No. 20-1824

IN THE 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.

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

MOTION FOR STAY PENDING APPEAL

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INTRODUCTION AND SUMMARY

The district court entered a nationwide preliminary injunction barring the Food and Drug Administration (FDA) from enforcing longstanding regulatory requirements regarding the dispensing of Mifeprex, a drug used to terminate an early pregnancy, during the COVID-19 pandemic. The district court concluded that the mere continued existence of these requirements during the pandemic have made them an undue burden on abortion access. But the court ignored that the requirements apply to a drug pertaining to just one method of abortion that is approved for just a subset of pregnant women (those through 10 weeks pregnant), and that another method of abortion is widely available. And the court failed to recognize that the incidental effects of a pandemic are not grounds to set aside otherwise valid safety requirements. The district court's decision inappropriately compels FDA to increase access to a certain method of abortion during a global pandemic, at risk to women seeking this method. This Court should stay the injunction to prevent this improper interference with FDA's handling of a public health emergency.

Pursuant to the challenged requirements, drug sponsors must ensure that Mifeprex or its generic (collectively, Mifeprex) is dispensed to patients in person, by a certified healthcare provider, and at the provider's office, clinic, or hospital. For twenty years, FDA has maintained these requirements so that patients can timely obtain the drug and receive proper counseling. In FDA's expert view, the requirements help

mitigate serious risks—including incomplete abortion or bleeding that can require surgical intervention—which can increase if the patient delays taking the drug or does not receive proper counseling about the possible complications. Despite FDA's consistent judgment, the district court held that these longstanding requirements are likely "medically unnecessary," and that having patients make a single trip to obtain the drug in person likely poses a substantial obstacle to women seeking an abortion during the pandemic.

FDA is likely to prevail in its appeal. As a threshold matter, the district court erred in allowing plaintiff organizations to assert the rights of non-party patients against requirements that generally apply to a different set of non-parties—namely, drug sponsors. And on the merits, the court improperly found that the pandemic rendered the requirements unconstitutional despite the availability of another abortion method. Mifeprex is approved only for abortions through ten weeks' gestation, so the requirements at issue do not pose an undue burden on abortion access. Women through ten weeks pregnant retain the option of either a medication abortion pursuant to the requirements or a surgical abortion, so they are no worse off than women with more advanced pregnancies, and no worse off than had FDA never approved Mifeprex in the first place. Moreover, a one-time trip to obtain Mifeprex is at most a minimal burden, and the COVID-19 pandemic does not transform it into a substantial one.

The remaining factors also favor a stay. The balance of harms and public interest weigh in favor of continued enforcement of requirements that FDA has deemed necessary to mitigate Mifeprex's serious risks. Plaintiffs also cannot rely on harms borne by non-party patients or speculation about undocumented harms to unnamed physicians, nor have they shown that a one-time clinic visit constitutes irreparable harm.

At a minimum, the district court's injunction is overbroad. Despite construing plaintiffs' suit as an "as-applied" challenge, Addendum (Add.) 35, the district court enjoined application of the requirements for the duration of the current public health emergency, not just as to the physicians for whom plaintiffs had shown harm, but as to all of plaintiffs' member physicians, all "similarly situated" non-parties, and other non-parties "involved in implementing the injunctive relief." Add. 84. Such an overbroad injunction violates both Article III and equitable principles.

BACKGROUND

1.a. When FDA approves a drug sponsor's application to market a new drug, it may require drug sponsors to ensure compliance with a Risk Evaluation and Mitigation Strategy (REMS) that FDA finds "necessary to ensure that the benefits of the drug outweigh the risks." 21 U.S.C. § 355-1(a). That REMS may include one or more of the statutorily listed Elements to Assure Safe Use, such as conditions on the prescription, dispensing, or use of the drug. *Id.* § 355-1(f)(3)(A)-(F).

b. In 2000, during the Clinton administration, FDA approved Mifeprex for use to terminate a pregnancy through seven weeks. Dkt. 62-3, at 2. But FDA concluded that the drug carried serious risks for up to seven percent of patients, including incomplete abortion or bleeding that could require surgical intervention. Dkt. 1-3, at 18. It also found that those risks increase if a patient takes the drug after the approved gestational period or in cases of ectopic pregnancy. *Id.* at 5-6. To mitigate these risks, FDA approved the drug with certain restrictions, such as a requirement that prescribers certify that they can accurately date pregnancies and diagnose ectopic pregnancies. At issue here are requirements that the drug be dispensed only by or under the supervision of a certified healthcare provider in a hospital, clinic, or medical office, and a requirement that patients sign a form acknowledging the drug's risks (the challenged requirements). Dkt. 62-3, at 7.

Since then, FDA has kept the challenged requirements largely without change. The requirements were deemed part of an approved REMS by operation of law after Congress created the REMS framework in 2007, and FDA reaffirmed them in 2011, 2013, and 2016. Dkt. 62-5, at 2-7; Dkt. 62-6, at 4, 16; Dkt. 62-10, at 2-4. In its 2013 review, FDA identified at least two reasons for keeping the requirements. First, in-person dispensing permits counseling at the time of dispensing that could help patients know what to do if they experience certain adverse events. Dkt. 62-6, at 16-17. Second, in-person dispensing avoids 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. *Id.* That concern was particularly important because delay in initiating the abortion could increase the risks of serious complications. *Id.*

In 2016, FDA conducted another review in response to the Mifeprex drug sponsor's supplemental new drug application. FDA made several changes, which included extending the approved use of the drug through ten weeks of pregnancy and modifying the REMS by removing the requirement that patients take the drug in the provider's presence. Dkt. 62-7, at 26-32; Dkt. 62-8, at 4-5; Dkt. 62-9, at 20. But after a clinical review documenting thousands of adverse events between 2000 and 2014, FDA did not alter the challenged requirements because the drug's safety profile had "not substantially changed." Dkt. 62-10, at 4.

2. In April 2020, several of the plaintiff organizations sent FDA letters requesting that it suspend the challenged requirements during the COVID-19 pandemic so that patients could obtain the drug by mail. Dkt. 1-1, at 29-30. Several weeks later, plaintiffs filed suit, alleging that enforcement of the challenged requirements during the pandemic violates the substantive due process rights of their members' patients, and the equal-protection rights of plaintiffs' members.

On July 13, 2020, the district court granted plaintiffs' motion for a preliminary injunction, holding that plaintiffs were likely to show that the challenged requirements pose an unconstitutional undue burden on the abortion rights of their members'

patients insofar as they require patients to obtain the drug in person, but that on the existing record the plaintiffs had not shown a likelihood of prevailing on their equal-protection challenge. Add. 63-68. The court thus enjoined the challenged requirements to the extent they require in-person contact. And though the court found that plaintiffs had raised only an as-applied challenge, it granted a nationwide injunction with respect to all of plaintiffs' members, all "similarly situated" non-parties, and other non-parties "involved in implementing the injunctive relief." Add. 84.

3. The government filed a notice of appeal and sought a stay from the district court, which the court denied on July 30, 2020.

ARGUMENT

In deciding whether to grant a stay pending appeal, the Court considers four factors: (1) the applicant's likelihood of success on the merits; (2) whether the applicant will suffer irreparable injury; (3) the balance of hardships to other parties interested in the proceeding; and (4) the public interest. *Nken v. Holder*, 556 U.S. 418, 434 (2009). All four factors weigh in favor of a stay.

I. The Government Is Likely To Succeed On The Merits.

A. The district court misapplied third-party standing doctrine. Plaintiff organizations seek to enjoin application of requirements to one set of non-parties (drug sponsors) by raising rights of another set of non-parties (patients). But the general rule is that plaintiffs "must assert [their] own legal rights and interests," *Warth v. Seldin*, 422

U.S. 490, 499 (1975), with an "exception" where plaintiffs demonstrate two things: "a 'close' relationship" with the persons who possess the right, and "a 'hindrance'" that keeps those other persons from filing suit on their own. *Kowalski v. Tesmer*, 543 U.S. 125, 129-130 (2004). Plaintiffs have shown neither.

As for a "close relationship," plaintiffs allege only brief interactions with patients seeking a prescription for Mifeprex, and the object of their lawsuit is to *reduce* contact with their patients. See Dkt. No. 1, ¶ 9. The only evidence that the district court cited to show a close relationship was a single physician's declaration stating that some of her patients have previously expressed relief that she provides medication abortions in addition to other services, and that one long-time patient recently asked her for a medication abortion. Add. 26. But those statements are hardly evidence that the thousands of physicians who are members of the plaintiff organizations *generally* have close relationships with patients who seek a Mifeprex prescription.

As for a "hindrance," the district court found one because many patients of plaintiffs' members have low incomes, and abortion is a time-sensitive and private matter. Add. 28-30. Yet those observations apply to abortion patients in general, and it is unlikely that they truly constitute a meaningful hindrance in light of the many cases prospective abortion patients have brought in recent decades. *See Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2323 n.1 (2016) (Thomas, J., dissenting) (collecting cases).

The court also noted that the COVID-19 pandemic generally makes lawsuits more difficult, Add. 30, but that is true for all litigants, including plaintiffs.

The district court further held that abortion providers *always* have third-party standing to represent their patients. Add. 23-24. No such categorical rule exists. In the Supreme Court's recent decision in *June Medical*, the plurality engaged in an extensive analysis to find that plaintiff abortion providers had third-party standing. *See June Med. Servs. L.L.C. v. Russo*, 140 S. Ct. 2103, 2118-20 (2020) (plurality). But if the district court were correct, the plurality could have cited the supposedly categorical rule and moved on.

It is true that the Supreme Court has relaxed the ordinary two-part test when "enforcement of the challenged restriction *against the litigant* would result indirectly in the violation of third parties' rights," *June Medical*, 140 S. Ct. at 2118 (plurality) (quoting *Kowalski*, 543 U. S. at 130), and consistent with that approach has "long permitted abortion providers to invoke the rights of their actual or potential patients in challenges to abortion-related regulations," *see id.* (plurality). But that is not the situation here. Plaintiffs do not allege that they are likely to face enforcement *against them*; rather, they wish to stop enforcement against drug sponsors who are responsible for ensuring compliance with the challenged requirements. In a different section of its opinion, the district court hypothesized that plaintiffs' members might face enforcement actions because prescribing Mifeprex and "facilitat[ing] or arrang[ing] for mifepristone to be

delivered through mail-order pharmacies" might count as "introduc[ing] or deliver[ing]" the drug "into interstate commerce" in violation of 21 U.S.C. § 355(p). Add. 21. But plaintiffs have not advanced that particular theory—and, indeed, FDA has never brought such an enforcement action against any certified prescriber. Plaintiffs' failure to establish that they face a likely FDA enforcement action for failing to comply with the challenged requirements makes their suit subject to the ordinary two-part test for third-party standing, which they have failed to meet.

B.1. The district court likewise erred in holding that the challenged requirements pose an undue burden on abortion access. Under *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992), a 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." *Id.* at 877 (plurality). As the Chief Justice's controlling opinion in *June Medical* recently explained, the undue burden test "requir[es] a substantial obstacle before" a court may "strik[e] down an abortion regulation." 140 S. Ct. at 2139 (Roberts, C.J., concurring in the judgment).

a. 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]." *Gonzales v. Carhart*, 550 U.S. 124, 163-165 (2007). The challenged requirements concern only medication abortions using Mifeprex, which is approved for use only during the first ten weeks of pregnancy. If requiring an in-person surgical abortion for women

who seek abortions after ten weeks does not impose an undue burden, requiring in-person interaction cannot be an undue burden for earlier abortions simply because plaintiffs would prefer another alternative. *See id.* (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 All. 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).

The district court nonetheless held that a law may be an undue burden if it results in patients "seek[ing] a more invasive form of abortion." Add. 50. But that holding contravenes *Gonzales*. *See* 550 U.S. at 165. As this Court has explained, a law is an undue burden only if it "essentially depriv[es] women of the choice to have an abortion." *Greenville Women's Clinic v. Bryant*, 222 F.3d 157, 167 (4th Cir. 2000). A requirement that patients make a one-time trip to a medical office, clinic, or hospital does not deprive women of the "ability to make a decision to have an abortion," *id.* at 169-70 (emphasis omitted).

The out-of-circuit decision that the district court relied on (Add. 40) does not support its contrary conclusion. In *Planned Parenthood Arizona, Inc. v. Humble*, 753 F.3d 905 (9th Cir. 2014), there was evidence that a ban on certain off-label medication abortions might cause some clinics to close and some patients to "forego abortion entirely." *Id.* at 915-16. The district court identified no such evidence here. The court also relied on statements in *Stenberg v. Carhart*, 530 U.S. 914 (2000), but ignored that the Supreme Court's later decision in *Gonzales* makes clear that a regulation does not pose a substantial obstacle if it allows other "commonly used and generally accepted method[s]." 550 U.S. at 165.

b. The district court further erred in holding that a regulatory requirement may become unconstitutional because of incidental effects caused by an unforeseen global pandemic. "The 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 Bryant*, 222 F.3d at 167-70. And "although government may not place obstacles in the path of a woman's exercise of her freedom of choice, it need not remove those not of its own creation." *Harris v. McRae*, 448 U.S. 297, 316 (1980).

The district court's decision violates these principles. The court's finding of a substantial obstacle reduces to the observation that COVID-19 has made going anywhere riskier or more difficult than in normal times, especially for certain

individuals. Yet that undifferentiated difficulty arising from an unforeseen global pandemic is an "incidental effect" not traceable to the challenged requirements. *Casey*, 505 U.S. at 874 (plurality); *see Whole Woman's Health*, 136 S. Ct. at 2313 (plaintiffs challenging an abortion regulation bear the "burden to present evidence of causation"). In striking down the requirements because of such incidental effects, the district court inappropriately created an affirmative duty for FDA to "remove [obstacles] not of its own creation" in the midst of a pandemic. *McRae*, 448 U.S. at 316.

c. Even on its own terms, the district court was mistaken in concluding that the pandemic creates a substantial obstacle to obtaining medication abortions using Mifeprex. A one-time clinic visit, even if an obstacle, is not a substantial one. *Cf. Casey*, 505 U.S. at 886 (plurality) (mandatory 24-hour waiting period requiring "at least two visits to the doctor" not a substantial obstacle). These same patients would likely need to visit a clinic or other facility in person for any vaccine or minor procedure. Moreover, plaintiffs have offered no evidence that clinics are not complying with CDC guidelines to lower the risk of exposure.[1] And, as plaintiffs have emphasized, encouragement of telehealth services for other patients is likely to substantially reduce the number of persons present at a clinic. *See* Dkt. 11-1, at 19-21.

[1] *See* CDC, *Print Resources* (July 10, 2020), https://go.usa.gov/xfRQV.

The district court expressed generalized concerns that travel and childcare are more difficult during the pandemic, but those concerns do not show that a one-time visit to obtain the drug in person is any more of a burden than visiting any other place. The court's only particularized evidence consisted of anecdotes taken from a few declarations. But plaintiffs are challenging the as-applied effect of the challenged requirements on the patients of thousands of physicians around the country. A few anecdotes do not justify a generalization about all of those patients. And even the chosen anecdotes do not show a *substantial* obstacle. *See Bryant*, 222 F.3d at 171 (finding no undue burden where regulation had potential to increase cost of abortion by $75 and require some patients to travel an additional 70 miles). Indeed, the alleged burden here comes nowhere close to the burdens that the Supreme Court has found to be a substantial obstacle. *See, e.g.*, *Hellerstedt*, 136 S. Ct. at 2312 (noting that law had caused nearly half the clinics in the state to close).

The district court also speculated that the pandemic's effects could cause so much delay (because some clinics have closed or reduced services) that patients would lose the ability to obtain a medication abortion within the first 10 weeks of pregnancy. But as noted, there is no constitutional right to the abortion method of one's choice, as long as there are other "reasonable alternative procedures" or "commonly used and generally accepted method[s]," *Gonzales*, 550 U.S. at 163-165—as is the case here. Moreover, the court cited no evidence that the challenged requirements would as a

general matter delay a medication abortion beyond the ten-week limit. To the contrary, preventing delay is one of the justifications FDA provided for the requirements. *See* Dkt. 62-6, at 16-17. And the district court ignored the risk that the mail could be delayed, as indeed it sometimes has been due to the pandemic.[2]

2. Plaintiffs' failure to show that the challenged requirements pose a substantial obstacle to abortion access should end the court's inquiry. Yet the district court concluded in the alternative that the Supreme Court's decision in *Whole Women's Health*, 136 S. Ct. 2292, allowed it to balance a regulation's burdens and benefits whether or not plaintiffs showed a substantial obstacle. That was mistaken. All nine Justices in *June Medical* emphasized the importance of demonstrating that a law poses a substantial obstacle to abortion access in order to obtain relief, *see* 140 S. Ct. at 2112, 2120, 2130 (plurality); *id.* at 2135-39 (Roberts, C.J., concurring in the judgment); *id.* at 2153-54 (Alito, J., joined by Thomas, Gorsuch, and Kavanaugh, JJ., dissenting). And at least five Justices explicitly rejected the free-floating cost-benefit test that the district court adopted, *see id.* at 2135-39 (Roberts, C.J., concurring in the judgment); *id.* at 2153-54 (Alito, J., joined by Thomas, Gorsuch, and Kavanaugh, JJ., dissenting); *id.* at 2182 (Kavanaugh, J., dissenting).

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[2] *See, e.g.*, U.S. Postal Serv., *USPS Coronavirus Updates: Expected Delivery Changes* (Apr. 17, 2020), https://go.usa.gov/xfRQd.

In holding the opposite, the district court misread the concurring opinion's admonition that "[w]e should respect the statement in *Whole Woman's Health* that it was applying the undue burden standard of *Casey*." 140 S. Ct. at 2138 (Roberts, J., concurring in the judgment). The concurrence did not opine that a free-floating balancing test is consistent with *Casey*. To the contrary, it noted that *Whole Woman's Health*'s language could be misconstrued when "[r]ead in isolation from *Casey*," and that the opinion in *Whole Woman's Health* should not be read as endorsing an amorphous balancing of "imponderables" not suited to courts. *Id.* at 2135-36.

In any event, the district court mistakenly set aside FDA's expert judgment. FDA reaffirmed the challenged requirements after reviewing thousands of adverse events resulting from use of Mifeprex. The agency concluded that in-person counseling at the time of dispensing could help patients understand possible serious complications and what to do if they experienced an adverse event. Dkt. 62-6, at 16-17. It also concluded that delay in taking the drug could increase the risk a patient would suffer serious complications, and that in-person dispensing could help avoid delay associated with obtaining the drug from a pharmacy, such as delay caused by local pharmacies not stocking the drug. *Id.* Those considerations readily justify the challenged requirements.

The district court nonetheless agreed with the opinion of a few physicians and a non-profit that the requirement is "'medically unnecessary.'" Add. 51-52, 56. In doing so, it noted that FDA had not considered the availability of telehealth counseling and

concluded that telehealth counseling is just as effective as counseling in person. Add. 53-56. But the district court failed to appreciate questions that it should have left for FDA to resolve, such as whether counseling at the time of dispensing might be more effective because it might be closer in time to when the patient takes the drug or more effective at communicating risks. The doubt on those questions requiring data and expertise should have led the district court to stay its hand, not to impose its own view or the view of a few physicians on FDA.

The court also brushed aside FDA's concern about delay on the theory that "healthcare provider[s]" can exercise their own "medical judgment" about what is safest. Add. 57-58. But federal law grants FDA authority to impose conditions on the dispensing of a drug without having to assume that providers will always exercise sound judgment. *See Gonzales*, 550 U.S. at 163 ("The law need not give abortion doctors unfettered choice in the course of their medical practice"); *cf. Casey*, 505 U.S. at 886 (plurality) ("while the waiting period does limit a physician's discretion, that is not, standing alone, a reason to invalidate it"). The district court provided no authority for the proposition that a regulatory requirement lacks a benefit based on an assumption that providers will always behave wisely. And the court ignored that the provider might never find out about delay caused by the mail or by mail-order pharmacies being out of stock.

The district court's other reasons for discounting FDA's concern about delay were based on misapprehensions and unwarranted generalizations. The court said that the "degree of risk" is "relevant here only to the extent it provides a basis to require advanced counseling"—appearing to ignore FDA's evidence-backed conclusion that delay increases the risks. Add. 59. The court also reiterated its assertion that the challenged requirements would generally cause delays, Add. 58, despite lacking a basis for any such generalization. And based on a few declarations stating that use of same-day courier services could avoid the possible delays that FDA was concerned about, the district court inappropriately speculated that this might be true as a general matter and sufficient to mitigate FDA's concerns. *Id.*

The district court misunderstood other points as well. That FDA now allows patients to take Mifeprex at home instead of at a clinic does not mean that the challenged requirements "do[] not actually address any interest in having the patient take the [drug] as soon as possible." Add. 53-55, 58. The requirements mitigate the risk of some possible sources of delay, even if it does not mitigate all possible delay. *Cf. Williams-Yulee v. Florida Bar*, 575 U.S. 433, 449 (2015) (even under strict scrutiny, the government "need not address all aspects of a problem in one fell swoop"). Nor does the fact that FDA has encouraged telehealth services and suspended some in-person requirements for a few entirely different drugs, Add. 61, have anything to do with the need for the challenged requirements with respect to *this* drug. FDA evaluates the

necessity of in-person dispensing for each drug individually, not en masse. And the district court was incorrect that in 2016 FDA had not reaffirmed these requirements. Based on data showing thousands of adverse events, FDA concluded that the drug's safety profile had "not substantially changed." Dkt. 62-10, at 4.

