No. 22-1362

In the United States Court of Appeals for the Eighth Circuit

PLANNED PARENTHOOD MINNESOTA, NORTH DAKOTA, SOUTH DAKOTA; SARAH A. TRAXLER,

Plaintiffs-Appellees,

v.

KRISTI NOEM, IN HER OFFICIAL CAPACITY AS GOVERNOR OF SOUTH DAKOTA, JOAN ADAM, IN HER OFFICIAL CAPACITY AS INTERIM SECRETARY OF HEALTH, DEPARTMENT OF HEALTH, AND PHILIP MEYER, D.O., IN HIS OFFICIAL CAPACITY AS PRESIDENT, SOUTH DAKOTA BOARD OF MEDICAL AND OSTEOPATHIC EXAMINERS,

Defendants-Appellees.

On Appeal from the United States District Court
for the District of South Dakota
Case No. 4:22-cv-04009-KES

MOTION TO STAY PRELIMINARY INJUNCTION PENDING APPEAL AND MOTION FOR EXPEDITED CONSIDERATION

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The South Dakota Department of Health has issued a rule that governs the dispensation of abortion-inducing drugs. *See* S.D. Admin. R. 44:67:04:13 ("the Rule") (Exhibit 1). The Rule took effect on January 27, 2022. *See id.* This litigation concerns the requirements of the Rule that govern the distribution of misoprostol—the second of the two drugs that are used to terminate the fetus.

Under the current FDA protocol, a drug-induced abortion involves the ingestion of two different drugs that must be taken at separate times. The first of these drugs is mifepristone, or mifeprex, which blocks the operation of pregnancy hormones and causes the death of the fetus. The second drug, misoprostol, is taken 24–48 hours later to induce contractions. Approximately 1 out of 20 patients who take mifeprex will abort within 24–48 hours before taking misoprostol. *See* Harrison Decl., ECF No. 19-2, at ¶ 31. And 39% of women who are less than 7 weeks pregnant will eventually abort with mifeprex alone, so long as the recommended dosage of mifeprex (200 mg) is used. *See id.* at ¶ 8.

Before the Rule took effect, abortion patients would receive mifeprex and misoprostol during a single appointment, which must occur at least 72 hours after an initial appointment where the patient provides informed consent. *See* Traxler Decl., ECF No. 5, at ¶¶ 31–32. During this second appointment, a physician would first dispense the mifeprex, which the patient ingests at the abortion clinic. *See id.* at ¶ 32. After the patient finishes taking mifeprex, the

physician would dispense the misoprostol and instruct the patient to take it 24–48 hours later at a location of her choosing. *See id.*

The Rule changes this regime by allowing the physician to dispense only mifeprex during the second appointment, and requiring the pregnant woman to return to the abortion clinic to receive the misoprostol. *See* Exhibit 1. The misoprostol appointment must occur between 24 and 72 hours after the patient takes mifeprex. *See id.* The Rule also requires the abortion clinic to schedule an additional follow-up appointment with the patient on the 14th day after taking the drugs to confirm that the abortion has been completed. *See id.*

On January 19, 2022, abortion providers sued Governor Noem and state health officials, claiming that the separate-appointment requirement for misoprostol imposes an "undue burden" on abortion patients and violates the Equal Protection Clause. *See* Complaint, ECF No. 1, at 26. The plaintiffs moved for a TRO and preliminary injunction later that day. The district court issued a TRO on January 26, 2022, and a preliminary injunction on February 8, 2022. *See* Exhibit 2. On February 15, 2022, the defendants appealed and asked the district court to stay its preliminary injunction.

The defendants respectfully ask this Court to stay the preliminary-injunction order pending appeal, as the injunction is inflicting immediate and irreparable injury on the State by thwarting the enforcement of its laws. *See Maryland v. King*, 567 U.S. 1301 (2012) (Roberts, C.J., in chambers).

I. The Court Should Stay The Preliminary Injunction Pending Appeal

In deciding whether to stay a preliminary injunction pending appeal, a court must consider 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 the other parties interested in the proceeding; and (4) where the public interest lies." *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987). Each of these factors favors a stay.

