dispensing requirement, however, is not to monitor patients for complications, but rather to ensure that: (1) at the time of dispensing, the patient has the opportunity to receive counseling about the risk of serious complications associated with Mifeprex and what to do should they arise; and (2) there is no delay in the patient receiving their Mifeprex prescription, which could increase the risks of serious bleeding or infection. *See* Defs.' Opp. at 24; Defs.' Opp. Ex. 14 at 0356-57. As Defendants explained, *see* Defs.' Opp. at 5, in 2016, FDA approved the drug sponsor's request to eliminate the in-person administration requirement because the data on home use showed no significant difference in patient safety. *See* Defs.' Opp. Ex. 17 at 0728 (Dkt. 62-9). FDA did not reach a similar conclusion as to the in-person dispensing requirement (nor was it asked to

evaluate the continuing need for the in-person dispensing requirement). Accordingly, it left the in-person dispensing requirement in place.

As to deference, the Court noted that FDA has not fully evaluated the in-person requirements since 2013 and thus has not determined whether the requirements remain necessary in the context of telemedicine or the pandemic. *See* Mem. Op. at 53-55. As such, the Court afforded FDA's 2013 decision to retain the requirements "only limited deference because its analysis is dated and did not take account of intervening events." Mem. Op. at 54. In reaching this conclusion, the Court relied on the Supreme Court's statement in *Whole Woman's Health* that courts should avoid "giv[ing] '[u]ncritical deference' to the findings of the legislature." Mem. Op. at 38-39, 54. But FDA is not a legislature—it is an expert scientific agency responsible for protecting public health by ensuring the safety and effectiveness of drugs. FDA's evaluation of a drug's risks to determine the appropriate restrictions necessary for safe use is a matter quintessentially within FDA's expert scientific judgment. *See* Defs.' Opp. at 26. Given this background, the Court should not substitute its own judgment for that of FDA, even in the context of a constitutional question. *See, e.g.*, *Abigail Alliance v. Eschenbach*, 495 F.3d 695, 709 (D.C. Cir. 2007) (expressing skepticism at "a constitutional right to override the collective judgment of the scientific and medical communities expressed through the FDA's clinical testing process"); *All. for Nat. Health U.S. v. Sebelius*, 786 F. Supp. 2d 1, 12 (D.D.C. 2011) ("While the Court is obligated to conduct an independent review of the record and must do so without reliance on the FDA's determinations as to constitutional questions, it must also give deference to an agency's assessment of scientific or technical data within its area of expertise.") (internal quotation marks and citation omitted)).

Even if FDA did not fully reevaluate the in-person dispensing requirement during its 2016 Review, that does not permit the Court to substitute its judgment for that of FDA. As Defendants explained, *see* Defs.' Opp. at 4, FDA does not approve modifications to a drug's REMS absent an adequate rationale, including data to support the proposed changes. In 2016, the drug sponsor proposed specific changes to the Mifeprex REMS and submitted data in support of those changes. *See* Defs.' Opp. at 5; Defs.' Opp. Ex. 15 at 0464-70. But the drug sponsor did not propose eliminating or modifying the in-person dispensing requirement or submit data supporting such a change. *See* Defs.' Opp. at 5; Defs.' Opp. Ex. 16 at 0414-15. Importantly, FDA determined during its 2013 Review, based on its experience and scientific expertise, that the in-person dispensing requirement is necessary to mitigate the serious risks associated with Mifeprex, *see* Defs.' Opp. Ex. 14 at 0344, 0356-57—a decision FDA reaffirmed in 2016 when it concluded that the "safety profile of Mifeprex ha[d] not substantially changed," Defs.' Opp. at 4. Until FDA reconsiders its decision, FDA's scientific judgment is entitled to significant deference. *See, e.g.*, *Rempfer v. Sharfstein*, 583 F.3d 860, 867 (D.C. Cir. 2009) (affording a "high level of deference" to FDA's "scientific judgment within its area of expertise"); *Ohio Valley Envmtl. Coal. v. Aracoma Coal Co.*, 556 F.3d 177, 205 (4th Cir. 2009) ("When an agency is called upon to make complex predictions within its area of special expertise, a reviewing court must be at its most deferential.").

Finally, the Court erred in its application of *Casey*'s large fraction standard. After concluding that Plaintiffs' claim is a "classic as-applied challenge," *see* Mem. Op. at 35, the Court nevertheless proceeded to apply *Casey*'s large fraction standard for facial challenges. Mem. Op. at 60-63. In an "as applied" challenge, however, the proper inquiry for assessing an undue burden claim is whether the challenged law poses a substantial obstacle "as applied" to the

plaintiffs or a specific subset of the plaintiffs under present circumstances, not merely a large fraction of them.

In any event, the Court also incorrectly applied *Casey*'s large fraction test to the narrow subset of women who seek a medication abortion during the pandemic but do not "actually require an in-person visit with their healthcare provider in order to be properly assessed and counseled." Mem. Op. at 40-41. As the Court acknowledged, *see* Mem. Op. at 38, the proper inquiry for the substantial obstacle test is "the group for whom the law is a restriction." *Casey*, 505 U.S. at 894. It cannot be correct that both the numerator and denominator of the large-fraction inquiry are women who *in fact* are burdened by the law, as that fraction is "always '1,' which is pretty large as fractions go." *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2343 n.11 (2016) (Alito, J., dissenting). Instead, the relevant denominator should at a minimum include all women impacted by the in-person requirements, which includes all women seeking a medication abortion. *See id.* at 2320 (majority op.) (discussing relevant category for large-fraction inquiry). And in any event, regardless of the denominator used here, Plaintiffs' claim fails because, as this Court noted, "specific statistics on how many women face an undue burden are not available." Mem. Op. at 62; *see, e.g.*, *In re Rutledge*, 956 F.3d at 1032 (finding abuse of discretion where there were "no concrete district court findings estimating the number of women who would be unduly burdened" by the directive and whether they constituted a large fraction of women seeking non-essential surgical abortions in Arkansas). Thus, Plaintiffs have not shown that the in-person requirements pose a substantial obstacle to a large fraction of women seeking medication abortion.