3. The district court concluded that the plaintiffs' claim "is plainly an 'as applied' challenge" and that it therefore did not need to apply the standard for facial claims. Add. 35. But it nonetheless went on to apply the "large fraction" standard sometimes used for facial challenges to abortion regulations, under which a regulation is unconstitutional if it poses an undue burden for a large fraction of those women to whom the regulation is relevant. *Casey*, 505 U.S. at 895 (plurality). If the claim is "as-applied," as the district court emphasized, that analysis was mistaken. Plaintiffs must show that the challenged requirements pose a substantial obstacle "as applied" to either all or a specified subset of their members during the pandemic—not merely a large fraction of them.

In any event, the district court's cursory large-fraction analysis was flawed. The district court held that the relevant population was those patients for whom the challenged requirements lack any benefit, Add. 62-63, but the population to whom the requirements are relevant is all women seeking a medication abortion using Mifeprex. All of them are subject to the minimal burden of obtaining the drug in person. And however one applies the "large fraction" test, plaintiffs have not shown any substantial

obstacle, much less one affecting a large fraction of patients seeking a medication abortion. The district court's own analysis highlights this deficiency, stating that it was "infer[ring] that the challenges for receiving in-person medical care are significant" even though it lacked data on "how many of the affected women face an undue burden." Add. 62-63.

II. The Remaining Factors Favor A Stay.

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 generally "should not be subject to second-guessing by an unelected federal judiciary, which lacks the background, competence, and expertise to assess public health." *South Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613, 1613-14 (2020) (Roberts, C.J., concurring in denial of application for injunctive relief) (alteration and quotation marks omitted). By interfering with FDA's handling of a public health emergency, and ordering non-enforcement of requirements necessary to mitigate serious risks for patients, the district court's injunction causes irreparable harm to the government and the public interest, *see Nken v. Holder*, 556 U.S. 418, 435 (2009) (noting that the government's harm and the public interest "merge"). And that harm outweighs any purported harm to plaintiffs.

The district court engaged in exactly the kind of judicial second-guessing that is especially inappropriate during a public health emergency, opining that its injunction

would "safeguard public health" by "eliminating unnecessary in-person visits during the pandemic." Add. 72. The court further asserted that the government suffered no harm and that plaintiffs suffered irreparable harm because of the purported "risk" that some patients would "los[e] the ability to obtain an abortion." Add. 70. But, as explained, plaintiffs cannot assert the harms of non-party patients, and there is no basis in the record to conclude that a one-time clinic visit bars any patients from obtaining an abortion.

III. This Court Should At Least Stay The Injunction's Overbroad Scope.

At a minimum, the scope of the injunction violates Article III and equitable principles of relief, both of which require that the "plaintiff's remedy . . . be tailored to redress the plaintiff's particular injury." *Gill v. Whitford*, 138 S. Ct. 1916, 1933-34 (2018). Despite construing plaintiffs' claim as an "as-applied" challenge, the district court's injunction provides relief to patients of all physicians who are members of plaintiff organizations, along with all "similarly situated" non-parties and other non-parties "involved in implementing the injunctive relief." Add. 84. But plaintiffs cannot claim to represent the interests of *all* patients who seek an abortion using Mifeprex, and, even by the district court's analysis, have at most established injury only as to one member physician, *see* Add. 19-22, 30. The district court offered no reason why providing relief to *other* physicians or their patients—some of whom may agree with the challenged

requirements—is in any way necessary to prevent the plaintiffs' asserted injuries during these proceedings.

Instead, the district court claimed authority to effectively turn this case into a one-sided class action (binding the government as to all potential claimants but not binding all potential claimants) because, in its view, that would be more efficient. The court determined that it could grant universal relief because (1) the challenged requirements apply to non-parties; (2) many other non-parties may have difficulty bringing suit; (3) other suits might be duplicative; (4) a universal injunction would be easier to administer; and (5) plaintiff organizations already represented most of the physicians in the country. Add. 75-80. That reasoning directly flouts Article III and this Court's express directives that injunctions are improper when they are "broader than necessary to afford full relief" to plaintiffs and "substantially thwart the development of important questions of law by freezing the first final decision rendered on a particular legal issue." *Virginia Soc'y for Human Life, Inc. v. FEC*, 263 F.3d 379, 393 (4th Cir. 2001) (quoting *United States v. Mendoza*, 464 U.S. 154, 160 (1984)). The case on which the district court relied to the contrary does not compel the contrary conclusion, as it emphasized that the injunction there, unlike here, was "in fact quite narrow." *See Roe v. Department of Def.*, 947 F.3d 207, 232-33 (4th Cir. 2020), *as amended* (Jan. 14, 2020).

CONCLUSION

This Court should stay the district court's preliminary injunction pending appeal. At a minimum, the Court should stay the injunction insofar as it applies more broadly than necessary to remedy any harms demonstrated by plaintiffs.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Motion complies with the type-volume limitation of Federal Rule of Appellate Procedure 27 because it contains 5,188 words. This Motion complies with the typeface and the type style requirements of Federal Rule of Appellate Procedure 27 because this brief has been prepared in a proportionally spaced typeface using Word 14-point Garamond typeface.

s/ Joshua Dos Santos
JOSHUA DOS SANTOS

CERTIFICATE OF SERVICE

I hereby certify that on July 30, 2020, 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.

s/ Joshua Dos Santos
JOSHUA DOS SANTOS

ADDENDUM

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UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, *on behalf of its members and members' patients*,
COUNCIL OF UNIVERSITY CHAIRS OF OBSTETRICS AND GYNECOLOGY, *on behalf of its members and members' patients*,
NEW YORK STATE ACADEMY OF FAMILY PHYSICIANS, *on behalf of its members and members' patients*,
SISTERSONG WOMEN OF COLOR REPRODUCTIVE JUSTICE COLLECTIVE, *on behalf of its members and members' patients*, and
HONOR MACNAUGHTON, M.D.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,
STEPHEN M. HAHN, M.D., *in his official capacity as Commissioner of Food and Drugs, and his employees, agents and successors in office*,
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES and
ALEX AZAR, J.D., *in his official capacity as Secretary, United States Department of Health and Human Services, and his employees, agents and successors in office*,

Defendants.

Civil Action No. TDC-20-1320

MEMORANDUM OPINION

Plaintiffs American College of Obstetricians and Gynecologists ("ACOG"), Council of University Chairs of Obstetrics and Gynecology ("CUCOG"), New York State Academy of

Family Physicians ("NYSAFP"), SisterSong Women of Color Reproductive Justice Collective ("SisterSong"), and Honor MacNaughton, M.D. have filed a civil action against the United States Food and Drug Administration ("FDA"), FDA Commissioner Stephen M. Hahn, the United States Department of Health and Human Services ("HHS"), and Secretary of Health and Human Services Alex Azar ("the Secretary"), challenging the enforcement during the COVID-19 pandemic of certain FDA requirements relating to in-person dispensing and signature requirements for an oral medication used to induce an abortion or to manage a miscarriage. Plaintiffs have filed a Motion for a Preliminary Injunction seeking an order barring the enforcement of these requirements during the pandemic. The Motion is fully briefed, and the Court held a hearing on the Motion on June 19, 2020. For the reasons set forth below, Plaintiffs' Motion for a Preliminary Injunction is GRANTED IN PART and DENIED IN PART.

BACKGROUND

I. Medication Abortion

On September 28, 2000, FDA approved Mifeprex, the brand name for the drug mifepristone (collectively, "mifepristone"), as the first non-surgical abortion drug that, when taken in conjunction with another drug, misoprostol, can cause the early termination of an intrauterine pregnancy. In 2019, FDA approved a generic version of mifepristone. The use of mifepristone and misoprostol to cause an abortion, referred to as a medication abortion, is a two-part regimen ("the Mifepristone-Misoprostol Regimen"). First, the patient takes mifepristone, a single 200 mg tablet taken orally. Mifepristone blocks the body's receptors for the hormone necessary to sustain pregnancy, which then causes the pregnancy tissue and lining of the uterus to break down and separate from the uterine wall. Then, 24 to 48 hours after taking mifepristone, the patient takes misoprostol, another oral medication. Misoprostol causes uterine contractions that expel the

contents of the uterus. As a result, between 2 and 24 hours after taking misoprostol, the patient will experience cramping and bleeding that signals the pregnancy is being expelled.

The use of mifepristone in conjunction with misoprostol is also a widely accepted medical regimen to manage a miscarriage. While misoprostol alone has been prescribed after a miscarriage to completely expel the pregnancy, taking mifepristone first decreases the need for a follow-up, in-office procedure to fully evacuate the uterus.

II. FDA Regulation

When FDA first approved mifepristone in 2000, it recognized that the drug carried serious risks, such as an incomplete abortion or serious bleeding. In an effort to mitigate potential complications, FDA put in place several restrictions on dispensing and distributing the drug, including that the drug be prescribed only by a qualified physician and that it be administered in a hospital, clinic, or medical office only by or under the supervision of such a physician. In 2007, FDA deemed the imposed restrictions to be an approved Risk Evaluation and Mitigation Strategy ("REMS"), a statutorily authorized designation which allows for additional FDA restrictions beyond those set forth on the drug's labeling. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-399i (2018), the federal government can enforce REMS against healthcare providers and the manufacturer of the drug, known as the "drug sponsor." *See, e.g.*, 21 U.S.C. § 355(p)(1)(B) (prohibiting a person from introducing or delivering a new drug into interstate commerce if the person fails to maintain compliance with the REMS); 21 U.S.C. § 333(f)(4)(A) (subjecting a drug manufacturer as a "responsible person" to civil penalties for violations of the REMS scheme).

In 2011, FDA approved the existing mifepristone REMS with additional Elements to Assure Safe Use ("ETASU"), a special category of REMS. An ETASU can be imposed on a drug

that has been "shown to be effective" but is "associated with a serious adverse drug experience" such that it can be approved only on the condition that the designated elements are satisfied. 21 U.S.C. § 355-1(f)(3). The ETASU requirements imposed in 2011 consisted of provisions mandating that the drug be prescribed only by specially certified physicians, that it be dispensed only in hospitals, clinics, or medical offices, and that it be dispensed only with documentation that certain safe-use conditions were met, such as securing the signature of the patient on a Patient Agreement Form and providing that form and a Medication Guide to the patient.

In 2013, FDA reviewed the existing REMS and reaffirmed the elements already in place. Three years later, in 2016, in response to a supplemental application by the drug sponsor requesting modifications to the REMS, 21 U.S.C. § 355-1(g)(4), FDA conducted another review of the existing mifepristone REMS. In that review, FDA determined that "no new safety concerns have arisen in recent years and that the known serious risks occur rarely," and that "[g]iven that the numbers of . . . adverse events appear to be stable or decreased over time, it is likely that . . . serious adverse events will remain acceptably low." 2016 Clinical Review at 39, 47, 49, Opp'n Mot. PI Ex. 19, ECF No. 62-11. As a result of the review, FDA made several changes to the REMS. Going forward, FDA permitted certain nonphysicians to prescribe the drug as long as they meet certain certification requirements, in part because the review "clearly demonstrate[d] that efficacy is the same with non-physician providers compared to physicians." *Id.* at 43. FDA also eliminated the requirement that the drug be administered in a hospital, clinic, or medical office and instead permitted it to be self-administered by the patient at a different location, based on the finding that there is "no significant difference in either efficacy or safety" for women who take both mifepristone and misoprostol at home as compared to women who take mifepristone at a medical office and misoprostol at home. *Id.* at 39. FDA also extended the gestational period during which

the medication is approved for use from seven weeks to ten weeks into a pregnancy. Of the requests made during this REMS review, the drug sponsor did not ask for changes to, or elimination of, the requirement that the drug be dispensed only in person at a healthcare facility.

Mifepristone is thus presently subject to three ETASU requirements. The first ETASU requirement, adopted pursuant to the "ETASU A" category which requires that "health care providers who prescribe the drug have particular training or experience or are specially certified," 21 U.S.C. § 355-1(f)(3)(A), provides that prescribing healthcare providers must certify in a written form submitted to the drug sponsor that they have certain required qualifications, such as the ability to assess the duration of the pregnancy and to diagnose an ectopic pregnancy, and will comply with specific use guidelines, including providing counseling about the risks of the Mifepristone-Misoprostol Regimen, providing and reviewing the Patient Agreement Form, as discussed below, and recording the serial number of each package of mifepristone in the patient's medical records.

The second ETASU requirement, imposed under the "ETASU C" category which "requires that the drug be dispensed to patients only in certain health care settings," 21 U.S.C. § 355-1(f)(3)(c), provides that mifepristone may be dispensed only in a hospital, clinic, or medical office, by or under the supervision of a certified healthcare provider ("the In-Person Dispensing Requirement"). Under this requirement, patients are not permitted to obtain mifepristone through a mail-order or retail pharmacy or to receive the medication by mail from their healthcare provider even if otherwise permitted by state law. Of the approximately 17 drugs subject to ETASU C, mifepristone is the only one for which the patient may take the medication alone, without clinical supervision.

The third ETASU requirement, adopted under the "ETASU D" category which provides that the drug "be dispensed to patients with evidence or other documentation of safe-use

conditions," 21 U.S.C. § 355-1(f)(3)(D), requires that the certified healthcare provider give a copy of a Patient Agreement Form disclosing certain information about mifepristone and its risks to the patient, that the healthcare provider review it with the patient and counsel her about the risk of serious complications, and that the patient sign the form acknowledging that she had read and received the form and received the counseling. The language in the Patient Agreement Form can be read as requiring that the prescriber and patient be in the same location when this paperwork is completed, as the form states above the provider's signature line: "The patient signed the PATIENT AGREEMENT in my presence after I counseled her and answered all her questions." Mifepristone REMS, Patient Agreement Form, Compl. Ex. 2, ECF No. 1-4. In this action, Plaintiffs challenge the present enforcement of both this "In-Person Signature Requirement" and the In-Person Dispensing Requirement (collectively, "the In-Person Requirements").

III. Current Mifepristone-Misoprostol Regimen

Under the current FDA requirements, certified healthcare providers typically prescribe and dispense the drugs for a medication abortion using the following regimen. First, the healthcare provider must assess a patient's eligibility for a medication abortion. This assessment includes determining that the patient has been pregnant for less than the maximum ten weeks to be eligible for a medication abortion and that the patient does not have an ectopic pregnancy, one in which the fertilized egg is growing outside the uterus, a condition which would disqualify the patient for the Mifepristone-Misoprostol Regimen. FDA does not restrict where and how this initial assessment is conducted. Based on the healthcare provider's best medical judgment, it may take place in person and may require an ultrasound or blood work to establish the existence of a pregnancy. In recent times, the assessment has also occurred entirely through remote technologies such as a video connection over the internet, referred to as telemedicine, through which the

healthcare provider makes the necessary determinations based on the patient's reported medical history, last menstrual period, results of over-the-counter pregnancy tests, and symptoms. Once a patient has been deemed eligible for a medication abortion, the patient is counseled on the risks and alternatives, and the healthcare provider reviews with the patient other required information. After the healthcare provider has obtained the patient's informed consent, the prescriptions for mifepristone and misoprostol are issued. At this stage, the healthcare provider gives the patient specific instructions for the use of the drugs and follow-up care, including information about potentially serious complications and how to address them if they arise.

If not already at the healthcare provider's hospital, clinic, or medical office, the patient then visits that facility to pick up the prescribed mifepristone. While onsite, the patient must sign the Patient Agreement Form containing information about mifepristone and its risks previously discussed during the consultation. She then receives a copy of the Patient Agreement Form and the mifepristone Medication Guide, which contains substantially similar information. Once the patient has the drug, she can take it orally at any location of her choosing, including at home. Then, 24 to 48 hours later, the patient orally takes misoprostol, which can be obtained through a retail or mail-order pharmacy, or at the same healthcare facility. That drug can also be taken at a location of the patient's choosing, and the physical response to the drugs does not begin until 2 to 24 hours after misoprostol is taken. Under current FDA labeling for mifepristone, the healthcare provider will have discussed with the patient the necessity of arranging to be in a comfortable location shortly after taking misoprostol when cramping and bleeding associated with the regimen begin. Finally, patients are advised to follow up with their healthcare provider 7 to 14 days after the completion of the Mifepristone-Misoprostol Regimen to ensure that the abortion was successful. This consultation need not take place in person.

IV. COVID-19

COVID-19 is a highly contagious and life-threatening respiratory disease caused by the SARS-CoV-2 novel coronavirus that is transmitted through respiratory transmission, including droplet and possibly aerosolized transmission, and the touching of contaminated surfaces. Reingold Decl. ¶¶ 13-14, Mot. PI Ex. 2, ECF No. 11-4. Because many individuals infected with the coronavirus lack symptoms and the disease currently lacks an effective vaccine, it is exceedingly difficult to control its spread. *Id.* ¶ 17. Since the first confirmed case of COVID-19 was reported in the United States in late January 2020, the Centers for Disease Control and Prevention ("CDC"), a component of HHS, has reported that there have been over three million cases of COVID-19, and over 130,000 deaths, across the nation. *See Cases in the U.S.*, U.S. Ctrs. For Disease Control & Prevention, https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html (last updated July 10, 2020) ("CDC, *COVID-19 Cases*").[1] At the initial peak of the pandemic in March 2020, the CDC reported more than 43,000 new COVID-19 cases per day nationwide. *See New Cases by Day*, U.S. Ctrs. For Disease Control & Prevention, https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html (last updated July 9, 2020) ("CDC, *New Cases by Day*"). Now, during July 2020, new cases per day have surpassed 44,000 each day so far this month. *Id.* Worldwide, there have been more than 11 million cases and over 545,000 deaths. *Coronavirus Disease (COVID-19) Situation Report – 171*, World Health Organization (July 9, 2020), https://www.who.int/docs/default-source/corona

[1] At the hearing on the Motion, the parties agreed that the Court may take judicial notice of updated facts relating to the state of the COVID-19 pandemic as of the date of the issuance of this opinion. *See United States v. Garcia*, 855 F.3d 615, 621 (4th Cir. 2017) ("Under Federal Rule of Evidence 201(b), the district court may judicially notice a fact that is not subject to reasonable dispute . . . This court and numerous others routinely take judicial notice of information contained on state and federal government websites.").

viruse/situation-reports/20200709-covid-19-sitrep-171.pdf?sfvrsn=9aba7ec7_2 ("WHO, *COVID-19 Situation Report*").

On March 13, 2020, the President of the United States issued a proclamation to declare that the "COVID-19 outbreak in the United States constitutes a national emergency" and to authorize the Secretary of HHS to temporarily waive or modify certain Medicare, Medicaid, and health insurance requirements for the duration of the public health emergency. *See Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak*, White House (Mar. 13, 2020), https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/. The Governors of all 50 states have declared a state of emergency or public health emergency and have issued some combination of stay-at-home orders, restrictions on the operation of businesses and restaurants, and limitations on social gatherings in response to the pandemic. *See Executive Orders*, Council of State Govt's, https://web.csg.org/covid19/executive-orders/ (last visited July 7, 2020). Several states have also banned elective surgeries, including abortions, because of the pandemic. *See, e.g.*, *In re Rutledge*, 956 F.3d 1018, 1023 (8th Cir. 2020); *Adams & Boyle, P.C. v. Slatery*, 956 F.3d 913, 924 (6th Cir. 2020).

A. Federal Agency Action

In response to this unprecedented public health crisis, federal agencies have issued guidance or instituted waivers in recognition of the health risks associated with patient travel to medical facilities during the pandemic. On January 31, 2020, the Secretary declared a public health emergency ("PHE") pursuant to the Public Health Service Act, 42 U.S.C. § 247d (2018). *See Determination that a Public Health Emergency Exists*, Health & Human Servs. (Jan. 31, 2020), https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx. Under this

provision, the Secretary may declare that "a disease or disorder presents a public health emergency" or that "a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists." 42 U.S.C. § 247d(a) . Upon such a declaration, the Secretary "may take such action as may be appropriate to respond to the public health emergency." *Id.*

In March and April 2020, FDA informed drug sponsors for two specific drugs, Spravato and Tysabri, that during the pandemic it would not enforce the associated ETASU C requirement that a drug be administered or dispensed only at a hospital, clinic, or medical office—the same limitation imposed on mifepristone—even though both still must be administered in-person by a physician. In March 2020, FDA also announced that during the PHE, it would not enforce certain REMS ETASU requirements that mandate that a patient undergo certain in-person procedures, such as laboratory tests or imaging studies such as magnetic resonance imaging ("MRI"), before prescribing certain drugs, when a health care professional exercising medical judgment determines that the patient can safely forgo the procedure. U.S. Food & Drug Admin., *Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency: Guidance for Industry and Health Care Professionals* 7, (Mar. 2020), https://www.fda.gov/media/136317/download ("FDA, *COVID-19 REMS Guidance*") (cited in Reingold Decl. ¶ 46).