A. The Defendants' Appeal Is Likely To Succeed

The district court's decision to facially enjoin the enforcement of the Rule[1] is unlikely to be sustained on appeal. First, this Court is likely to reject the district court's refusal to apply rational-basis review when asking whether the Rule is "reasonably related" to a "legitimate state interest." *See* Exhibit 2, at 23–28. Second, the plaintiffs failed to produce evidence that the Rule will unduly burden a "large fraction" of abortion patients for whom the Rule is relevant—and they certainly did not make a "clear showing" that a large fraction of abortion patients will be unduly burdened by the Rule. *See Winter v. Natural Resources Defense Council*, 555 U.S. 7, 20 (2008) ("[I]njunctive relief . . . may only be awarded upon *a clear showing* that the plaintiff is entitled

1. For simplicity and ease of exposition, we will use "the Rule" to refer to the separate-appointment requirement for misoprostol—the only portion of Rule 44:67:04:13 that the district enjoined the defendants from enforcing.

to such relief." (emphasis added)). Third, the appeal of the district court's equal-protection holding is likely to succeed because the district court misapplied the undue-burden standard and the rational-basis test.

1. The Rule Is "Reasonably Related" To A "Legitimate Purpose"

A court may not enjoin the enforcement of the Rule unless it: (1) imposes a "substantial obstacle" to abortion access; or (2) is not "reasonably related" to a "legitimate state interest." *June Medical Services LLC v. Russo*, 140 S. Ct. 2103, 2135 (2020) (Roberts, C.J., concurring in the judgment); *Hopkins v. Jegley*, 968 F.3d 912, 915 (8th Cir. 2020) (holding that "Chief Justice Roberts's . . . opinion" in *June Medical* "is controlling"). The district court held that the Rule is *not* "reasonably related" to a "legitimate" state interest, and it refused to equate this standard with rational-basis review. *See* Exhibit 2, at 25 ("[T]he court will not apply rational basis review and will apply the Supreme Court's analysis in *Hellerstedt* and *Gonzales* to this threshold issue."). The Court's conclusion and analysis are unlikely to survive appellate review.

The "threshold requirement" in Chief Justice Roberts's *June Medical* concurrence is rational-basis review. Asking whether a law is "*reasonably* related" to a "legitimate state interest" is no different from asking whether a law is "*rationally* related" to a "legitimate state interest." The words "rational" and "reasonable" are synonyms. *See* rational, dictionary.com (defining "rational" as "agreeable to reason; reasonable; sensible"), https://bit.ly/3uJLvGF. And the Supreme Court and the Eighth Circuit have

repeatedly equated the so-called "reasonable relation" test with rational-basis review. *See, e.g.*, *Friedman v. Rogers*, 440 U.S. 1, 17 (1979) (holding that a rule governing the membership of a state's optometry board was "related reasonably" to a "legitimate purpose," and equating that standard with whether a law is "rationally related to a legitimate state interest"); *Honeywell, Inc. v. Minnesota Life & Health Insurance Guaranty Ass'n*, 110 F.3d 547, 554–55 (8th Cir. 1997) (en banc) ("[T]he modern framework for substantive due process analysis concerning economic legislation requires only an inquiry into whether the legislation is reasonably related to a legitimate governmental purpose. . . . which articulate[s] a rational basis test."); *Parrish v. Mallinger*, 133 F.3d 612, 614–15 (8th Cir. 1998) ("Legislation authorizing the paying of an inmate's restitution debt out of his prison account 'is reasonably related to a legitimate governmental purpose' and therefore satisfies the modern, highly deferential substantive due process standard."); *Casbah, Inc. v. Thone*, 651 F.2d 551, 557 (8th Cir. 1981) ("Where no suspect classifications are involved and no fundamental rights, the question under equal protection analysis is whether the legislation is reasonably related to a legitimate state purpose. Similarly, we apply here the rational basis standard of review." (citations omitted)). In addition, the Sixth Circuit has specifically equated the "threshold requirement" in Chief Justice Roberts's *June Medical* concurrence with rational-basis review:

> Under the Chief Justice's controlling opinion, a law regulating abortion is valid if it satisfies two requirements. First, it must be

> "'reasonably related' to a legitimate state interest." . . . [T]his requirement is met whenever a state has a rational basis to . . . use its regulatory power . . .

EMW Women's Surgical Center, P.S.C. v. Friedlander, 978 F.3d 418, 433 (6th Cir. 2020) (citations and some internal quotation marks omitted).