II. The Remaining Factors Favor a Stay.

Both Defendants and the public will be irreparably harmed if the preliminary injunction is not stayed. The federal government is irreparably harmed whenever it is enjoined from enforcing its public health and safety regulations. *Cf. Maryland v. King*, 567 U.S. 1301 (2012) (Roberts, C.J., in chambers) (noting that anytime the government "is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury"). The "Constitution principally entrusts the safety and the health of the people" to officials who must "act in areas fraught with medical and scientific uncertainties," and who therefore, as a general matter, "should not be subject to second-guessing by an unelected federal judiciary, which lacks the background, competence, and expertise to assess public health." *S. Bay United Pentecostal Church v. Newsom*, No. 19A1044, 2020 WL 2813056, at *1 (U.S. May 29, 2020) (Roberts, C.J., concurring in denial of application for injunctive relief) (internal quotation marks omitted). The injury to the public is particularly acute, where, as here, FDA has determined that the challenged requirements are necessary to ensure patient safety. *See* Defs.' Opp. at 31-32. As explained, the evidence shows that Mifeprex's safety profile "ha[s] not substantially changed" since the drug was first approved with the in-person dispensing requirement in place. *See* Defs.' Opp. at 23; Defs.' Opp. Ex. 18 at 0681.

By contrast, Plaintiffs will not suffer irreparable injury from the entry of a stay. The Court reasoned that Plaintiffs would face irreparable harm without a preliminary injunction because of "the risk of losing the ability to obtain an abortion." Mem. Op. at 70. As discussed *supra*, however, Plaintiffs cannot show irreparable harm based on injuries to patients whom they lack standing to represent or alleged injuries to non-member physicians, and they have not shown any injury rising to the level of irreparable harm. There is no evidence that, for example,

the in-person requirements have forced, or would force, patients to forgo a medication abortion or to undergo a more invasive abortion procedure because of challenges during the pandemic. *See* Defs.' Opp. at 19-21.

III. The Court Should At Least Stay the Preliminary Injunction In Part.

At a minimum, the Court should stay its injunction to the extent the injunction is broader than necessary to redress Plaintiffs' demonstrated injuries. *See* Defs.' Opp. at 33-34. As Defendants explained, *see* Defs.' Opp. at 33, absent a class action, a court generally lacks power under Article III to award such sweeping nationwide relief. And even apart from Article III's constraints, longstanding equity principles establish that an injunction should "be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994). Despite concluding that Plaintiffs' claim is an "as-applied" challenge, the Court enjoined FDA's enforcement of the in-person requirements against not only Plaintiffs and their members, but also against *all other* "similarly situated individuals or entities." Prelim. Inj. at 2 (Dkt. 92). In doing so, the Court erroneously allowed Plaintiffs to circumvent the procedures for class actions set forth in Federal Rule of Civil Procedure 23.

The Court sought to justify the scope of its injunction on the ground that "membership of the Organizational Plaintiffs is extensive in number and geography" and "would necessarily cover over 90 percent of OB/GYN physicians in the United States and apply to some extent in all 50 states." Mem. Op. at 73-74. As Defendants explained, *see* Defs.' Opp. at 34, however, Plaintiffs are not in a position to speak on behalf of "all similarly situated individuals or entities," let alone all unidentified potential patients of all of their unidentified members—some of whom may agree with the in-person dispensing requirement—because Plaintiffs never sought to certify

a class. *See Virginia Soc'y for Human Life, Inc. v. FEC*, 263 F.3d 379, 393 (4th Cir. 2001), *overruled on other grounds by The Real Truth About Abortion, Inc. v. FEC*, 681 F.3d 544 (4th Cir. 2012). Even by the Court's own analysis, only a single member (Dr. Paladine) of one Plaintiff organization (NYSAFP) has demonstrated an injury. Mem. Op. at 19-22, 30. That is insufficient to justify an injunction covering every member of every Plaintiff organization, much less every physician in the United States, none of whom have demonstrated that such relief is necessary to redress their injuries. *Cf. Town of Chester v. Laroe Estates, Inc.*, 137 S. Ct. 1645, 1650 (2017) (plaintiff must "demonstrate standing separately for each form of relief sought"). The Court also reasoned that a "Plaintiffs-only injunction would be practically difficult for the parties to comply with and for the Court to enforce," Mem. Op. at 77, but such an injunction would simply prevent FDA from bringing an enforcement action against a drug sponsor based on violations by those members of Plaintiffs' organizations that have demonstrated an irreparable injury.

CONCLUSION

For the reasons discussed above, Defendants respectfully request that the Court stay its preliminary injunction pending appeal. At a minimum, the Court should stay its injunction to the extent it applies more broadly than necessary to redress Plaintiffs' demonstrated harms. If the Court, upon reviewing this motion, concludes that a stay is inappropriate, Defendants respectfully ask that the Court summarily deny the motion without awaiting a response from Plaintiffs, so that Defendants can seek relief from the Fourth Circuit expeditiously.

Dated: July 24, 2020

Respectfully submitted,

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