Based on his PHE declaration, the Secretary, with the concurrence of the Acting Administrator of the Drug Enforcement Administration ("DEA"), invoked the use of the "telemedicine exception" in the Controlled Substances Act ("CSA"), 21 U.S.C. § 802(54)(D), which permits practitioners to forgo otherwise mandatory requirements that they conduct an in-person evaluation of a patient before prescribing certain controlled substances, including opioids, and to permit them instead to rely on telemedicine to assess a patient before issuing a prescription.

More broadly, HHS has acted to advance the use of telemedicine during the pandemic. On March 17, 2020, the Secretary announced that HHS was taking measures to facilitate telemedicine so that patients can "access healthcare they need from their home, without worrying about putting themselves or others at risk during the COVID-19 outbreak." *Secretary Azar Announces Historic Expansion of Telehealth Access to Combat COVID-19*, Health & Human Servs. (Mar. 17, 2020), https://www.hhs.gov/about/news/2020/03/17/secretary-azar-announces-historic-expansion-of-telehealth-access-to-combat-covid-19.html ("Azar, *Telehealth Announcement*"). That day, HHS also announced that it would waive penalties for good-faith violations of privacy requirements by health care providers using standard online communications platforms such as FaceTime and Zoom to see patients. *OCR Announces Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency*, Health & Human Servs. (Mar. 17, 2020), https://www.hhs.gov/about/news/2020/03/17/ocr-announces-notification-of-enforcement-discretion-for-telehealth-remote-communications-during-the-covid-19.html. Another HHS component agency, the Centers for Medicare and Medicaid Services ("CMS"), temporarily expanded Medicare coverage to include a broader range of telemedicine services during the pandemic to "limit risk of exposure and spread of the virus." *President Trump Expands Telehealth Benefits for Medicare Beneficiaries During COVID-19 Outbreak*, Ctrs. For Medicare & Medicaid Servs. (Mar. 17, 2020), https://www.cms.gov/newsroom/press-releases/president-trump-expands-telehealth-benefits-medicare-beneficiaries-during-covid-19-outbreak ("CMS, *Telehealth Announcement*") (quoted in Reingold Decl. ¶ 45).

CDC has also issued advisory guidance to health care professionals to use telemedicine "whenever possible" as "the best way to protect patients and staff from COVID-19." *Prepare Your Practice for COVID-19*, U.S. Ctrs. For Disease Control & Prevention,

https://www.cdc.gov/coronavirus/2019-ncov/hcp/preparedness-resources.html (last updated June 12, 2020) ("CDC, *Prepare Your Practice*") (quoted in Reingold Decl. ¶ 40). CDC has separately advised patients to "[u]se telemedicine or communicate with your doctor or nurse by phone or email," to reschedule procedures not urgently needed, and to limit in-person visits to the pharmacy by using mail-order or delivery services where possible. *Coronavirus Disease 2019 (COVID 19): Doctor Visits and Getting Medicines*, U.S. Ctrs. For Disease Control & Prevention, https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/doctor-visits-medicine.html (last updated June 8, 2020) ("CDC, *Doctors and Medicines*") (quoted and cited in Reingold Decl. ¶ 42).

B. Impact on Medication Abortion Care

Plaintiffs have presented the expert opinion of Dr. Arthur Reingold, Division Head of Epidemiology at the University of California at Berkeley School of Public Health, as well as expert opinions from six physicians who provide or oversee abortion services in locations across the United States, including in New York, Massachusetts, Maryland, Washington, D.C., New Mexico, and California. The physicians include: Dr. Allison Bryant Mantha ("Dr. Bryant"), a board-certified obstetrician/gynecologist ("OB/GYN") practicing at Massachusetts General Hospital in Boston, Massachusetts and an Associate Professor at Harvard Medical School; Dr. Heather Paladine, a physician practicing at a community health center in New York City who is also the Assistant Attending Physician at New York Presbyterian Hospital and an Assistant Professor of Medicine at Columbia University Medical Center; Dr. Angela Chen, a board-certified OB/GYN practicing at the University of California at Los Angeles ("UCLA") Medical Center and an Associate Clinical Professor in the Department of Obstetrics and Gynecology at the David Geffen School of Medicine at UCLA; Dr. Serina Floyd, a board-certified OB/GYN who is the Medical Director of Planned Parenthood of Metropolitan Washington, D.C. ("PPMW") overseeing care at

PPMW clinics in Maryland and Washington, D.C. and an Assistant Professor of Medical Education at the University of Virginia; Dr. Eve Espey, a licensed OB/GYN practicing at the University of New Mexico Hospital in Albuquerque, New Mexico and the Chair of the Department of Obstetrics and Gynecology at the University of New Mexico School of Medicine; and Dr. Honor MacNaughton, a board-certified physician practicing in family planning clinics in Massachusetts and an Associate Professor at Tufts University School of Medicine.

These experts have testified to the challenges that COVID-19 presents to patients fulfilling the In-Person Requirements in order to obtain a medication abortion and to the ability of healthcare providers to meet all medically necessary requirements through telemedicine. First, they have asserted that COVID-19 has adversely impacted the availability of in-person abortion care in the United States. According to Dr. Paladine, at various times, medical offices and clinics have either closed entirely or reduced the number of in-person appointments so that visits to obtain mifepristone have been stopped or delayed. Paladine Decl. ¶ 13, Mot. PI Ex. 3, ECF No. 11-5. For example, her own clinic closed entirely to in-person visits, then reopened operating at only 10 percent of capacity. *Id.* ¶¶ 13-14. She estimates that it will operate at 25 percent capacity through Spring 2021. *Id.* ¶ 14. According to Dr. MacNaughton, the COVID-19 pandemic caused the hospital system in which she works to close all but three primary care clinics to in-person visits, so that abortion or miscarriage patients had to be referred to family planning clinics, which are only open one half-day per week and are often located outside the patient's local community, in order to obtain mifepristone. MacNaughton Decl. ¶¶ 7-8, Mot. PI Ex. 7, ECF No. 11-9. Because most of the primary care clinics were closed to in-person care, many of Dr. MacNaughton's colleagues were not able to provide mifepristone to these patients because of the In-Person Requirements. *Id.* ¶ 7.

Even if healthcare facilities are open, abortion patients face particular challenges in traveling to them for in-person appointments during the pandemic, many of which arise because 60 percent of women obtaining abortion care are people of color and 75 percent are poor or low-income. Bryant Decl. ¶¶ 18-19, Mot. PI Ex. 1, ECF No. 11-3. As noted by Dr. Reingold, the health risks from exposure are particularly amplified in communities of color, where individuals are suffering higher rates of serious illness and death from COVID-19. Reingold Decl. ¶ 52. One study has shown that African Americans have three and a half times the risk of death as whites. *Id.* ¶ 51. These same communities are also more likely to be working in essential jobs that require interaction with the public and to live in crowded or multigenerational housing in which the risk of viral spread, and the risk to more vulnerable elderly relatives, is increased. *Id.* ¶¶ 51-54.

Securing transportation to a medical office is more difficult for abortion patients from these communities. According to Monica Simpson, the Executive Director of SisterSong, a national, multi-ethnic membership organization dedicated to improving policies and systems relating to the reproductive lives of marginalized communities, because "people of color are less likely to own a car than white people," they "rely more heavily on public transportation, borrowing a car, getting a ride from a friend, or paying for a car service, all of which expose them to risks of infection." Simpson Decl. ¶ 9, Mot. PI Ex. 8, ECF No. 11-10 (citing *Car Access United States*, Nat'l Equality Atlas, https://nationalequityatlas.org/indicators/Car_access (last visited May 22, 2020)). According to Dr. Reingold, both public transportation and sharing an enclosed car with others increases the risk of exposure to COVID-19. Reingold Decl. ¶ 36. As noted by Dr. Espey, for abortion patients in rural states such as New Mexico face trips that can last several hours each way and thus must accept additional risks associated with stops at gas stations and restrooms. Espey Decl. ¶¶ 10-11, Mot. PI Ex. 6, ECF No. 11-8.

Moreover, where 60 percent of abortion patients already have children, they face the additional barrier of arranging for childcare during medical visits. According to Dr. Bryant and Dr. Chen, this challenge is more acute during the pandemic because many schools and daycare centers have closed, medical offices may not permit patients to bring children to the office, regular childcare networks have been disrupted, and having elderly relatives care for children presents significant health risks. Bryant Decl. ¶ 95; Chen Decl. ¶¶ 10, 18, Mot. PI Ex. 4, ECF No. 11-6. The transportation and childcare difficulties are magnified by the economic downturn resulting from the pandemic which disproportionately impacts the same communities. According to an April 2020 study, 61 percent of Hispanic Americans and 44 percent of African Americans reported that they or someone in their household had experienced a job or wage loss due to the coronavirus outbreak, as compared with 38 percent of white adults. Simpson Decl. ¶ 7. Thus, during the economic crisis resulting from the pandemic, "even paying for transportation to the clinic presents a hardship" for many patients. MacNaughton Decl.¶ 13.

At the same time, the demand for abortion services is likely increasing. According to Dr. Bryant, these same challenges of closed physician offices and transportation and childcare difficulties have made it more difficult for women to obtain prescriptions for oral, injection, or intra-uterine contraception or to travel to pharmacies to obtain contraceptive devices. Bryant Decl. ¶ 20. She asserts that the economic downturn resulting from the pandemic has also caused some to be unable to pay the cost of prescription contraceptives. *Id.* As to women who then become pregnant, "many people are suddenly and unforeseeably unemployed, and struggling to manage their existing obligations, including caring for their existing children . . . some people for whom a pregnancy would otherwise have been welcome now feel unable to have a baby at this time." *Id.*

The six physicians have attested that they have used telemedicine across their practice during the pandemic in order to reduce the burden and risk to patient, themselves, their families and their communities while at the same time meeting patients' health needs. *See id.* ¶ 97; Paladine Decl. ¶¶ 12-27; Chen Decl. ¶¶ 6, 8; Floyd Decl. ¶¶ 6, 11-12, 14, Mot. PI Ex. 5, ECF No. 11-7; Espey Decl. ¶¶ 1, 3; MacNaughton Decl. ¶¶ 5, 9. According to these physicians, telemedicine can be used to meet the REMS requirements of an assessment of an abortion patient, required counseling and discussion of the Patient Agreement Form, and securing of a signature on that form without having to meet in person with the patient. They also assert that mifepristone can be safely and promptly delivered by mail or delivery service to a patient at or near the time of the signing of the Patient Agreement Form. Accordingly, they conclude that in light of telemedicine, the In-Person Requirements are medically unnecessary. *See, e.g.*, Chen Decl. ¶ 6; Floyd Decl. ¶ 16; Espey Decl. ¶ 8; MacNaughton Decl. ¶ 17.

V. Procedural History

On May 27, 2020, Plaintiffs filed the Complaint in this case, which seeks declaratory and injunctive relief. In particular, Plaintiffs seek a declaratory judgment that the application of the In-Person Requirements during the COVID-19 pandemic violates the Fifth Amendment to the United States Constitution. Plaintiffs simultaneously filed the pending Motion for a Preliminary Injunction to bar enforcement of the In-Person Requirements during the pendency of this case. On June 10, 2020, Defendants filed a memorandum in opposition to the Motion. On June 19, 2020, the Court held a hearing on the Motion. On July 1, 2020, with leave of the Court, the parties submitted supplemental briefs addressing how the United States Supreme Court's June 29, 2020 decision in *June Medical Services LLC v. Russo*, ___ S. Ct. ___, No. 18-1323, 2020 WL 3492640 (U.S. June 29, 2020), informed the issues presented in this case.

On June 3, 2020, 22 states and the District of Columbia ("the Supporting States") submitted an amicus brief in support of Plaintiff's Motion for Preliminary Injunction. On June 3, 2020, after the Court granted a motion for leave to file an amicus brief, 15 medical associations filed a separate amicus brief in support of Plaintiffs. On June 8, 2020, ten different states ("the Opposing States") filed a motion to intervene in the present case on the side of Defendants. The Court denied the motion but accepted the Opposing States' memorandum filed in opposition to the Motion as an amicus brief. Although the Court has carefully considered all arguments offered by *amici*, it need not address in this opinion the arguments asserted solely by *amici*. *See Snyder v. Phelps*, 580 F.3d 206, 216 (4th Cir. 2009) (stating that "[p]ut simply, our Court and our sister circuits have consistently been wary, even prohibitive, of addressing an issue raised solely by an amicus"). Moreover, where the proper role of *amici* is "assisting in a case of general public interest, supplementing the efforts of counsel, and drawing the court's attention to law that escaped consideration," the Court need not and does not consider the specific facts and evidence offered by *amici* on both sides, particularly where some of that evidence relates to interests and issues not raised by the parties and outside the scope of the present dispute. *See, e.g.*, *Miller-Wohl Co. v. Comm'r of Labor & Indus. State of Mont.*, 694 F.2d 203, 204 (9th Cir. 1982) (holding that because "[a]n amicus curiae is not a party to litigation," courts will "rarely" give "party prerogatives to those not formal parties"); *WildEarth Guardians v. Jeffries*, 370 F. Supp. 3d 1208, 1228 (D. Or. 2019) (ruling that an amicus's motion to submit extra-record evidence was improper).

DISCUSSION

Plaintiffs seek a preliminary injunction barring Defendants from enforcing the In-Person Requirements for the duration of the COVID-19 pandemic based on their claim that, in the context of the pandemic, they infringe on the constitutional rights to an abortion and to equal protection of

the law protected by the Due Process Clause of the Fifth Amendment. In order to obtain a preliminary injunction, moving parties must establish that: (1) they are likely to succeed on the merits; (2) they are likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in their favor; and (4) an injunction is in the public interest. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). A moving party must satisfy each requirement as articulated. *See Pashby v. Delia*, 709 F.3d 307, 320 (4th Cir. 2013). Because a preliminary injunction is "an extraordinary remedy," it "may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter*, 555 U.S. at 22.

I. Standing

As a threshold issue, Defendants argue that Plaintiffs lack standing to assert the constitutional claims in the Amended Complaint. Article III of the Constitution limits the judicial power of the federal courts to actual "Cases" or "Controversies." U.S. Const. art. III, § 2, cl. 1. To invoke this power, a litigant must have standing. *Hollingsworth v. Perry*, 570 U.S. 693, 704 (2013). A plaintiff establishes standing by demonstrating (1) a "concrete and particularized" injury that is "actual or imminent"; (2) "fairly traceable to the challenged conduct"; and (3) "likely to be redressed by a favorable judicial decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992); *Covenant Media of S.C., LLC v. City of N. Charleston*, 493 F.3d 421, 428 (4th Cir. 2007).

Typically, a litigant "must assert [the party's] own legal rights and interests, and cannot rest [a] claim to relief on the legal rights or interests of third parties." *Kowalski v. Tesmer*, 543 U.S. 125, 129 (2004) (quoting *Warth v. Seldin*, 422 U.S. 490, 499 (1975)). Membership associations, however, may assert standing as representatives of their members if the organization can establish "associational standing," which requires a showing that (1) its members would have standing to sue in their own right; (2) "the interests it seeks to protect are germane to the

organization's purpose"; and (3) "neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977). Here, Defendants challenge only the first element. To meet that requirement, an organization must "make specific allegations establishing that at least one identified member had suffered or would suffer harm." *S. Walk at Broadlands Homeowner's Ass'n v. OpenBand at Broadlands, LLC*, 713 F.3d 175, 184 (4th Cir. 2013) (quoting *Summers v. Earth Island Inst.*, 555 U.S. 488, 498 (2009)); *see also Lujan*, 504 U.S. at 563 (stating that a single member with standing in his or her own right is sufficient to establish that an organization has standing). Thus, the four organizational Plaintiffs, ACOG, CUCOG, NYSAFP, and SisterSong ("the Organizational Plaintiffs"), which consist of professional membership organizations for obstetrician-gynecologists and non-profit membership organizations providing medical care to various communities, each may establish standing by showing that one of its members has standing. Standing must be separately established for each claim. *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006).

Where the presence of one plaintiff with standing renders a claim justiciable, the Court will focus its analysis on whether Plaintiff NYSAFP, through its member Dr. Heather L. Paladine, has associational standing. *See Bostic v. Schaefer*, 760 F.3d 352, 370-71 (4th Cir. 2014).

A. Injury-in-Fact

Defendants first argue that Plaintiffs have not demonstrated that they or any of their members have an actual or imminent injury arising from the challenged REMS requirements. *See Lujan*, 504 U.S. at 560 (stating that plaintiffs must first establish an "injury in fact" that is "actual or imminent" and not "conjectural" or "hypothetical"). In the abortion context, the United States Supreme Court has found that where a physician is the one against whom abortion statutes or

regulations "directly operate in the event he procures an abortion that does not meet the statutory exceptions and conditions," then the physician has "assert[ed] a sufficiently direct threat of personal detriment." *Doe v. Bolton*, 410 U.S. 179, 188 (1973); *see also Planned Parenthood of Cent. Missouri v. Danforth*, 428 U.S. 52, 62 (1976); *Nyberg v. City of Virginia*, 495 F.2d 1342, 1344 (8th Cir. 1974) (stating that *Doe* is not limited to affording standing to a physician only when threatened with criminal prosecution). Indeed, the Supreme Court has recognized instances in which subjecting a doctor to such direct penalties for certain medical actions relating to performing an abortion was alone sufficient to establish standing. *See Doe*, 410 U.S. at 188; *Danforth*, 428 U.S. at 62. Standing can also derive from a different, lesser injury, such as a potential financial impact on a physician from an abortion restriction. *See Singleton v. Wulff*, 428 U.S. 106, 112-13 (1976) (finding that physicians "suffer[ed] concrete injury from the operation of the challenged statute" which prevented them from receiving Medicaid reimbursements if certain requirements about the nature of the procedure were not met).

Defendants argue that there is no cognizable injury to the physician members of the Organizational Plaintiffs, as any enforcement action by FDA for a failure to comply with the In-Person Requirements would be brought against the drug sponsors, in this case Danco Laboratories, LLC and GenBioPro, Inc., not the healthcare providers. As Defendants have acknowledged, however, FDA has the statutory authority to pursue an enforcement action against any person who violates 21 U.S.C. § 355(p), which renders it unlawful to "introduce or deliver for introduction into interstate commerce a new drug" while "fail[ing] to maintain compliance" with REMS requirements. *Id.* § 355(p)(1); *see also* 21 U.S.C. § 331(d) (prohibiting the introduction into interstate commerce of an article in violation of § 355). A violation of this provision could result in criminal penalties. 21 U.S.C. § 333(a). Although FDA asserts that it has not, to date, taken

such enforcement actions against physicians under this provision, it acknowledges that it may do so. Defs.' Letter at 1, ECF No. 75. Where Plaintiffs have suggested that their proposed course of action would be to allow physicians to facilitate or arrange for mifepristone to be delivered to patients through mail-order pharmacies, there exists the potential for such shipments to travel in interstate commerce, depending on the location of such pharmacies. Thus, physicians face a potential injury or sanction if they do not comply with the In-Person Requirements. *See Doe*, 410 U.S. at 188; *June Med. Servs.* 2020 WL 3492640, at *10 (plurality opinion) (stating that the "threatened imposition of governmental sanctions" for noncompliance eliminates any risk that their claims are abstract or hypothetical).

Moreover, a healthcare provider's violation of the In-Person Requirements would likely result in the loss of the ability to prescribe mifepristone. Because the mifepristone REMS specifically require the drug sponsor to "[e]nsure that mifepristone is available to be dispensed to patients only in clinics, medical offices, and hospitals," the drug sponsor would necessarily have to cease shipment of the drug to healthcare providers who do not comply with this requirement. *See* Mifepristone REMS ¶¶ II.A.2.a.i., II.B.1.A.i.d., Compl. Ex. 2, ECF No. 1-4. Similarly, under the REMS, if a physician who is certified to dispense mifepristone fails to follow the use guidelines, including the In-Person Signature Requirement, the drug sponsor is required to decertify the healthcare provider and no longer ship mifepristone to that provider. *Id.* ¶¶ II.A.1.c.i., II.B.i.d. This consequence is reiterated in the Prescriber Agreement Form, the contract between the drug sponsor and prescribing healthcare providers, which states that upon a failure to comply with the same guidelines, "the distributor may stop shipping Mifeprex to you." Mifepristone REMS, Prescriber Agreement Form, Compl. Ex. 2, ECF No. 1-4. Notably, Plaintiffs specifically

allege that Dr. Paladine and Dr. MacNaughton both "prescribe mifepristone, pursuant to a certified mifepristone prescriber agreement under the REMS." Am. Compl. ¶ 27, 31, ECF No. 74-1.