The district court claimed that it need not apply rational-basis review because of language in *Casey*, *Hellerstet*, and *Gonzales*. *See* Exhibit 2, at 23–25. But none of those cases were purporting to interpret or apply the "threshold requirement" from Chief Justice Roberts's *June Medical* concurrence. The relevant passage from *Casey* reads as follows:

> [A] statute which, while furthering . . . [a] valid state interest, has the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends.

Id. at 23–24 (quoting *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 877 (1992)). This passage is explaining the "substantial obstacle" prong of the undue-burden test—which is a separate inquiry from whether a law is "reasonably related" to a "legitimate state interest." *See June Medical*, 140 S. Ct. at 2135 (Roberts, C.J., concurring in the judgment) ("Laws that do not pose a substantial obstacle to abortion access are permissible, so long as they are 'reasonably related' to a legitimate state interest."). It is of course true that laws that impose a "substantial obstacle" to abortion access are impermissible under *Casey*, but that has nothing to do with whether the threshold requirement of a "reasonable relation" to a "legitimate state interest" has been met.

The district court also relied on this passage from *Hellerstedt*:

> The Court of Appeals wrote that a state law is "constitutional if: (1) it does not have the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus; and (2) it is reasonably related to (or designed to further) a legitimate state interest." The Court of Appeals went on to hold that "the district court erred by substituting its own judgment for that of the legislature" when it conducted its "undue burden inquiry," in part because "medical uncertainty underlying a statute is for resolution by legislatures, not the courts."
>
> The Court of Appeals' articulation of the relevant standard is incorrect. The first part of the Court of Appeals' test may be read to imply that a district court should not consider the existence or nonexistence of medical benefits when considering whether a regulation of abortion constitutes an undue burden. The rule announced in *Casey,* however, requires that courts consider the burdens a law imposes on abortion access together with the benefits those laws confer. And the second part of the test is wrong to equate the judicial review applicable to the regulation of a constitutionally protected personal liberty with the less strict review applicable where, for example, economic legislation is at issue. The Court of Appeals' approach simply does not match the standard that this Court laid out in *Casey,* which asks courts to consider whether any burden imposed on abortion access is "undue."

Whole Woman's Health v. Hellerstedt, 136 S. Ct. 2292, 2309–10 (2016) (citations omitted); *see also* Exhibit 2, at 24 (quoting part of this passage). But this portion of *Hellerstedt* was repudiated by Chief Justice Roberts's concurrence in *June Medical*, which backed the Fifth Circuit's interpretation of the "undue burden" test and rejected the characterization adopted by the *Hellerstedt* majority. *See June Medical*, 140 S. Ct. at 2135–39 (Roberts, C.J., concurring in

the judgment); *see also id.* at 2135 ("Laws that do not pose a substantial obstacle to abortion access are permissible, so long as they are 'reasonably related' to a legitimate state interest."); *Hopkins*, 968 F.3d at 915 ("Chief Justice Roberts's . . . opinion" in *June Medical* "is controlling").

Finally, the district court relied on *Hellerstedt*'s description of *Gonzales v. Carhart*, 550 U.S. 124 (2007), which held that courts have an independent obligation review legislative findings that appear in statutes:

> [I]n *Gonzales* the Court, while pointing out that we must review legislative "factfinding under a deferential standard," added that we must not "place dispositive weight" on those "findings." *Gonzalez* went on to point out that the "Court retains an independent constitutional duty to review factual findings where constitutional rights are at stake."

Hellerstedt, 136 S. Ct. at 2310. But no one in this case is asking a court to accept the truth of any "findings" that appear in the Rule or any other enactment. Instead, the parties are disputing whether the "threshold" reasonable-relation test in the *June Medical* concurrence requires anything other than rational-basis review. *Gonzales* has nothing to say on that question.

The district court's opinion is also problematic because it never explains *what*, exactly, the "threshold" reasonable-relation test requires. The district court made clear that it was refusing to apply rational-basis review. *See* Exhibit 2, at 25 ("[T]he Court will not apply rational-basis review"). But it never described the standard of review that it *was* applying. The district-court opinion does not say whether it is applying intermediate scrutiny, strict scrutiny,

Hellerstedt's benefits vs. burdens analysis, or something else.[2] And it does not explain how a "reasonable relation" test can trigger anything more than conventional rational-basis review.