Thus, the operation of this regulatory scheme, and the sanction of the inability to continue prescribing the medication embedded in it, creates an imminent injury to Dr. Paladine in that if she fails to strictly follow the REMS guidelines, she may face criminal sanctions and in any event will lose the ability to dispense mifepristone, to the detriment of her ability to benefit from the practice of medicine, including by prescribing the drug to her patients who qualify for Medicaid. *See* Paladine Decl. ¶ 9, *Singleton*, 428 U.S. at 110, 113 (finding that physicians had standing to challenge the restriction on government funding of "nonmedically indicated abortions" because physicians would lose Medicaid reimbursement for performing such abortions). Accordingly, the Court finds that Plaintiffs have sufficiently demonstrated an injury-in-fact.

B. Third-Party Standing

Defendants also argue that Plaintiffs lack standing because even if they face an injury from the In-Person Requirements, they cannot assert the constitutional right to an abortion of their patients. Plaintiffs, however, assert that healthcare providers may do so under the doctrine of third-party standing because they are the "proper proponent of the particular legal rights on which they based their suit." *Singleton*, 428 U.S. at 112. This third-party standing requirement is a matter of prudential standing and allows a plaintiff to assert third-party rights where "the enforcement of the challenged restriction against *the litigant* would result indirectly in the violation of third parties' rights." *June Med. Servs.*, 2020 WL 3492640, at *8-9 (plurality opinion). Generally, a plaintiff may assert the constitutional rights of a third party if the plaintiff has "close relationship" to the third party and if there exists some "hindrance to the third party's ability to protect his or her own interests." *Powers v. Ohio*, 499 U.S. 400, 411 (1991); *see Kowalski*, 543 U.S. at 130. Here, the

third parties are the patients who are purportedly harmed by the REMS requirements that inhibit their right to abortion.

For decades, courts have routinely recognized categorically that abortion and reproductive health care providers and physicians have third-party standing to assert the rights of their patients. In *Singleton*, a plurality of the Supreme Court found that "it is generally appropriate to allow a physician to assert the rights of women patients as against governmental interference with the abortion decision." *Singleton*, 428 U.S. at 118. *Singleton* concluded that "[t]he closeness of the relationship" between a doctor and an abortion patient "is patent" because "[a] woman cannot safely secure an abortion without the aid of a physician," and "the constitutionally protected abortion decision is one in which the physician is intimately involved." *Id.* at 117. *Singleton* also found that "[a]s to the woman's assertion of her own rights, there are several obstacles," including the desire to protect her privacy, the imminent mootness of her claim once an abortion is no longer available, as an option. *Id.* The Supreme Court has applied this general principle without controversy in numerous subsequent cases brought by physicians or abortion service providers. *See, e.g.*, *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2301 (2016); *Gonzales v. Carhart*, 550 U.S. 124, 133 (2007); *Stenberg v. Carhart*, 530 U.S. 914, 922 (2000); *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 845 (1992). The United States Court of Appeals for the Fourth Circuit has likewise generally permitted physicians and abortion providers to challenge abortion restrictions on behalf of their patients. *See Richmond Med. Ctr. for Women v. Herring*, 570 F.3d 165, 169 (4th Cir. 2009) (denying on the merits a constitutional challenge by an abortion clinic and a physician to a Virginia abortion statute); *Greenville Women's Clinic v. Bryant*, 222 F.3d 157, 194 n.16 (4th Cir. 2000) ("Because Regulation 61–12 applies to first trimester abortion providers, the plaintiffs have standing to challenge the constitutionality of the

regulation."); *Manning v. Hunt*, 119 F.3d 254, 259, 276 (4th Cir. 1997) (affirming the district court's denial of a motion for a preliminary injunction without questioning the finding that the plaintiff physicians and medical clinic had standing to challenge the abortion restriction).

Most recently, the plurality opinion in *June Medical Services*, joined by four Justices, stated that the Court has "long permitted abortion providers to invoke the rights of their actual or potential patients in challenges to abortion-related regulations" in finding that physicians who provided abortion care had standing to challenge a Louisiana statute requiring such physicians to have admitting privileges at a hospital within 30 miles of the abortion clinic. *June Med. Servs.*, 2020 WL 3492640, at *9 (citing nine different Supreme Court cases in which healthcare providers have invoked the rights of patients or potential patients in abortion-related constitutional challenges). A fifth Justice, Chief Justice Roberts, agreed with the plurality's standing analysis. *Id.* at *26 n.4 (Roberts, C.J., concurring) ("For the reasons the plurality explains . . . I agree that the abortion providers in this case have standing to assert the constitutional rights of their patients."). Thus, it is firmly established that abortion care physicians have third-party standing to challenge abortion restrictions infringing on their patients' constitutional rights.

Nevertheless, Defendants argue that even though Plaintiffs fall within this well-recognized category of plaintiffs with third party standing, under *Kowalski*, Plaintiffs must still demonstrate through specific evidence that in this particular case, Plaintiffs have a "close relationship" to the third-party abortion patients, and that there is some "hindrance to the third party's ability to protect his or her own interests." *Kowalski*, 543 U.S. at 130. Although the Court does not agree that such case-specific evidence is necessary, as set forth below, the Court finds that Plaintiffs have, in fact, provided sufficient evidence to satisfy both elements.

1. Patient Injury

As a threshold matter relating to third-party standing, Defendants assert that Plaintiffs have not provided evidence of an imminent threat of injury to patients seeking a medication abortion to allow them to be the basis for the application of third-party standing in this case. Defendants argue that Plaintiffs have not demonstrated that the In-Person Requirements create an imminent risk that abortion patients will contract COVID-19 because it depends on "a series of speculative events [that] would have to transpire before the alleged injury" of contracting the coronavirus could occur, particularly where abortion patients, based on their age, are more likely to be at lower risk. Opp'n Mot. PI at 8, ECF No. 62.

Defendants misconstrue the alleged injury here. Plaintiffs seek injunctive relief to remedy not the risk of contracting COVID-19, but the harm to a patient's fundamental constitutional right of privacy as it relates to the decision to obtain an abortion, which is protected by the United States Constitution. Am. Compl. ¶ 123; *see Roe v. Wade*, 410 U.S. 113, 154 (1973). To the extent that there is a plausible basis to claim an infringement on that right caused by the combination of the In-Person Requirements and COVID-19, Plaintiffs have asserted a non-speculative injury. Indeed, Dr. Paladine has specifically identified a patient who can plausibly claim an infringement to her constitutional right. Dr. Paladine stated in her declaration that one of her patients sought a medical consultation for a possible medication abortion, but she had to turn the patient away because Dr. Paladine's community health center was closed due to COVID-19, and she would have been unable to dispense mifepristone. Paladine Decl. ¶ 18. Thus, while the existence of the pandemic is a relevant fact, the alleged injury, which is sufficiently asserted by Plaintiffs, is to the patients' constitutional rights relating to abortion.

2. Close Relationship

Defendants claim that Plaintiffs have not established that their physician members have a close relationship to their patients because in the case of medication abortion treatment, a healthcare provider's relationship with patients is brief and thus distinguishable from relationships between doctors performing surgical abortions and their patients upon which standing has traditionally been found.

Regardless of whether Defendants have identified a meaningful distinction, Plaintiffs have provided specific evidence of close physician-patient relationships, including between Dr. Paladine and her patients. In her declaration, Dr. Paladine states that she has many patients who she sees "regularly for ongoing prenatal, postpartum, or chronic disease management care" and who, because of this relationship, have "express[ed] relief that they can also turn to [her] when they need abortion care." Paladine Decl. ¶ 17. As discussed above, Dr. Paladine has specifically described conducting a telemedicine session with a long-time patient, for whom she had previously provided both prenatal and postpartum care, and who was then seeking abortion care when she recently missed her period. *Id.* ¶ 18. Because of the closure of her medical office due to COVID-19 and the In-Person Dispensing Requirement under the REMS, Dr. Paladine could not provide this patient with medication abortion services, including mifepristone, and the patient was unable to get such care elsewhere. *Id.* This account establishes that Dr. Paladine has a close relationship with a patient whose constitutional right to abortion has been adversely affected by the In-Person Dispensing Requirement. As in *Singleton*, the patient's "enjoyment of the right" to an abortion is "inextricably bound up with" the activity that Dr. Paladine wishes to pursue, specifically dispensing mifepristone without an in-person meeting. *Singleton*, 428 U.S. at 114-15 (plurality opinion). Dr. Paladine thus satisfies the close relationship requirement because she is "fully, or

very nearly, as effective a proponent of the right" as the patient, *id*. at 115, and is the "obvious claimant," *June Med. Servs.*, 2020 WL 3492640, at *9 (plurality opinion).

Defendants further argue that even if a close relationship exists, third-party standing should not be found because "[P]laintiffs' interest in greater flexibility to provide prescriptions remotely despite FDA's concerns about patient safety is at least potentially in conflict with the interests of patients in seeking safe, reliable care." Opp'n Mot. PI at 10. On this point, however, Defendants rely exclusively on *Elk Grove Unified School District v. Newdow*, 542 U.S. 1 (2004), in which the Supreme Court found that a father lacked third-party standing to challenge the requirement that schoolchildren recite the Pledge of Allegiance, particularly the language "under God," because his interests were potentially in conflict with the rights of his child where the child's mother had sole custody rights and did not agree with the father's position. *Id.* at 15-17. Significantly, the Court specifically distinguished the father-child relationship at issue with the physician-patient relationship in *Singleton*, in which it found no conflict. *Id.* at 15. More importantly, the Supreme Court has never found that, in the abortion context, physicians who challenge abortion restriction laws have interests that conflict with those of their patients, and the Court did not accept this argument when it was advanced in *June Medical Services*. *See June Med. Servs.*, 2020 WL 3492640, at *49-50 (Alito, J., dissenting) (endorsing this argument on behalf of only three Justices).

The record here also reflects that on this issue, the physicians and patients, including Dr. Paladine and her patients, share the common interest of providing access to a medication abortion to eligible patients in a timely manner while avoiding health risks during the COVID-19 pandemic arising from in-person visits. For example, Dr. MacNaughton has stated in her declaration, "[m]y patients tell us they do not want to come in person for care" because "[t]hey are afraid of the risks

associated with travel outside their homes, and they do not want to come into a health care facility where they fear they will encounter others who are infectious." MacNaughton Decl. ¶ 14. Where Dr. Paladine has concluded in her professional judgment that in certain instances no in-person contact is needed to safely prescribe and deliver mifepristone, her interests are aligned with patients like her own who seek abortion care but cannot be served when the medical office is closed. Paladine Decl. ¶¶ 16, 18, 26. Significantly, Plaintiffs do not seek to prevent in-person dispensing or even in-person examinations when warranted; rather, they seek only the flexibility, when it is appropriate based on medical judgment, to deliver mifepristone without an in-person visit. Defendants, meanwhile, have not presented any evidence showing that the physicians and patients have divergent, or even non-parallel, interests. The Court therefore rejects the conflict-of-interest argument and finds that the first prudential element of a "close relationship" has been met.

3. Hindrance

Defendants also argue that Plaintiffs have provided no evidence demonstrating that their patients are hindered from vindicating their own abortion rights. As discussed above, the Supreme Court has generally concluded that a woman who may have reason to challenge an abortion restriction has "several obstacles" to bringing a case, including privacy concerns from the publicity of a court suit and issues of imminent mootness due to the timing of a pregnancy. *Singleton*, 428 U.S. at 117 (plurality opinion). Although acknowledging that these barriers are not insurmountable because a plaintiff could use a pseudonym and mootness could be overcome if the issue is "capable of repetition yet evading review," *Singleton* still found sufficient hindrance "to allow a physician to assert the rights of women patients as against governmental interference with the abortion decision." *Id*. The Supreme Court and the Fourth Circuit have consistently permitted

physicians and abortion clinics to bring constitutional claims on behalf of abortion patients without identifying specific evidence that the patients were hindered from suing in their own right. *See supra* part I.B. No such evidence is required here.

Even if specific evidence were required beyond the factors articulated in *Singleton*, the record provides sufficient facts to illustrate that Plaintiffs' patients are hindered from acting on their own. The physicians have identified the time-sensitivity of securing an abortion, particularly a medication abortion, which must occur within 10 or 11 weeks of pregnancy. Bryant Decl. ¶ 102. Because "[d]elaying abortion care imposes serious medical risk" both "associated with pregnancy and increased risks associated with later, rather than timely, abortion," *id.* ¶¶ 101-102, there is pressure on a woman to arrange for the in-person visit needed to obtain a medication abortion at the same time that she would be filing suit. *See Adams & Boyle*, 956 F.3d at 929 (finding that abortion is a "uniquely 'time-sensitive procedure,' both as a biological matter and a regulatory matter"). They have also attested to the fact that 75 percent of abortion patients are poor or low income, and 60 percent have at least one child, Bryant Decl. ¶¶ 17-18, such that these patients face numerous specific challenges to pursue a medication abortion before even considering filing a constitutional challenge in court, particularly during the COVID-19 pandemic. Dr. Bryant has stated: "Many of these patients have struggled concurrently with housing instability, difficulty arranging childcare, and inability to keep utilities running. The added burden of securing transportation to our practice is nearly insurmountable for some, which often leads to missed or delayed care. All of these burdens have been exacerbated during COVID." *Id.* ¶ 92. According to Dr. Paladine, "These patients will either have to forgo care, leave their children with others in their community who may be at high risk of infection, or have their children travel with them through the city and to [the] office, increasing their risk of exposure to the virus," particularly since

most rely on public transportation. *Id.* ¶¶ 19-20. Such challenges would be faced by the specific patient referenced by Dr. Paladine, who sought an abortion while having two young children, including an eight-month-old infant. *Id.* ¶ 18.

Finally, beyond the challenges directly associated with obtaining a medication abortion, these patients face economic and public health obstacles to pursuing a lawsuit during the COVID-19 pandemic. Since 60 percent of abortion patients are people of color, as are over 75 percent of Dr. Paladine's patients, many are at higher risk for death or serious illness from COVID-19. *Id.* ¶¶ 10-11; Bryant Decl. ¶¶ 12, 19; Reingold Decl. ¶52. The many low-income abortion patients face greater health risks due to living in crowded or multigenerational housing and working in essential jobs with exposure to the public. Reingold Del. ¶¶ 51-54. These specific dangers and challenges of the COVID-19 pandemic would further hinder patients' ability to pursue litigation to vindicate their rights. Thus, Plaintiffs' patients face obstacles arising from their simultaneous efforts to obtain an abortion and the unique health and economic challenges presented by the COVID-19 pandemic that hinder their ability to bring a lawsuit to enforce their own constitutional rights.

In summary, as to the Plaintiffs' due process claim, the Court finds that Dr. Paladine, who is a member of NYSAFP, has third-party standing, and that NYSAFP, through Dr. Paladine, has associational standing. Accordingly, the Court may consider the merits of this claim.

C. Equal Protection

Plaintiffs have asserted a separate claim in which they contend that the disparity in the treatment of mifepristone, as compared to other drugs for which in-person requirements have been waived for the duration of the pandemic, violates the equal protection rights of the physicians and

patients who prescribe and take mifepristone. The Court's third-party standing analysis as to the due process claim is equally applicable here. *See supra* part I.B.

Plaintiffs also argue that their physician members have direct standing because their own constitutional rights are at stake. This theory of standing does not depend on the third-party standing doctrine because the physicians assert that as prescribing physicians they are subjected to differential treatment as compared to other physicians who prescribe other drugs subject to more favorable rules during the COVID-19 pandemic. *See Ne. Fla. Chapter of Associated Gen. Contractors of Am. v. City of Jacksonville*, 508 U.S. 656, 666 (1993) (stating that in an equal protection case, "the denial of equal treatment resulting from the imposition of [a] barrier" is sufficient injury to satisfy the "injury in fact" requirement). Because physicians prescribing mifepristone have an equal protection right to be free from unequal treatment as compared to other doctors, the imminent injury to physicians such as Dr. Paladine is sufficient alone to establish standing to assert this claim. *Id.* In turn, Plaintiffs such as NYSAPF, of which Dr. Paladine is a member, have associational standing to assert this claim on behalf of their physician members.

II. Likelihood of Success on the Merits

A plaintiff seeking a preliminary injunction must first show that there is a likelihood of success on the merits. *Winter*, 555 U.S. at 20. As the Supreme Court has recognized, "a preliminary injunction is customarily granted on the basis of procedures that are less formal and evidence that is less complete than in a trial on the merits. A party thus is not required to prove his case in full at a preliminary-injunction hearing." *Univ. of Texas v. Camenisch*, 451 U.S. 390, 395 (1981). In this case, both Plaintiffs and Defendants declined the opportunity to present witnesses at an evidentiary hearing and instead requested that the Court decide whether there is a likelihood of success on the merits based on the documentary evidence submitted with the briefs,

including declarations by witnesses. Thus, the Court will consider the evidence available based on the present record and decide, whether at this early stage, a preliminary injunction is warranted, even if a more robust record may be necessary to decide the full merits of the claims.

A. Due Process

Plaintiffs first argue that they are likely to succeed on the merits of their claim, under the substantive due process component of the Fifth Amendment's Due Process Clause, that the In-Person Requirements violate their patients' constitutional rights to an abortion.

1. The Undue Burden Standard

A woman's constitutional right to obtain an abortion was first recognized by the United States Supreme Court in *Roe v. Wade*, 410 U.S. 113 (1973), in which the Court concluded that "the right of personal privacy includes the abortion decision." *Id.* at 154. That right, however, "is not unqualified" and "must be considered against important state interests in regulation." *Id.* Two decades later, in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992), a plurality of the Supreme Court articulated for the first time the "undue burden" standard, under which a regulation that has "the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus" is an "undue burden" that is an unconstitutional infringement on a woman's fundamental right of privacy. *Id.* at 877. In particular, "[u]nnecessary health regulations" that have such a "purpose or effect . . . impose an undue burden on the right." *Id.* at 878.

The Supreme Court reaffirmed the applicability of the undue burden standard to constitutional challenges to restrictions relating to abortion in *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016), in which the Court applied the standard to strike down a Texas statute requiring doctors performing abortions to have admitting privileges at a hospital within 30

miles of the clinic at which the abortion procedure would be performed, and requiring abortion facilities to meet state standards for surgical facilities. *Id.* at 2311, 2314. In so ruling, the Court provided clarification on how courts should apply the undue burden standard. In rejecting the formulation of the test crafted by the United States Court of Appeals for the Fifth Circuit, which suggested that a district court need not consider the existence or nonexistence of a medical benefit arising from a statutory or regulatory abortion restriction, the Supreme Court explained that *Casey* "requires that courts consider the burdens a law imposes on abortion access together with the benefits those laws confer." *Id.* at 2309. On June 29, 2020, a plurality of the Supreme Court reaffirmed this standard in *June Medical Services.* 2020 WL 3492640, at *10.

In the face of this clear Supreme Court precedent, Defendants nevertheless argue for the application of a different standard never applied by the Supreme Court in an abortion case. Defendants assert that the Court should apply a general test for a facial challenge to the constitutionality of a statute set forth in *United States v. Salerno*, 481 U.S. 739 (1987), a pre-*Casey* case involving a challenge to the constitutionality of the Bail Reform Act, 18 U.S.C. §§ 3141-3150 (2018). In *Salerno*, the Court held that the appropriate question to consider on such a claim is whether "the challenger [can] establish that no set of circumstances exists under which the Act would be valid." *Id.* at 745. In *Casey*, however, a facial challenge to a spousal-notification law was reviewed under the undue burden standard and found to be unconstitutional. *See Casey*, 505 U.S. at 887, 895. *Casey* thus adopted a specific standard for the specialized context of a challenge based on the constitutional right to an abortion.

Defendants argue that uncertainty remains about whether *Salerno* should be applied to abortion cases. They rely on post-*Casey* rulings by the Fourth Circuit that have discussed, but have not explicitly decided, whether the *Salerno* rule is applicable to an abortion case post-*Casey*.

In *Manning*, the Fourth Circuit applied the *Salerno* standard where the district court had done so without objection, noted that absent explicit overruling it is bound to apply *Salerno*, but specifically noted that the issue of whether the *Salerno* standard was appropriate "is not now properly before the Court." *Manning*, 119 F.3d at 268 & n.4. In *Greenville Women's Clinic*, the Fourth Circuit referenced *Manning*'s discussion of the issue but analyzed the relevant provision under both *Salerno* and *Casey*. *Greenville Women's Clinic*, 222 F.3d at 164-65. More recently, in considering the constitutionality of a state statute restricting abortion, the Fourth Circuit noted that *Casey* considered a facial challenge under the undue burden standard, discussed the alternative *Salerno* standard, but determined that it did not need to resolve the uncertainty under the facts of the case. *See Richmond Med. Ctr.*, 570 F.3d at 174.

Even if these equivocal discussions could be construed as favoring the applicability of the *Salerno* standard to abortion cases, the Court finds that it does not apply here. First, application of *Salerno* is incompatible with Supreme Court precedent. Despite the debate among the lower courts, in the numerous abortion cases since *Salerno* and *Casey*, the Supreme Court has never applied *Salerno* as the applicable standard and instead has consistently applied the undue burden standard, including in facial challenges. *See e.g.*, *Gonzales*, 550 U.S. at 150, 168 (holding that the plaintiffs' facial challenge to the constitutionality of Partial-Birth Abortion Ban Act for not having a health exception did not meet the undue burden standard); *Mazurek v. Armstrong*, 520 U.S. 968, 971, 974 (1997) (overturning the lower court's finding that the plaintiffs had shown a likelihood of success on the merits under the undue burden standard on a challenge to a state law requiring abortions to be performed by licensed physicians only). Most importantly, in *Whole Woman's Health*, in which the plaintiffs mounted a facial challenge to the provision of the Texas law requiring abortion facilities to meet certain surgical center requirements, the Court applied the

undue burden standard to both that challenge and the as-applied challenge to the admitting privileges requirements imposed by the same law. 136 S. Ct. at 2303, 2309. Tellingly, the only indirect reference to the *Salerno* standard appears in the dissent, which argues that "[t]he proper standard for facial challenges is unsettled in the abortion context," a position that necessarily was not accepted by a majority of the Court. *Id.* at 2343 n.11 (Alito, J., dissenting). Finally, the undue burden standard was applied in the Supreme Court's most recent opinion, *June Medical Services*. 2020 WL 3492640, at *10 (plurality opinion). Based on the unbroken string of Supreme Court cases applying the undue burden standard to facial and as-applied abortion challenges alike, the Court rejects the argument that the *Salerno* standard is applicable in such cases.

Second and more importantly, although the parties have given conflicting views on the nature of this challenge, the Court finds that it is plainly an "as applied" challenge to which *Salerno* is inapplicable. A facial challenge is "a claim that the law or policy at issue is unconstitutional in all its applications." *Bucklew v. Precythe*, 139 S. Ct. 1112, 1127-28 (2019). An "as applied" challenge does not question the "general validity" of a statute or a rule but instead claims that the provision is constitutionally invalid because "in particular circumstances" it "operates to deprive an individual of a protected right." *See Boddie v. Connecticut*, 401 U.S. 371, 379 (1971). Here, Plaintiffs argue not that the In-Person Requirements violate their constitutional rights under all circumstances, but that they are unconstitutional in the particular circumstances caused by the COVID-19 pandemic. *See id.* As a classic as-applied challenge, Plaintiffs' claim would not be subject to *Salerno* under any circumstances and is instead subject to the undue burden standard.

Accordingly, the Court concludes that the appropriate standard for the challenge in this case is the undue burden standard, as stated by the Supreme Court in *Casey* and reaffirmed in *Whole Woman's Health* and *June Medical Services*.

2. Undue Burden Principles

In applying the undue burden test, the Court will apply key principles elucidated in post-*Casey* precedent, including several set forth in *Whole Woman's Health* and reaffirmed in *June Medical Services.* First, *Whole Woman's Health* clarified the substantial obstacle requirement of *Casey*. Defendants argue that "[b]ecause plaintiffs are unlikely to establish that the in-person requirement constitutes a substantial obstacle to a large fraction of patients seeking an abortion, the Court need not consider the requirement's benefits." Opp'n Mot. PI at 22. In *Whole Woman's Health*, however, pursuant to its holding that "courts consider the burdens a law imposes on abortion access together with the benefits those laws confer," the Court assessed whether the provisions under review had any benefit and also analyzed whether the requirements were unduly burdensome. 136 S. Ct. at 2309-15. The plurality in *June Medical Services* reaffirmed that general approach and likewise considered both benefits and burdens. 2020 WL 3492640, at *10.

Defendants argue that *June Medical Services* altered the standard because in his concurring opinion, Chief Justice Roberts criticized *Whole Woman's Health*'s test of balancing of benefits and burdens as not derived from *Casey* and stated, "I would adhere to the holding of *Casey*, requiring a substantial obstacle before striking down an abortion regulation." *June Med. Servs.*, 2020 WL 3492640, at *26 (Roberts, C.J., concurring). The Chief Justice further stated that he agreed with the plurality's finding that the Louisiana law, in fact, presented a "substantial obstacle" and thus joined in the result. *Id.* Where the Chief Justice's concurrence in the judgment was necessary to reach a majority, the holding of *June Medical Services* is fairly limited to the reasoning that represents a "common denominator" that he shared with the plurality. *See Marks v. United States*, 430 U.S. 188, 193 (1977) ("When 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.") (citation omitted)); *A.T. Massey Coal Co. v. Massanari*, 305 F.3d 226, 236 (4th Cir. 2002) (holding that the *Marks* rule does not apply "unless the narrowest opinion represents a common denominator of the Court's reasoning" and embodies a position "implicitly approved by at least five Justices who support the judgment"). But the plurality did not agree with the Chief Justice's criticism of the balancing test, and neither the plurality nor the Chief Justice predicated the decision on an overruling of *Whole Woman's Health*. *See June Med. Servs.*, 2020 WL 3492640, at *37 (Thomas, J., dissenting) ("[T]he fact that no five Justices can agree on the proper interpretation of our precedents today evinces that our abortion jurisprudence remains in a state of utter entropy."); *King v. Palmer*, 950 F.2d 771, 783 (D.C. Cir. 1991) (en banc) (noting that the majority view under *Marks* does not include the reasoning of dissenting Justices). Indeed, the Chief Justice emphasized the importance of *stare decisis* in deciding to "adhere to" *Whole Woman's Health* "in deciding the present case," recognized that *Whole Woman's Health* adopted a balancing test, and specifically stated that "[w]e should respect the statement in *Whole Woman's Health* that it was applying the undue burden standard." *June Med. Servs.*, 2020 WL 3492640, at *22-23, *26 (Roberts, C.J., concurring). To the extent that there is a "common denominator," it is that the five Justices agreed that a "substantial obstacle" based solely on consideration of burdens is *sufficient* to satisfy the undue burden standard, not that it is *necessary*. *See A.T. Massey Coal Co.*, 305 F.3d at 236. Accordingly, *June Medical Services* is appropriately considered to have been decided without the need to apply or reaffirm the balancing test of *Whole Woman's Health*, not that *Whole Woman's Health* and its balancing test have been overruled.

Where *Whole Woman's Health* remains the most recent majority opinion delineating the full parameters of the undue burden test, the Court finds that its balancing test remains binding on

this Court. Therefore, the Court may weigh the stated burdens and benefits alleged in this case to decide if the In-Person Requirements pose a substantial obstacle in violation of a patient's constitutional rights. *See Whole Woman's Health*, 136 S. Ct. at 2309.

Second, *Whole Woman's Health* clarified the share of all abortion patients for whom the restriction must be an undue burden in order to be unconstitutional. In *Casey*, the Supreme Court stated that "[l]egislation is measured for consistency with the Constitution by its impact on those whose conduct it affects," and thus "[t]he proper focus of constitutional inquiry is the group for whom the law is a restriction, not the group for whom the law is irrelevant." 505 U.S. at 894. Accordingly, the Court found an "undue burden" where "in a large fraction of the cases" in which the restriction was "relevant," it constituted a "substantial obstacle to a woman's choice." *Id.* at 895. In *Casey*, the Court found that this standard was met as to a spousal notification requirement where it would create a "substantial obstacle" for "a significant number of women." *Id.* at 893-94. In *Whole Woman's Health*, the Court further explained that the relevant denominator of this "large fraction" is not all women of reproductive age, all pregnant women, or even the class of women seeking an abortion, but those women for whom the provision "is an actual rather than an irrelevant restriction." 136 S. Ct. at 2320 (quoting *Casey*, 505 U.S. at 895). In *June Medical Services*, the Court rejected an argument that an undue burden would arise only if it affected every woman seeking an abortion and reaffirmed that the "large fraction" standard set forth in *Whole Woman's Health* governs. *June Med. Servs.*, 2020 WL 3492640, at *21 (plurality opinion).

Third, *Whole Woman's Health* clarified the degree to which a district court should defer to the findings of the legislature or other governmental body imposing the legal restriction, including findings relating to the medical benefit of the restriction. Rejecting the argument that courts must accept or give "[u]ncritical deference" to the findings of the legislature on such

matters, the Supreme Court held that courts may place "considerable weight upon evidence and argument presented in judicial proceedings." *Id.* at 2310. Although courts are to review "legislative factfinding under a deferential standard," they "must not place dispositive weight" on the assessments or conclusions of the entity that was responsible for the rule. *Id.* at 2310 (quoting *Gonzales*, 550 U.S. at 165). Ultimately, a court "retains an independent constitutional duty to review factual findings where constitutional rights are at stake." *Id.* (quoting *Gonzales*, 550 U.S. at 165). *June Medical Services* reaffirmed these principles. 2020 WL 3492640, at *10 (plurality opinion).

Finally, the Court notes that, contrary to Defendants' claim that there can be no undue burden if a woman ultimately can obtain an abortion through other available and generally accepted methods, a restriction can impose an undue burden even if it does not entirely prevent women from obtaining an abortion of any kind. In *Stenberg v. Carhart*, 530 U.S. 914 (2000), the plaintiff sought to invalidate a Nebraska law that banned certain "partial-birth abortion[s]" in part because even though other methods of abortion would remain available, significant medical authority supported the proposition that in some circumstances, the abortion procedure to be banned was the safest procedure. *Id.* at 931-932, 936-37. In finding that the law was unconstitutional without an exception for when the procedure is necessary to protect the health of the mother, the Supreme Court stated that "a State cannot subject women's health to significant risks . . . where state regulations force women to use riskier methods of abortion" because "a risk to a women's health is the same whether it happens to arise from regulating a particular method of abortion, or from barring abortion entirely." *Id.* at 931, 938; *see also Planned Parenthood of Wis., Inc. v. Schimel*, 806 F.3d 908, 918 (7th Cir. 2015) (holding that a statute requiring abortion providers to have hospital admitting privileges created an undue burden because it would cause

certain abortion clinics to close and thus could cause delays in obtaining an abortion that would require some women to "forgo first-trimester abortions and instead get second-trimester ones, which are more expensive and present greater health risks").

In the specific context of a medication abortion, in *Planned Parenthood Arizona v. Humble*, 753 F.3d 905 (9th Cir. 2014), the court reversed the denial of a preliminary injunction against an Arizona law requiring that mifepristone be prescribed only in accordance with an FDA-approved, on-label regimen. *Id.* at 907. The court found that the ban on the use of a separate, off-label mifepristone regimen for a medication abortion created an undue burden because it imposed costs and delays that deterred some women from obtaining a medication abortion "even if some women who are denied a [mifepristone] medication abortion . . . nonetheless obtain an abortion" through other means. *Id.* at 917. Finding that a burden does not need to be "absolute to be undue," the court held that "[t]he availability of on-label medication abortions during the first seven weeks of pregnancy, and surgical abortions thereafter, does not preclude a finding of undue burden." *Id.*

3. Burdens

Within this legal framework, the Court considers Plaintiffs' claim that, in light of the COVID-19 pandemic, the In-Person Requirements cause an undue burden in violation of the Constitution, imposing a substantial obstacle on a large fraction of the relevant women seeking a medication abortion. The operative question is whether it creates such an obstacle for a "significant number" of the women for whom the In-Person Requirements are "an actual rather than an irrelevant restriction," *Casey*, 505 U.S. at 893; *Whole Woman's Health*, 136 S. Ct. at 2320, which the Court defines to be those women seeking a medication abortion through the Mifepristone-Misoprostol Regimen during the COVID-19 pandemic but who do not, based on their healthcare provider's medical judgment, actually require an in-person visit with their

healthcare provider in order to be properly assessed and counseled. *Cf. Casey*, 505 U.S. at 893, 895 (defining the relevant class for assessing whether a spousal notification requirement created an undue burden as "married women seeking abortions who do not wish to notify their husbands of their intentions and who do not qualify for one of the statutory exceptions to the notice requirement").

The first step in this analysis is to assess the burdens to such patients. In assessing whether the burdens of an abortion restriction create an undue burden, courts have considered a range of relevant factors, including increases in travel distance or time to an abortion facility, greater difficulties in securing transportation to the facility, the need to arrange for childcare during visits relating to abortion procedures, additional costs associated with the abortion, the ability of abortion providers to keep up with patient demand, and other practical considerations in light of the reality on the ground. *See, e.g.*, *Whole Woman's Health*, 136 S. Ct. at 2317-18 (considering increased cost and travel time for women to visit facilities and decreased ability to provide quality care at remaining clinics that had to operate at maximum capacity); *Robinson v. Attorney General*, 957 F.3d 1171, 1180, 1182 (11th Cir. 2020) (denying a stay of a preliminary injunction granted in part based on the burdens of travel challenges, arranging for child care, taking time off from work, and affording an abortion); *Humble*, 753 F.3d at 915-16 (considering "practical considerations, such as the frequency with which clinics can see patients and the difficulties women face in obtaining time off from work or transportation to a clinic" as well as the "cost of [an] extra dosage of medicine," the need for an additional clinic visit, and "increase[d] costs to the patient for transportation, gas, [and] lodging"). Indeed, FDA acknowledged that in-person requirements impose real burdens on abortion patients when, in 2016, it allowed for misosprotol, the other pill in the medication abortion regimen, to be obtained and self-administered without an in-person visit

in part to "[m]inimize loss of income (for childcare or missed days of work)" and to "avoid another visit and the time, transportation, loss of work, inconvenience, etc. that such a visit would involve." 2016 Clinical Review at 38, 41.

At an initial level, the affected medication abortion patients face the specter of an unprecedented global pandemic involving COVID-19, a highly contagious and life-threatening respiratory disease. Where the President has declared the COVID-19 pandemic a national emergency, and there are now over three million cases in the United States and over 130,000 deaths, its impact is nationwide. The Governors of all 50 states have each declared a state of emergency and have issued, at different times, some combination of stay-at-home orders, restrictions on the operation of businesses and institutions, limitations on social gatherings, and even bans on elective surgeries. Overall, the impact of the pandemic is increasing, not decreasing. As of July 1, 2020, the number of cases has been increasing in 42 states. Johns Hopkins University & Medicine, *Testing Trends Tool*, https://coronavirus.jhu.edu/testing/tracker/overview (last visited July 1, 2020) ("JHU, *COVID-19 Statistics*"). The daily reported number of new cases in July has surpassed the daily reported cases at the peak of the pandemic in March 2020. *See* CDC, *New Cases by Day* (comparing data on number of new cases from March and April 2020 with data in July 2020). Because many individuals infected with coronavirus lack symptoms, and there is no effective cure or vaccine, any time that abortion patients venture out of their residence, including to fulfill the In-Person Requirements, they risk contracting a highly dangerous disease.

Although Dr. Reingold has stated, in his expert opinion, that the In-Person Requirements "unnecessarily increase[] the infection risk for patients, their families, health care professionals, and the larger communities in which they work and live," Reingold Decl. ¶ 10, Defendants argue that the actual risk to any individual abortion patient traveling to a medical office is low, and that

the overall difficulty of such travel for the broader population does not impose a substantial obstacle. Their claims, however, are belied by their own actions. Following the Secretary's declaration that the COVID-19 pandemic is a public health emergency pursuant to the Public Health Service Act, HHS has taken specific actions to effectively waive various in-person requirements relating to drug distribution for the duration of the pandemic. These actions have included:

- In March 2020, FDA announced that during the public health emergency, it would not enforce REMS ETASU requirements that mandated that a patient undergo certain in-person procedures, such as laboratory tests or MRIs, before prescribing certain drugs, when a health care professional exercising medical judgment has determined that the patient could safely forgo the procedure.

- In March and April 2020, FDA agreed that during the pandemic it would not enforce the ETASU C requirement that two specific drugs, Spravato and Tysabri, be administered and dispensed in a healthcare facility, even though both still must be administered in-person by a physician.

- In March 2020, the Secretary, with concurrence of the Acting DEA Administrator, activated the "telemedicine exception" in the CSA, 21 U.S.C. § 802(54)(D), to allow physicians to use telemedicine to satisfy otherwise mandatory requirements that they conduct an in-person evaluation of a patient before prescribing certain controlled substances, including opioids.

As to the lifting of requirements to undergo otherwise mandatory testing and imaging before receiving certain drugs, FDA stated that it acted because completion of such procedures during the pandemic "may be difficult because patients may need to avoid public places," and traveling to undergo such procedures "can put patients and others at risk transmission of the coronavirus." FDA, *COVID-19 REMS Guidance* (quoted in Reingold Decl. ¶ 46). DEA stated that the telemedicine exception was invoked in order to provide greater flexibility in prescribing and dispensing drugs to "ensure necessary patient therapies remain accessible" during the nationwide public health emergency, *See* Letter from Thomas W. Prevoznik, Deputy Assistant Adm'r, Diversion Control Div., DEA 1 (Mar. 31, 2020), https://www.deadiversion.usdoj.gov/

GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf (cited in Reingold ¶ 48), even though it would mean that certain controlled substances—illegal drugs when not dispensed with a prescription—would be released into the community with fewer safeguards. These extraordinary actions exhibit a clear recognition by the federal government, including 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 presents a significant risk to patients.

Beyond these specific actions, HHS and its component agencies have taken multiple steps to advance the use of telemedicine during the pandemic, for the specific purpose of allowing patients to "access healthcare they need from their home, without worrying about putting themselves or others at risk during the COVID-19 outbreak." Azar, *Telehealth Announcement*. These actions include (1) HHS waiving penalties for good faith violations of privacy requirements by health care providers using standard online communications platforms; (2) CMS temporarily expanding Medicare coverage to include a broader range of telemedicine services during the pandemic to allow patients to access doctors without having to travel to healthcare facilities and to "limit risk of exposure and spread of the virus," CMS, *Telehealth Announcement*; (3) CDC issuing an advisory to health care professionals to use telemedicine "whenever possible" as "the best way to protect patients and staff from COVID-19," CDC, *Prepare Your Practice*; and (4) CDC separately advising patients to "[u]se telemedicine or communicate with your doctor or nurse by phone or email," to reschedule procedures that are not urgently needed, and to limit in-person visits to the pharmacy by using mail-order or delivery services where possible. CDC, *Doctors and Medicines*. As all of these actions illustrate, Defendants have effectively acknowledged that the COVID-19 pandemic has created a significant burden upon patients and the public that renders

travel to medical facilities fraught with health risk to themselves, medical professionals, others they encounter during such trips, and the members of their households to whom they return.

On top of this general burden arising from travel to medical offices during the pandemic, patients who may be required to travel to a medical facility to obtain mifepristone for a medication abortion face additional barriers arising from the pandemic. First, at various times, the pandemic has caused healthcare facilities providing medication abortion services to close such that there are circumstances where doctors are "completely unable to provide medication abortion care . . . because . . . patients [can]not come in to pick up their mifepristone prescription." Paladine Decl. ¶ 15. Even when medical offices reopen, their capacity to serve patients may be so limited that they are not able to offer medication abortion appointments. *Id.* ¶ 14. Because medical offices are modifying their practices to allow for proper social distancing, some facilities, such as Dr. Paladine's clinic, are scheduling only one patient appointment at a time, so that the office is operating "at around 10% of . . . previous in-person capacity" and cannot offer medication abortion appointments. *Id.* Given the ongoing threat of COVID-19, Dr. Paladine estimates that the clinic will be able to operate at only 25 percent of previous in-person capacity at least until Spring 2021, which will limit the ability of patients who need abortion care to come into the clinic to receive mifepristone. *Id.* Dr. MacNaughton has also described how the COVID-19 pandemic caused the hospital system in which she works to close all but three primary care clinics to in-person visits, so that abortion or miscarriage patients had to be referred to family planning clinics, which are only open one half-day per week and are often located outside the patient's local community, in order to obtain mifepristone. MacNaughton Decl. ¶¶ 7-8. The impact of such reduced capacity is exacerbated during the pandemic because, as noted by Dr. Bryant, the demand for abortion services is likely increasing because of the greater challenges associated with obtaining contraception and

the heightened economic challenges faced by women who become pregnant and their families. Bryant Decl. ¶¶ 18-19; *see also* Reingold Decl. ¶¶ 51-54.

Even with reduced cases of COVID-19 in certain states, these closures or limited openings will continue. According to Dr. Reingold, the United States "can expect resurgences of COVID-19, including significant community transmission, throughout 2020 and into 2021 across the United States, until the development and widespread use of a vaccine." Reingold Decl. ¶ 28. Where daily COVID-19 cases are on the rise in 42 states, JHU, *COVID-19 Statistics*, and the number of new cases daily is presently equal to or higher than at any time during the pandemic, CDC, *New Cases by Day*, offices that have reopened may close for a second time, which would cause them to "again be entirely barred from providing this urgent service" simply because there is no physical office in which the patient can be handed her medication. Paladine Decl. ¶ 15.

Second, even if an abortion patient can find a clinic that is open and can obtain an appointment, abortion patients generally face more significant health risks arising from traveling to a medical facility during the pandemic. According to a 2016 study, 60 percent of women who have abortions are people of color, and 75 percent are poor or low-income. Bryant Decl. ¶¶ 18, 19. Due to longstanding inequities, people of color are at a higher risk of death or serious illness from COVID-19—as much as three and half times the risk— because they are more likely to suffer from preexisting medical conditions and less likely to have access to quality medical care. *Id*. ¶¶ 12, 86; Simpson Decl. ¶ 7; Reingold Decl. ¶ 51. For example, in New Mexico, Native Americans constitute 11 percent of the population but 50 percent of deaths from COVID-19 in the state. Espey Decl. ¶ 10. These demographic groups also are more likely to work in essential jobs with exposure to the public, live in denser urban environments, and live in intergenerational or multi-family housing. Bryant Decl. ¶ 86; Reingold ¶¶ 36, 51-54. Thus, a large fraction of abortion patients face

heightened risk if they contract the coronavirus. Although Defendants argue that such patients are necessarily younger in age and thus at low risk for COVID-19, CDC has specifically identified pregnancy as a condition that may place an individual at increased risk for severe illness from COVID-19. *See People of Any Age with Underlying Medical Conditions*, U.S. Ctrs. for Disease Control & Prevention, https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html (last updated June 25, 2020). Moreover, if abortion patients contract COVID-19 they also face a higher likelihood of transmitting COVID-19 to their family members, including elderly relatives, living with them in intergenerational housing.

Third, these same factors create other serious hurdles that hinder an abortion patient's ability to travel to a medical facility during a pandemic, particularly transportation and childcare challenges. As noted by Simpson, the Executive Director of SisterSong, people of color are less likely to own a car than white people. Simpson Decl. ¶ 9. Consistent with this fact and the data showing that abortion patients are predominantly low income, Dr. Paladine has asserted that "[t]he vast majority of my patients cannot afford private transportation" and as a result, the In-Person Requirement "forces them to take an unnecessary trip on the subway and/or bus system, increasing the risk to their health and lives (and those of others)." Paladine Dec. ¶ 19; *see also* Chen Decl. ¶ 9. Other abortion patients without a car seek rides from friends or use a ride-share service. Simpson Decl. ¶ 9. According to Dr. Reingold, both public transportation and sharing an enclosed car with others increases the risk of exposure to COVID-19. Reingold Decl. ¶ 36. For abortion patients in rural communities, such as those of Dr. Espey in New Mexico, the trip can last several hours each way, which creates additional risks associated with stops at gas stations and restrooms. Espey Decl. ¶¶ 10-11.

Further, where approximately 60 percent of abortion patients seeking abortion care already have children, many abortion patients who would need to fulfill the In-Person Requirements must arrange for childcare in order to pick up their prescription. Bryant Decl. ¶¶ 23, 83. As Dr. Chen has observed, abortion patients may face "serious hurdles" in "finding any childcare during the COVID-19 crisis." Chen Decl. ¶ 10. Because many schools and childcare facilities have closed, Bryant Decl. ¶ 95, and where many medical facilities, such as Dr. Chen's practice, do not allow patients to bring children or others with them into the medical facility during the pandemic, these hurdles can prevent or, at a minimum, delay women from accessing the abortion care they need. Chen Decl. ¶ 10. In order to meet the In-Person Requirements, abortion patients therefore may 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." *Id.* As one example, Dr. Chen had a regular patient who sought a medication abortion but, because of COVID-19, was not able to rely on her usual childcare arrangement and was not allowed to bring her children to the medical office. As a result, she had to ask her elderly mother to travel to her home to care for her child, at significant risk to her mother and risking exposure to her and her child. Chen Decl. ¶ 18. Similarly, Dr. Floyd had a patient who during the pandemic had to borrow a car to come to the medical office to pick up mifepristone and also had to bring her three children with her because she could not find childcare, thus putting all parties at risk for viral exposure. Floyd Decl. ¶ 22. Dr. MacNaughton's patients also "often struggle to find childcare, and even more so during the COVID-19 crisis." MacNaughton Decl. ¶ 12. By 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 In-Person Requirements present a serious burden to many abortion patients.

Finally, where the pandemic has resulted in a severe economic crisis, and where a study cited by SisterSong reflects that people of color are also more likely to have suffered wage or job loss during the pandemic, Simpson Decl. ¶ 7, the transportation and childcare barriers are exacerbated. In such economic times, "even paying for transportation to the clinic presents a hardship." MacNaughton Decl. ¶ 13.

In light of the convergence of all of these factors stemming from the COVID-19 pandemic, the Court finds that the In-Person Requirements impose a substantial obstacle to abortion patients seeking medication abortion care. First, the federal government's general acknowledgment of the difficulty of traveling to medical offices as reflected in its waiver of several in-person requirements, the challenges caused by medical office closures and limited capacity, the heightened health risk that many abortion patients face due to demographic characteristics, the particularized risk and challenges associated with transportation to get to such offices, the greater difficulty of securing childcare under present conditions, and the impact of the economic downturn on the ability of patients to secure transportation and childcare combine to render an in-person visit to pick up medication and sign forms particularly burdensome and dangerous during the pandemic. A combination of such barriers can establish a substantial obstacle. *See, e.g.*, *June Med. Servs.*, 2020 WL 3492640, at *18-19 (plurality opinion); *Whole Woman's Health*, 136 S. Ct. at 2317-18.

Second, these barriers, in combination, delay abortion patients from receiving a medication abortion, which can either increase the health risk to them or, in light of the ten-week limit on the Mifepristone-Misoprostol Regimen, prevent them from receiving a medication abortion at all. *See* Bryant Decl. ¶ 101 (stating that "[d]elaying abortion care imposes serious medical risk, and that "the risks increase as pregnancy advances"). For example, as discussed above, Dr. Paladine had a patient who sought abortion services but could not be prescribed mifepristone because Dr.

Paladine's office was closed, and she still had not received abortion services several weeks later. Paladine Decl. ¶ 18. Similarly, Dr. Floyd has reported that she recently had a patient who had no car and thus paid someone to drive her to her abortion care appointment, only to have to leave without seeing the doctor when the driver became impatient with the wait and decided to leave. The patient then had to arrange for another ride for a second visit and thus had to "incur additional risk of viral exposure to come back to the clinic to pick up her medication." Floyd Decl. ¶ 21. By the time the patient was able to return to the office, she was only "a couple of days" away from "the limit when medication abortion care is available," such that with any further delay, "she would no longer have been eligible for a medication abortion and would have had to have an in-clinic procedure instead, further increasing her risk of exposure." *Id.*

Such delays in abortion care can constitute an undue burden either because they increase the risk from medication abortion or they cause the patient to miss the opportunity for a medication abortion such that they must seek a more invasive form of abortion. *See June Med. Servs.*, 2020 WL 3492640, at *18 (plurality opinion) (relying in part of the finding that "delays in obtaining an abortion increase the risk that a woman will experience complications from the procedure and may make it impossible for her to choose a noninvasive medication abortion"); *Stenberg*, 530 U.S. at 931, 938; *Humble*, 753 F.3d at 915 (holding that "practical considerations, such as the frequency with which clinics can see patients and difficulties women face in obtaining time off from work or transportation to a clinic, may effectively preclude medication abortion" before the applicable limit of eligibility); *Schimel*, 806 F.3d at 918.

The Court therefore finds that taken together, the burdens of the In-Person Requirements, in the specific context of the unprecedented COVID-19 pandemic, impose a "substantial obstacle in the path of women seeking an abortion." *Whole Woman's Health*, 136 S. Ct. at 2317-18.

4. Benefits

Under *Whole Woman's Health*, the Court must also consider the alleged benefits. 136 S. Ct. at 2309. Plaintiffs assert that the In-Person Requirements provide no medical benefit. Plaintiffs have offered the declaration of Dr. Bryant, a board-certified OB/GYN and an Associate Professor at Harvard Medical School, who has concluded that "there is no clinical reason to require patients to travel to a clinic, hospital, or medical office in person to obtain mifepristone." Bryant Decl. ¶ 69.

In her expert opinion, Dr. Bryant states that "[l]eading medical authorities agree that, for many patients, health care professionals can safely and effectively" use telemedicine to conduct the three main assessments needed to prescribe mifepristone as part of the Mifepristone-Misoprostol Regimen: a determination of the length of the pregnancy; whether the pregnancy is intrauterine or ectopic; and whether there are contraindications, such as allergies. *Id.* ¶ 49-50. Through this process, a healthcare provider can identify patients who need to be seen in-person before determining whether they are eligible for a medication abortion. *Id.* ¶ 50. Telemedicine provides comparable health outcomes to traditional methods and is integrated into obstetrics and gynecology. *Id.* ¶ 53.

Although Defendants generally raise the specter of health risks and complications, the actual operation of the Mifepristone-Misoprostol Regimen illustrates that the In-Person Requirements do not advance general interests of patient safety and thus constitute "unnecessary health regulations." *Whole Woman's Health*, 136 S. Ct. at 2309 (quoting *Casey*, 505 U.S. at 877 (plurality opinion)). Since there is no requirement for in-person administration of the drug and patients may take it at home, in-person dispensing does nothing to provide for monitoring of the patient for complications. Notably, any complications, such as infection or serious bleeding, do

not occur until hours or days after the pill is ingested, long after a patient would have left the medical facility after in-person dispensing or administration of the drug. Bryant Decl. ¶ 35. In particular, it is only after the patient takes misoprostol, the second pill in this medication abortion regimen, 24-48 hours after the ingestion of mifepristone, that the bleeding and cramping occurs, and the contents of the uterus are actually emptied. *Id.* There is no FDA requirement for any in-person follow up, which typically occurs by telephone. *Id.* ¶ 36.

Dr. Bryant also asserts that a healthcare provider can, through telemedicine, provide all necessary counseling and disclosure of risks. The Patient Agreement Form can be fully reviewed and discussed with the healthcare provider over telemedicine as well. *Id.* ¶¶ 50-54; Paladine Decl. ¶ 16. Accordingly, Dr. Bryant has concluded that "[t]here is no safety or medical benefit in requiring patients to make a trip to the health care facility just to pick up the mifepristone." Bryant Decl. ¶ 48. Five other physicians who regularly provide or oversee abortion care and prescribe mifepristone have also offered their expert opinions that the required assessment and counseling can frequently be accomplished successfully by telemedicine and that in such instances the In-Person Requirements "serve[] no medical purpose" and are "medically unnecessary." Chen Decl. ¶¶ 14-17; MacNaughton Decl. ¶ 18; Paladine Decl. ¶¶ 16, 26-27; Floyd Decl. ¶¶ 17-19; Espey Decl. ¶ 13. A recent comprehensive report on the safety of abortion by the National Academies of Sciences, Engineering, and Medicine, an independent, nonpartisan group, also found that "[t]here is no evidence that the dispensing or taking of [medication abortion pills] requires the physical presence of a clinician." Letter to FDA at 4, Compl. Ex. 4, ECF No. 1-6 (citing Nat'l Acads. of Sci., Eng'g & Med., *The Safety & Quality of Abortion Care in the United States* 79 (The National Academies Press, 2018) (https://www.nap.edu/read/24950/chapter/4#79)).

In the face of Plaintiffs' evidence that the In-Person Requirements constitute unnecessary regulations, Defendants rely entirely on FDA's prior determination that the requirement is necessary "to mitigate serious risk associated with the drug's use." Opp'n Mot. PI at 22. FDA, however, has not conducted any assessment of the benefit of the In-Person Requirements, in the context of present-day facts and circumstances. Although in March and April 2020, ACOG and other medical associations and entities formally requested that FDA agree not to enforce the In-Person Requirements during the COVID-19 pandemic, FDA has not responded to that request and has provided no sign that it has undertaken a formal review of the issue in light of the now widespread use of telemedicine and the ongoing pandemic.

In 2016, FDA considered and made significant changes to the mifepristone REMS, including the elimination of the requirements for in-person administration of mifepristone at a medical facility; extending the gestational period of approved use from seven to ten weeks; and allowing certain nonphysicians to prescribe the drug. However, as acknowledged by Defendants at the hearing on the Motion, because the drug sponsor did not request a change to the In-Person Dispensing Requirement, FDA did not specifically review that issue. In FDA's 2016 REMS Modification Memorandum, FDA provided only the following statement as explanation for the retention of the requirement: "This ensures that Mifeprex can only be dispensed by or under the direct supervision of a certified prescriber." 2016 REMS Modification Mem. at 3, Opp'n Mot. PI Ex. 18, ECF No. 62-10.

FDA's most recent analysis justifying the In-Person Requirements occurred in 2013, the last time it conducted a complete assessment of the mifepristone REMS. In renewing the REMS, FDA noted that mifepristone is "associated rarely with serious infection and hemorrhage sometimes resulting in transfusions, hospitalization, and death." 2013 REMS Review at 11, Opp'n

Mot. PI Ex. 14, ECF No. 62-6. As a result, FDA justified the decision to restrict the administration and dispensing of mifepristone to certain healthcare settings so as to effectively limit its distribution to knowledgeable healthcare providers with established relationships with the drug sponsor in order to prevent the following "worst case" scenario occurrences: patients not being properly counseled about the serious complications of the drug, patients failing to pick up the drug in a timely manner, resulting in ineffective or inappropriate use of the drug and possible complications, and patients having difficulty finding a pharmacy that stocks the drug. *Id.* at 13. Thus, the medical benefits identified by FDA consisted of providing an opportunity for in-person counseling prior to dispensing and avoiding potential difficulties in the receipt of mifepristone that could delay the taking of the drug.

Defendants argue that the Court should give "significant deference" to FDA's determination because it "lies squarely within FDA's area of special expertise" and is "based on dozens of clinical trials and agency reviews." Opp'n Mot. PI at 22. Although Defendants assert that FDA's determination "should not be subject to second-guessing by an unelected federal judiciary," *id.* at 25, the Supreme Court in *Whole Woman's Health* held that although courts are to review factfinding by a decision-making entity with deference, they should not place "dispositive weight" on the entity's conclusions and instead "retains an independent constitutional duty to review factual findings where constitutional rights are at stake." 136 S. Ct. at 2310 (quoting *Gonzales*, 550 U.S. at 165); *see also June Med. Servs.*, 2020 WL 3492640, at *10 (plurality opinion). Here, although FDA has subject matter expertise on this issue, its 2013 assessment is entitled to only limited deference because its analysis is dated and did not take account of intervening events. It did not consider the 2016 determinations that mifepristone no longer needed to be administered by a physician in person, but instead could be handed over by certain non-

physicians and taken at home by the patient, and that the window for taking mifepristone was extended from seven weeks into the pregnancy to ten weeks. Indeed, the 2016 review determined that there is "no significant difference in either efficacy or safety" for women who take both mifepristone and misoprostol at home as compared to women who take mifepristone in the office and misoprostol at home. 2016 Clinical Review at 39.

More importantly, as Defendants acknowledged at the hearing on the Motion, in the 2013 and 2016 reviews, FDA did not consider the use of telemedicine in any way, presumably because it was not frequently used at the time. As Plaintiffs' expert witnesses have stated, telemedicine is now in widespread use, including as an effective means to providing counseling relating to medication abortion. Chen Decl. ¶ 8; Bryant Decl. ¶ 53. Thus, both the 2013 and 2016 reviews are outdated on this point and of only limited value on the salient question of whether the In-Person Requirements remain necessary given the present-day ability to use telemedicine to counsel patients at or near the time the drug is provided. Accordingly, while the Court gives FDA's prior determination appropriate deference, 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.

The first alleged benefit of the In-Person Requirements is that they provide an opportunity for the healthcare provider to counsel the patient about the risks of complications associated with the medication, including serious infection, sometimes life-threatening bleeding, or incomplete abortion. Plaintiffs, however, have provided specific evidence from several physicians who attest that face-to-face counseling can be accomplished with equal effectiveness through telemedicine, especially during the pandemic. For example, Dr. Chen has stated in her declaration that she uses telemedicine to consult with patients seeking an abortion and discusses "the risks, benefits, and

alternatives for each kind of abortion care for which they are eligible" and answers any questions so that the patient can make an informed decision. Chen Decl. ¶ 14. If a patient is eligible for a medication abortion, she provides specific counseling by telemedicine, including reviewing the Patient Agreement Form, answering any questions, confirming whether the patient consents, discussing the specific instructions for use and follow-up steps, and informing the patient of how to handle serious but "very rare" complications. *Id.* ¶¶ 14-15. Although a patient must come to Dr. Chen's office to pick up the drug and sign the Patient Agreement Form, the information in the form is the same as was previously reviewed by telemedicine. *Id.* ¶ 16. Where all necessary counseling can occur through telemedicine, Chen concludes that the In-Person Requirements are "medically unnecessary." *Id.* ¶ 6.

Likewise, Dr. McNaughton has stated that at the hospitals and clinics at which she practices, telemedicine is used to determine eligibility for a medication abortion, to "discuss the risks, benefits, and alternatives associated with medication abortion," to review the Patient Agreement Form, and to provide instructions for how to take the medication. MacNaughton Decl. ¶ 11. As a result, she also views the In-Person Dispensing Requirement to be "medically unnecessary." *Id.* ¶ 16. Dr. Floyd, who oversees several clinics at which patients are counseled on abortion services through telemedicine, has stated that it is used to "obtain the information necessary to determine whether the patient is eligible for medication abortion" and to "discuss the risks, benefits, and alternatives," to review FDA's Patient Agreement Form and the Medication Guide for mifepristone, and to answer any questions. Floyd Decl. ¶ 17. Accordingly, she concludes that "there is no clinical reason why any of this has to happen in person." *Id.* ¶ 18. Notably, the In-Person Requirements do not specifically require that counseling occur in-person.

Significantly, Defendants have offered no evidence demonstrating that telemedicine counseling sessions are ineffective or insufficient for communicating information about the risks or alternatives to medication abortion. The 2013 and 2016 FDA reviews do not address this issue. If anything, the 2016 review revealed that, in light of a prior study demonstrating that "99 percent of abortion facilities surveyed provided pre-abortion counseling with patient education," the Patient Agreement Form that is the subject of the In-Person Signature Requirement is "duplicative and no longer necessary to ensure that the benefits of the drug outweigh the risks." 2016 Clinical Review at 88-89. Considering the evidence presented, the Court finds that in light of the advent of telemedicine, the In-Person Requirements do not demonstrably further the stated interest of counseling patients before the prescription of mifepristone.

Defendants' second identified benefit of the In-Person Requirements, specifically the In-Person Dispensing Requirement, is that it prevents any delay in filling the prescription that may occur if mail delivery or retail pharmacies are used, which in turn prevents delay in the initiation of the Mifepristone-Misoprostol Regimen. Defendants argue that a later start to the process can increase the health risks to the patient.

Defendants, however, offer no evidence that removing the In-Person Dispensing Requirement will result in delayed taking of mifepristone. First, Defendants misconstrue Plaintiffs' requested relief. Plaintiffs do not seek to bar in-person visits for examinations, counseling, or dispensing of mifepristone relating to medication abortion. Rather, they seek the temporary option to forgo in-person visits if, in a healthcare provider's medical judgment, it is not necessary to meet the patient's needs. If in-person dispensing is the most efficient meets of delivery for a particular patient, that option will remain available. In fact, as already discussed, *see supra* part II.A.3., under the circumstances of the pandemic, where medical offices are closed

or operating in a limited way, and patients face significant hurdles in visiting such offices because of health risks, transportation challenges, and childcare limitations, the In-Person Requirements are in many instances a slower means of providing the drug to the patient. *See, e.g.*, MacNaughton Decl. ¶ 15 ("The need to obtain mifepristone in person could push these patients beyond the time in pregnancy when medication abortion is an option, when they could otherwise participate in a telehealth visit, have their medications mailed to them, and avoid unnecessary delay."). Thus, under the present circumstances of the COVID-19 pandemic, a rigid In-Person Dispensing Requirement does not actually serve the purpose of preventing delays in the initiation of the Mifepristone-Misoprostol Regimen.

Second, the In-Person Dispensing Requirement specifically does not control when the mifepristone is actually taken. Since the 2016 elimination of the in-person administration requirement, a patient receiving mifepristone at a medical office may take the pill at home, at a time of her choosing, without clinical supervision. The requirement therefore does not actually address any interest in having the patient take the mifepristone as soon as possible.

Third, to the extent that timing might make any difference in an individual case, Plaintiffs have identified the option of a healthcare provider directing the use of a courier to deliver the medication directly from the medical office to the patient that would get the medication to the patient the same day. Reply Mot. PI at 6, ECF No. 73. Indeed, where the REMS require that the drug sponsor distribute mifepristone only to certified healthcare providers and not to retail pharmacies, Mifepristone REMS ¶ II.A.2., a temporary waiver of the In-Person Requirements would not open up the distribution chain in a way that takes control away from those healthcare providers. Rather, such healthcare providers would be able to choose the most efficient means of getting the drug from their office to their patient under the existing circumstances, whether by

mail, courier, or in-person. The Court therefore finds that the evidence does not support a finding that the In-Person Dispensing Requirement provides any significant health-related benefit relating to an alleged elimination of delay in the taking of mifepristone.

Finally, Defendants invoke general concerns about the medical risks of mifepristone, including the statement on the mifepristone drug label that "[a]bout 2 to 7 out of 100 women taking [the drug] will need a surgical procedure because the pregnancy did not completely pass from the uterus or to stop bleeding." Mifeprex Drug Label at 17, Compl. Ex. 1, ECF No. 1-3. In the most recent safety assessment of mifepristone conducted in 2016, however, FDA characterized the risk of mifepristone by stating that "[m]ajor adverse events . . . are exceedingly rare, generally far below 0.1% for any individual adverse event." 2016 Clinical Review at 47. In any event, the degree of risk associated with mifepristone is relevant here only to the extent it provides a basis to require advanced counseling of patients. Where Plaintiffs' evidence establishes that such counseling can and will occur through telemedicine, and there is no evidence that such counseling is insufficient to meet the interests of patients, the general risks of mifepristone do not reveal a significant health-related benefit of the In-Person Requirements.

Considering the evidence in the record, and affording due deference to FDA's dated analysis, the Court finds that the In-Person Requirements, in the context of the elimination of the in-person administration requirement in 2016, the present widespread availability of telemedicine, and the present delays associated with in-person visits to medical offices due to the COVID-19 pandemic, provide "no significant health-related benefit," *June Med. Servs.*, 2020 WL 3492640, at *20, and are "unnecessary regulations" under current circumstances, *Whole Woman's Health*, 136 S. Ct. at 2309.

5. Undue Burden Determination

Under *Whole Woman's Health*, the undue burden determination is based on whether, after consideration of both "the burdens a law imposes on abortion access together with the benefits those laws confer," the abortion restriction imposes a "substantial obstacle" on a "large fraction" of the women for whom it is relevant. 136 S. Ct. at 2309; *see also Humble*, 753 F.3d at 912-13 (holding that a court "must compare the extent of the burden a law imposes on a woman's right to abortion with the strength of the . . . justification for the law"). "[T]he more substantial the burden, the stronger the state's justification for the law must be to satisfy the undue burden test; conversely, the stronger the state's justification, the greater the burden may be before it becomes 'undue.'" *Humble*, 753 F.3d at 912-13.

In *Whole Woman's Health*, the Supreme Court held that where abortion patients had particularly low rates of serious complications and virtually no deaths, the Texas admitting-privileges requirement had "no . . . health-related benefit" because "there was no significant health-related problem that the new law helped to cure," and the surgical-center requirement likewise had "no benefit" because any complications requiring surgical intervention "would almost always arise only after the patient . . . left the facility." 136 S. Ct at 2311, 2315. Where these laws would result in abortion clinic closures that caused increased waiting times and crowding, and increased the travel time for abortion patients, the Court found that the restrictions imposed a "substantial obstacle" to a woman's choice and thus imposed an unconstitutional undue burden. *Id*. at 2309, 2313.

In *Humble*, the most analogous case to the present dispute, the court concluded that where there was "no evidence" that the FDA-approved on-label regimen" advances in any way its interest in women's health," the benefit of restricting use to only that method of abortion was outweighed

by the burdens on abortion patients because the increased cost of the on-label regimen and the requirement of a second in-person visit created hardship for patients who had difficulty getting time off of work or arranging for transportation to a clinic, all of which led to delays that could prevent the use of a medication abortion during the seven-week window. 753 F.3d at 915-16. Significantly, the court reached this conclusion even though the on-label regimen was the only medication abortion regimen approved by FDA. *See id.* at 909.

Here, as discussed above, the burdens of the In-Person Requirements in light of the COVID-19 pandemic are significant and likely place "a substantial obstacle in the path of a woman's choice." *June Med. Servs.*, 2020 WL 3492640, at *21 (quoting *Casey*, 505 U.S. at 895); *Whole Woman's Health*, 136 S. Ct. at 2312. Although a single in-person visit may not appear particularly onerous in normal times, by declaring a nationwide public health emergency and permitting nationwide waivers of several in-person requirements relating to the dispensing of drugs, Defendants and the federal government more broadly have effectively acknowledged that during the pandemic, medical visits present substantial challenges to any patient. When one considers these extraordinary circumstances alongside the facts that during the pandemic, medical offices that dispense mifepristone may be closed or operating with limited capacity, a disproportionate number of abortion patients are from demographic groups with heightened risk for serious illness from COVID-19, and such patients face particularized barriers posed by transportation, childcare, and the economic downturn during the pandemic, the burdens are properly characterized as creating such a substantial obstacle, particularly where any delay in obtaining mifepristone that extends past the tenth week of pregnancy can force a woman to consider more complicated, invasive surgical abortions. *See supra* part II.A.3.

Even if the burdens alone were insufficient to support a finding of a substantial obstacle, such a finding would necessarily follow upon consideration of the alleged benefits of the In-Person Requirements, which the evidence shows to likely be "unnecessary health regulations" under the present circumstances. *Whole Woman's Health*, 136 S. Ct. at 2309. Although the need to counsel patients is an important interest, the evidence in the record supports the conclusion that with personal counseling now occurring through telemedicine, the requirement is not actually necessary to meet this interest. Likewise, the stated interest in ensuring that patients receive the mifepristone promptly is not presently advanced by the In-Person Requirements, where they do not actually guarantee that a patient takes the pill promptly, there are other means of prompt delivery, and in light of the pandemic, it has actually delayed, not accelerated, the distribution of mifepristone in some instances. Thus, a comparison of these restrictions with no significant health-related benefit against the serious burdens imposed by the In-Person Requirements during the COVID-19 pandemic further establishes that the In-Person Requirements are likely imposing a substantial obstacle to a woman's choice during the pandemic.

Finally, the Court finds a likelihood that this substantial obstacle affects a "large fraction" or "significant number" of "those women for whom the provision is an actual rather than an irrelevant restriction." *Whole Woman's Health*, 136 S. Ct. at 2320; *Casey*, 505 U.S. at 893. Here, that universe consists of the women seeking a medication abortion through the Mifepristone-Misoprostol Regimen during the COVID-19 pandemic for whom an in-person visit is not medically necessary because an assessment by a healthcare provider of eligibility and counseling can properly occur by telemedicine. Where the federal government has imposed nationwide waivers for certain in-person requirements because of the COVID-19 pandemic, it is reasonable to infer that the challenges for receiving in-person medical care are significant, affect the

population generally, and are geographically widespread. Although at this preliminary stage, specific statistics on how many of the affected women face an undue burden are not available, Plaintiffs have submitted evidence that 75 percent of women obtaining abortion care are poor or low-income and 60 percent are people of color, and that these populations face a significantly higher health risk from COVID-19 and in turn face particularly significant transportation, childcare, and economic challenges during the pandemic that make accessing in-person care particularly difficult and dangerous. *See, e.g.*, Bryant Decl. ¶ 18; Simpson Decl. ¶ 7. The physician experts, such as Dr. Paladine, have corroborated these figures as to their own practices. *See* Paladine Decl. ¶ 10 (stating that "almost all" of her patients are people of color, and at least 75 percent are people of color). Within this framework, the extensive evidence relating to the burdens of the In-Person Requirements during the COVID-19 pandemic supports the "commonsense inference" that they present a substantial obstacle to a large fraction of the women for whom the In-Person Requirements are relevant. *Whole Woman's Health*, 136 S. Ct. at 2317 (holding that courts may draw "commonsense inferences" from the evidence in assessing whether an undue burden exists). The Court therefore finds that Plaintiffs have established a likelihood of success on the merits of their due process claim.

B. Equal Protection

Plaintiffs also assert a claim that the In-Person Requirements violate the equal protection rights of the physicians and patients who dispense and receive mifepristone because they unjustifiably treat them differently from similarly situated individuals who dispense and receive other drugs during the pandemic without such requirements. Because the Court has found a likelihood of success on the merits of the due process claim, it need not address this claim as it relates to the use of mifepristone for medication abortions. Where the due process claim is based

on the constitutional right to an abortion, however, it does not protect the rights of physicians and patients who dispense and receive the drug for miscarriage treatment. The Court will therefore consider the likelihood of success of the equal protection claim as applied to miscarriage treatment only.

The Equal Protection Clause generally requires that "all persons similarly situated should be treated alike." *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 439 (1985). Thus, a plaintiff challenging a statute or regulation on equal protection grounds must first establish that the plaintiff has been "treated differently from . . . similarly situated" individuals and that "the unequal treatment was the result of intentional or purposeful discrimination.'" *Kolbe v. Hogan*, 849 F.3d 114, 146 (4th Cir. 2017) (quoting *Morrison v. Garraghty*, 239 F.3d 648, 654 (4th Cir. 2001)) (internal citations omitted). Then, "[i]f that initial showing has been made, 'the court proceeds to determine whether the disparity in treatment can be justified under the requisite level of scrutiny.'" *Id.* (quoting *Morrison*, 239 F.3d at 654). Here, where individuals involved in miscarriage treatment are not subject to any heightened scrutiny, the requisite level of analysis is the rational basis test, under which the differential treatment must be "rationally related to a legitimate governmental purpose." *City of Cleburne*, 473 U.S. at 446.

Plaintiffs' equal protection theory is that FDA's failure to waive the In-Person Requirements during the pandemic treats those involved in the use of mifepristone for miscarriage treatment differently from those involved in the use of other prescription drugs for which in-person requirements were waived. Plaintiffs focus on three waivers of in-person requirements: (1) HHS, in conjunction with DEA, invoking a statutory "telemedicine exception" under the CSA to allow a requirement for an in-person evaluation requirement before a physician may prescribe certain controlled substances to be fulfilled through a telemedicine examination; (2) FDA announcing that

it will not enforce ETASU D and ETASU E requirements for patients to undergo certain in-person laboratory tests or imaging studies before they may receive prescriptions for certain drugs; and (3) FDA announcing that it will not enforce certain ETASU C requirements that two specific drugs be dispensed and administered at a hospital, clinic, or medical office, provided that such activity still occur in-person at a different location under the supervision of a physician.

Although these waivers of certain in-person requirements appear to reflect differential treatment during the pandemic of the relevant drugs, and by extension the individuals involved in the dispensing of those drugs, the Court finds that the record at present is insufficient to reach a conclusion that the treatment of any or all of these drugs are sufficiently "similarly situated," that the treatment is actually different, and that any differential treatment lacks a rational basis to support a finding of a likelihood of success on the merits of an equal protection claim.

First, as to the decision by HHS and DEA relating to controlled substances, the regulatory scheme underlying that decision, grounded in the CSA, 21 U.S.C. § 829(e), is different from the FDA REMS regime underlying the In-Person Requirements that arise under the FDCA, 21 U.S.C. §§ 355-1, 355-1(f)(3). The decision relating to controlled substances was based on a specific telemedicine exception to a specific in-person examination requirement during a public health emergency, 21 U.S.C. § 829(e), an exception not included in the FDCA. One decision appears to have been primarily made by DEA, a component agency of the United States Department of Justice, while the other was made by FDA within HHS. In the face of these clear distinctions, Plaintiffs have not offered evidence or analysis that sufficiently establishes that these two scenarios and the affected individuals are "similarly situated" for purposes of equal protection analysis. *Kolbe*, 849 F.3d at 146. For example, the Court lacks information on whether there are distinctions

between mifepristone and the drugs at issue in the CSA determination that warrant differential treatment.

Second, the Court similarly lacks information necessary to assess properly whether the ETASU D and ETASU E waivers relating to laboratory testing and imaging studies are "similarly situated" to potential waivers of the ETASU C requirements. *Id.* While the ETASU requirements are grounded in the same statutory provision, they arise under different subsections of the statute and appear to address different concerns. Although Defendants have argued that the In-Person Requirements are necessary to ensure sufficient opportunity for counseling and to minimize delays in receiving the drug, the limited information submitted relating to the temporary waiver of the laboratory testing and imaging study requirements suggests that these requirements serve different purposes relating to safe use of the medication and monitoring of a patient's condition. *See* FDA, *COVID-19 REMS Guidance* at 7 (citing 21 U.S.C. § 355-1(f)(3)(D)-(E)). Most importantly, 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 than the ETASU C requirements, such that waiver of one should necessarily warrant waiver of the other. Without further evidence or expert analysis to assist the Court in evaluating such distinctions, it cannot conclude that these those affected by the testing waivers are similarly situated to Plaintiffs.

Third, the record relating to the waiver of enforcement actions for two drugs subject to ETASU C requirements is too limited to draw fair conclusions. After the hearing on the Motion, Defendants disclosed that during the pandemic, following the request of two drug sponsors, FDA waived ETASU C requirements for Spravato, a nasal spray treatment for depression, and Tysabri, a drug for multiple sclerosis and Crohn's disease. Although these drugs are subject to the same

ETASU category as mifepristone, the information provided to date suggests that the temporary waiver does not actually eliminate an in-person dispensing or administration requirement, but instead permits that in-person activity to occur at a location other than a hospital, clinic, or medical office. Moreover, where 15 other drugs are subject to ETASU C's in-person dispensing or administration requirement but have not received any waiver, the Court would need additional information about those drugs and their treatment by FDA to fairly assess whether Plaintiffs are likely to succeed on a claim based on alleged differential treatment from other drugs subject to ETASU C requirements. *See* 21 U.S.C. § 355-1(a)(1)(A)-(F) (noting that REMS should be based on factors such as the estimated size of the population likely to use the drug, the seriousness of the condition to be treated, the expected benefits of the drug, the duration of treatment with the drug, the seriousness of potentially adverse events, and the drug's molecular entity).

Finally, although not specifically included as a similarly situated drug underlying the equal protection argument, Plaintiffs note that FDA permits the same chemical compound as mifepristone, marketed under the brand name Korlym® for daily use by patients with endogenous Cushing's syndrome, to be provided to patients without any REMS requirements and to be obtained from a mail-order pharmacy for delivery to the patient's home. According to Dr. Bryant, Korlym is taken in higher doses on a more frequent basis than mifepristone, which is typically taken only once for its intended purpose. Bryant Decl. ¶ 63. Nevertheless, where Korlym is taken by a different patient population, for a different medical condition, and with a different expected outcome, the Court is not prepared at this time to conclude that there is no rational basis for differential treatment of Korlym. Since mifepristone is taken as part of a regimen designed to result in the expelling of the contents of a pregnancy with potential complications, the Court would

need additional information about Cushing's syndrome and the potential complications associated with taking Korlym for that condition before reaching even a preliminary conclusion on that issue.

In summary, the Court finds that the present record leaves too many gaps to establish that Plaintiffs' identified comparator drugs are fairly deemed to be similarly situated or differentially treated, or that any disparate treatment of mifepristone prescribers and patients relative to those associated with the use of the other drugs lacks any rational basis. Accordingly, at this preliminary stage, the Court will not find a likelihood of success on the merits of the equal protection claim as to miscarriage treatment and will thus deny the Motion as to the In-Person Requirements as applied to that particular use.

III. Irreparable Harm

The second requirement for a preliminary injunction is that the plaintiff will likely suffer irreparable harm in the absence of preliminary relief. *See Winter*, 555 U.S. at 20. Plaintiffs assert that they have satisfied this prong because the denial of a constitutional right necessarily constitutes irreparable harm. They also argue that the In-Person Requirements cause irreparable harm because they "needlessly expose[] Plaintiffs' members, their patients, and their families to increased risk of life-threatening disease." Am. Mot. PI ("Mot. PI") at 33, ECF No. 12.

"[T]he denial of a constitutional right . . . constitutes irreparable harm for purposes of equitable jurisdiction." *Ross v. Meese*, 818 F.2d 1132, 1135 (4th Cir. 1987). Where the Court has found a likelihood of success on Plaintiffs' due process claim, the deprivation of such a constitutional right alone would constitute irreparable harm. *See Elrod v. Burns*, 427 U.S. 347, 373 (1976) (plurality opinion) (finding that infringement on a First Amendment right, even for "minimal periods of time, unquestionably constitutes irreparable injury"); *Humble*, 753 F.3d at 911 ("[T]he deprivation of constitutional rights unquestionably constitutes irreparable injury.").

Specifically, as discussed above, the In-Person Requirements, combined with the COVID-19 pandemic, place a substantial obstacle in the path of women seeking a medication abortion and that may delay or preclude a medication abortion and thus may necessitate a more invasive procedure. Particularly in light of the limited timeframe during which a medication abortion or any abortion must occur, such infringement on the right to an abortion would constitute irreparable harm. In a recent case challenging a state restriction on elective surgeries during the COVID-19 pandemic as infringing on the constitutional right to an abortion, the United States Court of Appeals for the Sixth Circuit found likely irreparable harm because a woman seeking an abortion during the pandemic stood "at risk of losing her constitutional rights or at least of incurring substantial physical, emotional, and financial harms en route to exercising those rights," such that it was "not a case that can be remedied with money damages, or a post-hoc apology." *Adams & Boyle*, 956 F.3d at 927-28; *see also Planned Parenthood of Wis., Inc. v. Van Hollen*, 738 F.3d 786, 795-96 (7th Cir. 2013) (finding irreparable harm in part based the potential delay in obtaining an abortion that "can result in the progression of a pregnancy to a state at which an abortion would be less safe and, eventually illegal").

Defendants argue that Plaintiffs cannot show irreparable harm because making an in-person visit solely to pick up medication does not constitute a "substantial obstacle" to obtaining an abortion, and that the risk of exposure to COVID-19 is "premised largely on speculation" and insufficient to establish irreparable harm. Opp'n Mot. PI at 31. To advance their claim, Defendants cite to two unpublished district court cases finding that, under specific facts relating to the risk of exposure to COVID-19 in a detention facility, there was no likely constitutional violation, and there was insufficient evidence that detainees would contract COVID-19 to otherwise meet the standard of likely irreparable harm. *See Aslanturk v. Hott*, No. 1:20-cv-00433,

2020 WL 2465663, at *14 (E.D. Va. May 8, 2020); *Toure v. Hott*, No. 1:20-cv-395, 2020 WL 2092639, at *13 (E.D. Va. Apr. 29, 2020). As discussed above, however, Plaintiffs' claim is focused not on the risk of contracting COVID-19, but on the risk of losing the ability to obtain an abortion. The Court has found that Plaintiffs have demonstrated a likelihood of success on this constitutional claim that is related to, but not dependent on, a likelihood that any particular woman seeking an abortion will contract COVID-19. *See supra* part II.A. Where Plaintiffs have established a likely violation of a constitutional right, particularly one that, given the limited timeframe for obtaining a medication abortion, would be permanently lost absent preliminary relief, the Court finds likely irreparable harm.

IV. Balance of Equities and Public Interest

The remaining requirements for a preliminary injunction are that the balance of equities tips in the plaintiff's favor, and that an injunction is in the public interest. *See Winter*, 555 U.S. at 20. When one party is the Government, these two factors merge and are properly considered together. *Nken v. Holder*, 556 U.S. 418, 435 (2009). Here, as discussed above, the Court has found a likelihood that enforcement of the In-Person Requirements during the COVID-19 pandemic would infringe on a constitutional right and that, as a result, Plaintiffs face irreparable harm in the absence of a preliminary injunction. *See supra* parts II.A., III The Government, however, 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. *See Newsom v. Albemarle Cty. Sch. Bd.*, 354 F.3d 249, 261 (4th Cir. 2003) (holding that a public school defendant was "in no way harmed by issuance of a preliminary injunction which prevents it from enforcing a regulation, which, on this record, is likely to be found unconstitutional"); *Centro Tepeyac v. Montgomery Cty.*, 722 F.3d 184, 191 (4th Cir. 2013) ("[P]recedent counsels that a state

is in no way harmed by issuance of a preliminary injunction which prevents the state from enforcing restrictions likely to be found unconstitutional. If anything, the system is improved by such an injunction.") (citations omitted).

Defendants argue that the balance of equities should tip in their favor because, based on FDA's scientific judgment, the In-Person Requirements are necessary to assure safe use of mifepristone and thus to protect patients' safety. Opp'n Mot. PI at 31-32. As discussed above, however, the most recent judgment on the In-Person Requirements occurred in 2013, and FDA has not since considered whether the requirements are still warranted in light of the 2016 changes to the mifepristone REMS and the present widespread use of telemedicine. Moreover, the proposed preliminary injunction would be limited in that it would merely allow healthcare providers to forgo the In-Person Requirements based on their medical judgment; it would not mandate dispensing or counseling without an in-person visit. Healthcare providers would still be permitted and expected to require in-person dispensing, and even an in-person examination if, based on their medical judgment, such steps were warranted by the needs of the patient. A preliminary injunction also would not eliminate any of the other FDA REMS, state laws, or other restrictions on the prescribing and dispensing of mifepristone. Thus, on balance, the equities weighs in Plaintiffs' favor.

Moreover, temporarily enjoining the In-Person Requirements plainly promotes "the public interest in . . . safeguarding public health" because it aligns with the public health guidance to eliminate unnecessary travel and in-person contact. *Pashby*, 709 F.3d at 331. Notably, this is not a case, like others advanced during the pandemic to uphold abortion rights, in which the Court is asked to allow women to venture to medical offices to have abortion procedures contrary to public health measures imposed by the government. *See, e.g.*, *Adams & Boyle*, 956 F.3d at 928 (finding that the balance of equities and public interest still favored allowing women to obtain surgical

abortions under certain circumstances to uphold their constitutional rights despite a public health order temporarily barring elective surgeries during the pandemic). Although Defendants contend that the risk of a patient's single visit to a medical clinic is limited, as Plaintiffs assert, the In-Person Requirements "jeopardize[] the safety not only of patients seeking [mifepristone], their clinicians, and other health care staff—but also that of the family members to whom they return; the neighbors with whom they share public transportation; and other members of the public with whom they will interact the next day." Mot. PI at 34. Particularly when all of the individual visits of medication abortion patients are combined, the preliminary injunction would 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. Indeed, Defendants themselves have instituted waivers of in-person requirements relating to other drugs for the specific purpose of protecting public health. Therefore, a preliminary injunction serves the public interest not only because upholding constitutional rights "surely serves the public interest," but also because it would help to safeguard public health by eliminating unnecessary in-person visits during the pandemic. *Centro Tepeyac*, 722 F.3d at 191 (*quoting Giovani Carandola, Ltd. v. Bason*, 303 F.3d 507 (4th Cir. 2002)). Accordingly, the Court finds that the balance of equities and the public interest favor the granting of a preliminary injunction.

V. Remedy

Where all four required elements have been established, the Court will grant a preliminary injunction to temporarily bar enforcement of the In-Person Requirements. The parties disagree on the scope of any such injunction. Plaintiffs seek a preliminary injunction barring FDA from enforcing the In-Person Requirements against Plaintiffs, their members, all similarly situated mifepristone prescribers, and any other individuals involved in implementing the injunctive relief

until the pandemic is over and travel at health care facilities no longer pose a significant threat of COVID-19 transmission and illness. At the hearing on the Motion, Plaintiffs mark this end point as the date when a vaccine is approved and available in the United States. Defendants object to such "sweeping relief" and assert that absent a certified class action, this Court may not grant relief beyond what is necessary to address the harm to Plaintiffs, and that nationwide relief is otherwise inappropriate given the varying levels of risk posed by COVID-19 in different places and among different age groups. Opp'n Mot. PI at 33, 35.

"It is well established . . . that a federal district court has wide discretion to fashion appropriate injunctive relief in a particular case." *Richmond Tenants Org., Inc. v. Kemp*, 956 F.2d 1300, 1308 (4th Cir. 1992). Such relief, if appropriate, may extend outside the district in which the court sits. *See Texas v. United States*, 809 F.3d 134, 188 (5th Cir. 2015) (holding that the "Constitution vests the District Court with 'the judicial Power of the United States,'" which "extends across the country" and includes the power "in appropriate circumstances, to issue nationwide injunctions") (quoting U.S. Const. art. III § 1)), *aff'd by an equally divided court*, 136 S. Ct. 2271 (2016). That discretion must be balanced against the tenet that a court ordinarily should craft a remedy that is "no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979).

At the outset, the Court notes that relief that addresses the harms to all Plaintiffs necessarily will have broad impact because the membership of the Organizational Plaintiffs is extensive in number and geography. ACOG has more than 60,000 members, including practitioners in all 50 states, the District of Columbia, Puerto Rico, and other locations in North and South America. At the hearing on the Motion, Plaintiffs asserted, and Defendants did not dispute, that ACOG members comprise 90 percent of the OB/GYN physicians in the United States. CUCOG is also 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. NYSAFP, which is the New York chapter of the Academy of Family Physicians, has over 3,000 practicing physician members and over 500 medical resident members who collectively serve millions of patients. SisterSong is the largest national multi-ethnic and multi-cultural Reproductive Justice collective in the country, with a membership representing Indigenous, African American, Arab and Middle Eastern, Asian and Pacific Islander, and Latina women and LGBTQ communities. Thus, even before considering an injunction applicable beyond the parties, a preliminary injunction in this case would necessarily cover over 90 percent of OB/GYN physicians in the United States and apply to some extent in all 50 states. *See Va. Soc'y for Human Life v. Fed. Election Comm'n*, 263 F.3d 379, 393 (4th Cir. 2001) (in vacating a nationwide injunction in a case filed by a single organization, acknowledging that "[n]ationwide injunctions are appropriate if necessary to afford relief to the prevailing party" and citing *Richmond Tenants Organization, Inc.*, 956 F.2d at 1302, in which such an injunction was "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).

Contrary to Defendants' claim, courts may, under appropriate circumstances, grant a preliminary injunction beyond relief directly applicable to the parties. In *Trump v. International Refugee Assistance Project* ("*IRAP*"), 137 S. Ct. 2080 (2017), the Supreme Court denied in part an application to stay a nationwide injunction of an Executive Order barring travel to the United States by nationals of certain designated countries and left in place an injunction barring its enforcement against not only the plaintiffs in the pending case, but also "those similarly situated" to the plaintiffs. *Id.* at 2088. In *Roe v. Department of Defense*, 947 F.3d 207 (4th Cir. 2020), the

Fourth Circuit, citing *IRAP*, recently affirmed the principle that an injunction extending relief to those who are similarly situated to the litigants is not categorically beyond the equitable power of district courts. *Id.* at 232. In *Roe*, two members of the United States Air Force diagnosed with human immunodeficiency virus ("HIV") sought to enjoin enforcement of the Department of Defense's policies relating to HIV-positive servicemembers that resulted in their discharge. *See id.* at 212. After finding that the plaintiffs were likely to succeed on the claims that their discharges violated their constitutional rights and the Administrative Procedure Act, the district court issued a preliminary injunction that barred the discharge and unequal treatment in promotions and transfers of both the plaintiffs and other "similarly situated" service members throughout the Air Force. *Id.* at 231-32. In affirming the scope of the injunction, the Fourth Circuit focused on the fact that the policy was not applied individually based on the specific characteristics of the plaintiffs, but was instead an "arbitrary, across-the-board determination that HIV-positive servicemembers must be deemed ineligible to deploy . . . regardless of each servicemember's actual physical condition," and concluded that "categorical polices relied upon by the Government call for categorical relief." *Id.* at 232-33. The court found that the broader preliminary injunction was further justified where "the longstanding stigma and discrimination facing those living with HIV may pose a challenge for other similarly situated servicemembers to bring suits on their own behalf and where "granting relief to all similarly situated servicemembers is . . . the only way to ensure uniform, fair, rational treatment of individuals who belong to a vulnerable, and often invisible, class." *Id.* at 233-34.

As in *Roe*, the policy at issue here, the In-Person Requirements, is a categorical policy applicable to all healthcare providers and patients involved in the prescribing of mifepristone, regardless of individual circumstances. *See Roe*, 947 F.3d at 232. It applies no matter whether

the healthcare provider's office or clinic is open or closed, whether the patient has economic, transportation, or childcare challenges in visiting the office, and whether the COVID-19 pandemic has rendered local travel unsafe. Such a categorical policy warrants categorical relief that includes others similarly situated to Plaintiffs. *See id.*

Additional considerations warrant an injunction that bars enforcement against similarly situated non-Plaintiffs. First, as in *Roe*, non-Plaintiffs adversely affected by the In-Person Requirements include abortion patients who "belong to a vulnerable, and often invisible, class," 947 F.3d at 233-34, in that they have challenges bringing suits on their own behalf based on legitimate privacy concerns, have a limited time period within which to file suit based on the nature of abortion, and, where they are predominantly low-income, people of color, have disproportionately significant economic and health concerns during the COVID-19 pandemic. *See supra* part I.B.3. An injunction covering similarly situated non-Plaintiffs would provide "uniform, fair, [and] rational treatment" of such vulnerable individuals. *Roe*, 947 F.3d at 233-34. Relatedly, to the extent that some patients or some of the limited number of OB/GYNs who are not members of ACOG were to choose to file suit following the issuance of a preliminary injunction that does not cover them, such litigation would be "duplicative." *Nat'l Min. Ass'n v. U.S. Army Corps of Engineers*, 145 F.3d 1399, 1409 (D.C. Cir. 1998). "Issuance of a broad injunction" is therefore also appropriate because it "obviates such repetitious filings." *Id.* (affirming in part on this basis a nationwide injunction against enforcement of a rule that exceeded an agency's authority under the Clean Water Act).

Second, enforcement of a Plaintiffs-only injunction would create practical, administrative complexities. In crafting an injunction, a district court may appropriately consider the "feasibility of equitable relief" and is empowered "to weigh the costs and benefits of injunctive relief and, in

particular, to assess the practical difficulties of enforcement of an injunction—difficulties that will fall in the first instance on the district court itself." *Lord & Taylor, LLC v. White Flint, L.P.*, 780 F.3d 211, 217 (4th Cir. 2015). A Plaintiffs-only injunction would be practically difficult for the parties to comply with and for the Court to enforce. Any failure to comply with the In-Person Requirements would necessitate a determination whether the physician is a member of one or more of the Organizational Plaintiffs before any enforcement action could be taken, and factual disputes could arise, such as on whether the physician's membership was current as of the operative date, and even on what the operative date was. Where 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.

For the same reasons, the Court will not apply a geographical limitation to the injunction. Although Defendants have argued that COVID-19 has had varying levels of impact in certain states and regions, the impacts of the pandemic have fluctuated even during the pendency of this Motion. For example, in their amicus brief, the Opposing States asserted that during the last week of May 2020, the rate of positive tests for COVID-19 continued to be in decline and remained stable at low levels, the death rate had also continued to decline for the sixth consecutive week, and states like Oklahoma had not been significantly affected. As of July 1, 2020, however, the number of daily COVID-19 cases is increasing in 42 different states, including Oklahoma, and those trends are changing daily. Where Dr. Reingold's expert opinion that there would be "resurgences of COVID-19" across the United States during 2020, including new "hot spot[s]" after stay-at-home orders were relaxed, has already proven to be correct, Reingold Decl. ¶ 28, the Court finds that crafting relief that attempts to account for both the unpredictable changes and

nuanced regional differences across 50 different states over an extended period of time is simply infeasible.

For all of these reasons, the preliminary injunction will apply to bar FDA enforcement of the In-Person Requirements against Plaintiffs, their members, and other similarly situated individuals, without geographic limitation.

The Court, however, will not agree with Plaintiffs' request that the preliminary injunction extend until "Defendants demonstrate that the pandemic is over" or that travel to health care facilities "no longer pose a significant threat" of COVID-19. Mot. PI at 35. Such terms lack clarity and are too subjective to be practically applied. *See Lord & Taylor*, 780 F.3d at 217-18. The Court also will decline the request that the preliminary injunction extend until a vaccine is developed and available. Where the Court has an obligation to "mold its decree to meet the exigencies of the particular case" and narrowly tailor an injunction that balances "the concrete burdens that would fall on the parties and . . . the public consequences of an injunction," *Roe*, 947 F.3d at 232, such an endpoint, which could be years into the future, is temporally overbroad based on the evidence presently before the Court. Rather, the Court will impose the preliminary injunction to remain in effect during the pendency of the public health emergency based on COVID-19 declared by the Secretary of HHS pursuant to the Public Health Service Act. On January 31, 2020, the Secretary issued a declaration of a public health emergency effective as of January 27, 2020, and he later renewed the declaration for another 90 days, beginning on April 26, 2020. *Renewal of Determination that a Public Health Emergency Exists*, Health and Human Servs (Apr. 21, 2020), https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.aspx; *see* 42 U.S.C. § 247d(a) (providing that a public health emergency declaration expires after 90 days if not renewed). Based on the declaration, FDA issued the guidance stating that it would exercise its

discretion to temporarily cease enforcement of certain ETASU requirements, and HHS and DEA waived in-person patient examinations requirements relating to prescriptions for certain controlled substances. Where the Secretary's § 247d PHE declaration is an objectively identifiable marker that the COVID-19 pandemic continues to have a significant impact on the nation warranting emergency relief, and in fact has been a precondition for emergency waivers of in-person requirements relating to the prescribing and dispensing of drugs based on the COVID-19 pandemic, the preliminary injunction will extend for the duration of the declared PHE, including the periods of any subsequent renewals of the declaration. Recognizing that the duration of the PHE is a decision to be made by a Defendant in this case, the Court will extend the preliminary injunction for an additional 30 days following the expiration of the PHE to allow Plaintiffs to file, and for the Court to resolve, a motion for an extension of the preliminary injunction if warranted by specific evidence demonstrating an ongoing public health justification for its continuation.

Finally, in imposing a preliminary injunction against Defendants' enforcement of the In-Person Requirements, the Court notes that it is not barring the enforcement of other REMS requirements not dependent on an in-person patient visit, or the enforcement of any other federal or state laws or regulations, which are not presently before the Court. Thus, while certified healthcare providers may directly arrange for mifepristone to be mailed or delivered to patients, and may have a patient sign a Patient Agreement Form during a telemedicine session and return it by mail or electronically, they must still comply with all other REMS requirements, including that they must review the Patient Agreement Form with the patient and explain the risks of the Mifepristone-Misoprostol Regimen through telemedicine prior to signature, provide copies of the form and the Medication Guide to the patient, and maintain a copy of the form. Even if dispensing need not physically occur in "clinics, medical offices and hospitals," it must still be conducted "by

or under the supervision of a certified prescriber," and the drug sponsor must still ensure that mifepristone is not "distributed to or dispensed through retail pharmacies," so the drug will still have to be distributed first to certified healthcare providers who then must arrange for the mailing or delivery of the mifepristone to their patients and must still arrange to record the serial numbers of the distributed packages of mifepristone. Mifepristone REMS ¶ II.A.

Accordingly, the Court will issue a preliminary injunction enjoining Defendants, their agents, employees, appointees, or successors, from enforcing, threatening to enforce, or otherwise applying the In-Person Requirements contained in the mifepristone REMS as to medication abortion patients, to extend until the resolution of this case or until 30 days after the end of the public health emergency declared by the Secretary of HHS pursuant to 42 U.S.C. § 247d, whichever comes first. A separate Order shall issue with the specific terms of the preliminary injunction.

CONCLUSION

For the foregoing reasons, the Motion for a Preliminary Injunction will be GRANTED IN PART and DENIED IN PART. It will be granted as to the due process claim arising from the in-person dispensing and signature requirements applicable to the prescribing of mifepristone to medication abortion patients, subject to the specific terms identified in the accompanying Preliminary Injunction, and will be otherwise denied.

Date: July 13, 2020

/s/ *Theodore D. Chuang*
THEODORE D. CHUANG
United States District Judge

UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, *on behalf of its members and members' patients*,
COUNCIL OF UNIVERSITY CHAIRS OF OBSTETRICS AND GYNECOLOGY, *on behalf of its members and members' patients*,
NEW YORK STATE ACADEMY OF FAMILY PHYSICIANS, *on behalf of its members and members' patients*,
SISTERSONG WOMEN OF COLOR REPRODUCTIVE JUSTICE COLLECTIVE, *on behalf of its members and members' patients*, and
HONOR MACNAUGHTON, M.D.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,
STEPHEN M. HAHN, M.D., *in his official capacity as Commissioner of Food and Drugs, and his employees, agents and successors in office*,
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES and ALEX AZAR, J.D., *in his official capacity as Secretary, United States Department of Health and Human Services, and his employees, agents and successors in office*,

Defendants.

Civil Action No. TDC-20-1320

ORDER

For the foregoing reasons, Plaintiffs' Motion for a Preliminary Injunction, ECF No. 11, is GRANTED IN PART and DENIED IN PART. The Motion is granted as to the due process claim

arising from the in-person dispensing and signature requirements applicable to the prescribing of mifepristone to medication abortion patients, subject to the specific terms identified in the accompanying Preliminary Injunction. The Motion is otherwise denied.

Date: July 13, 2020

/s/ *Theodore D. Chuang*
THEODORE D. CHUANG
United States District Judge

UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, *on behalf of its members and members' patients*,
COUNCIL OF UNIVERSITY CHAIRS OF OBSTETRICS AND GYNECOLOGY, *on behalf of its members and members' patients*,
NEW YORK STATE ACADEMY OF FAMILY PHYSICIANS, *on behalf of its members and members' patients*,
SISTERSONG WOMEN OF COLOR REPRODUCTIVE JUSTICE COLLECTIVE, *on behalf of its members and members' patients*, and
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UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES and ALEX AZAR, J.D., *in his official capacity as Secretary, United States Department of Health and Human Services, and his employees, agents and successors in office*,

Defendants.

Civil Action No. TDC-20-1320

PRELIMINARY INJUNCTION

For the reasons set forth in the accompanying Memorandum Opinion and Order, it is hereby ORDERED that:

1. Defendants United States Food and Drug Administration ("FDA"), FDA Commissioner Stephen M. Hahn, the United States Department of Health and Human Services ("HHS"), and Secretary of Health and Human Services Alex Azar ("the Secretary"); Defendants' agents, employees, appointees, or successors; and all other persons who are in active concert and participation with them, are ENJOINED from enforcing, threatening to enforce, or otherwise applying the following provisions of the "Elements to Assure Safe Use" ("ETASU"), 21 U.S.C. § 355-1(f)(3) (2018), set forth in the mifepristone Risk Evaluation and Mitigation Strategy ("REMS"), ECF No. 1-4, as to the dispensing of mifepristone for use as part of a medication abortion regimen, against Plaintiffs, their members, other similarly situated individuals or entities, and other individuals or entities involved in implementing the injunctive relief, without geographic limitation:

    a. ETASU C, 21 U.S.C. § 355-1(f)(3)(C), only to the extent that it requires that mifepristone may be dispensed only in clinics, medical offices, or hospitals, rather than by mail or delivery service. Dispensing by mail or delivery service must still occur by or under the supervision of a certified healthcare provider as defined in the REMS.

    b. ETASU D, 21 U.S.C. § 355-1(f)(3)(D), only to the extent that it: (1) requires patients obtaining mifepristone to sign the Patient Agreement Form in the physical presence of a certified healthcare provider, rather than by signing it physically or electronically during a telemedicine session with a certified healthcare provider and promptly returning the form electronically or by mail, or by giving oral assent to its terms during such a session that the healthcare provider then documents in the patient's record; and (2) requires the certified healthcare provider to present the patient with a copy of the form at a clinic, medical office, or hospital, rather than promptly providing a copy of the form electronically or by mail.

    c. ETASU A, 21 U.S.C. § 355-1(f)(3)(A), only to the extent that it requires certified healthcare providers seeking to prescribe mifepristone to attest that they will: (1) obtain the patient's physical signature on the Patient Agreement Form, rather than obtaining a physical or electronic signature during a telemedicine session with a certified healthcare provider and promptly

receiving a copy of the signed form electronically or by mail, or by obtaining oral assent to its terms during such a session that the healthcare provider then documents in the patient's record; (2) present the patient with a copy of the form at a clinic, medical office, or hospital, rather than promptly providing a copy of the form electronically or by mail; and (3) place in the patient's medical record a copy of the form containing the patient's physical signature, rather than placing a copy of the form signed electronically during a telemedicine session with a certified healthcare provider or documenting the patient's oral assent to its terms in the patient's record.

2. The preliminary injunction shall extend until 30 days after the end of the Public Health Emergency declared by the Secretary pursuant to 42 U.S.C. § 247d(a) associated with or related to SARS-CoV-2 transmission and the illness known as COVID-19, including the periods of any subsequent renewals of the declaration.

3. If the Public Health Emergency ends during the pendency of this case, Plaintiffs may file a motion to extend the preliminary injunction based on specific evidence, to be presented with that motion, that demonstrates an ongoing public health justification for the continuation of the preliminary injunction.

4. Pursuant to Federal Rule of Civil Procedure 65(c), Plaintiffs are required to post with this Court a bond of $1,000.

5. The preliminary injunction shall take effect upon the posting of the bond.

Violations of this Order shall subject Defendants and all other persons bound by this Order to all applicable penalties, including contempt of court.

Date: July 13, 2020

/s/ *Theodore D. Chuang*
THEODORE D. CHUANG
United States District Judge

UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, *on behalf of its members and members' patients*,
COUNCIL OF UNIVERSITY CHAIRS OF OBSTETRICS AND GYNECOLOGY, *on behalf of its members and members' patients*,
NEW YORK STATE ACADEMY OF FAMILY PHYSICIANS, *on behalf of its members and members' patients*,
SISTERSONG WOMEN OF COLOR REPRODUCTIVE JUSTICE COLLECTIVE, *on behalf of its members and members' patients*, and
HONOR MACNAUGHTON, M.D.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION;
STEPHEN M. HAHN, M.D., *in his official capacity as Commissioner of Food and Drugs, and his employees, agents and successors in office*,
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES and
ALEX AZAR, J.D., *in his official capacity as Secretary, United States Department of Health and Human Services, and his employees, agents and successors in office*,

Defendants.

Civil Action No. TDC-20-1320

ORDER

Pending before the Court is Defendants' Motion to Stay Preliminary Injunction Pending Appeal, ECF No. 104. In deciding whether to grant a stay, the Court considers 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).

Having reviewed the Motion to Stay, the Court finds that for reasons stated in the Court's Memorandum Opinion on Plaintiffs' Motion for a Preliminary Injunction, ECF No. 90, Defendants do not satisfy the requirements for a stay of the preliminary injunction. Accordingly, it is hereby ORDERED that Defendant's Motion to Stay Preliminary Injunction Pending Appeal, ECF No. 104, is DENIED.

Date: July 30, 2020

/s/ *Theodore D. Chuang*
THEODORE D. CHUANG
United States District Judge