As best we can tell, the district-court opinion appears to be applying some type of "heightened" rationality review that: (1) considers only the purposes declared by the state's officials ex ante; and (2) allows courts to determine whether Rule actually achieves those publicly announced purposes. *See* Exhibit 2, at 25–28. The district court acknowledged, for example, that the state has "legitimate" interests in requiring physicians to dispense abortion drugs in person because an in-person dispensing requirement can help detect contraindications and prevent telemedicine abortions. *See id.* at 27. But the district court found that a requirement to dispense misoprostol in a separate follow-up visit was not "reasonably related" to those interests, because (according to the district court) the extra appointment and time delay will "increase the risks to patients' health." *Id.* at 28. The district court did not, however, consider the declaration of the defendants' expert, which observes that requiring patients to return to the clinic before receiving misoprostol will improve patient safety by: (1) allowing the physician to determine

2. The opinion does say that it will "apply the Supreme Court's analysis in *Hellerstedt* and *Gonzales* to this threshold [reasonable relation] issue," Exhibit 2, at 25, but it does not purport to weigh the Rule's benefits and burdens in this portion of its opinion, and there are no "findings" that a court could review under *Gonzales*.

whether the patient has already aborted before receiving the second drug,[3] which removes the risk of complications from the unnecessary ingestion of misoprostol; (2) allowing a physician to determine whether the patient is experiencing complications from the first drug (mifeprex) that might require a surgical completion of the abortion; and (3) allowing a physician to assess the patient's needs for pain control before the misoprostol is administered. *See* Harrison Decl., ECF No. 19-2, at ¶¶ 31–34.

The standard of review that the district court applied is unknown to the law, and it bears no resemblance to the conventional rational-basis scrutiny that should have been used in assessing whether the Rule is "reasonably related" to a "legitimate state interest." *June Medical*, 140 S. Ct. at 2135 (Roberts, C.J., concurring in the judgment). On rational-basis review, a court is not to determine whether the Rule will actually improve or undermine patients' health. The district court's role is only to ask whether it is *possible to imagine* that the Rule might do something to advance the state's interests in patient safety. *See FCC v. Beach Communications, Inc.*, 508 U.S. 307, 315 (1993) (under rational-basis review, a legislative decision "is not subject to courtroom fact-finding and may be based on rational speculation unsupported by evidence or empirical data."). The Rule easily passes this threshold test, for the reasons provided by the defendants' expert.[4] *See Trump v. Ha-*

3. Approximately 1 out of 20 (5%) of patients who take mifeprex (the first drug) will abort within 24–48 hours before taking misoprostol. *See* Harrison Decl., ECF No. 19-2, at ¶ 31.

4. *See* Harrison Decl., ECF No. 19-2, at ¶ 31–34.

waii, 138 S. Ct. 2392, 2420 (2018) ("[T]he Court hardly ever strikes down a policy as illegitimate under rational basis scrutiny.").

2. The Plaintiffs Failed To Show That The Rule Will Unduly Burden A "Large Fraction" Of Abortion Patients

The district court enjoined the defendants from enforcing the disputed portion of the Rule in any situation. *See* Exhibit 2, at 40. But a "facial" remedy of that sort cannot be sustained unless the plaintiffs show that the Rule will impose an undue burden on a "large fraction" of patients for whom the Rule is relevant. *See Planned Parenthood of Arkansas & Eastern Oklahoma v. Jegley*, 864 F.3d 953, 958–59 (8th Cir. 2017); *In re Rutledge*, 956 F.3d 1018, 1032 (8th Cir. 2020); *Gonzales v. Carhart*, 550 U.S. 124, 167–68 (2007). The district court acknowledged the "large fraction" requirement, yet it held that the plaintiffs had shown that a "large fraction" of abortion patients would be unduly burdened by the Rule. *See* Exhibit 2, at 31–34. None of the district court's arguments are likely to survive appeal.

First, the district court concluded that the Rule would eliminate access to drug-induced abortions in South Dakota, and found that this would "unduly burden" 100% of South Dakota abortion patients seeking drug-induced abortions. *See* Exhibit 2, at 31 ("[T]he court finds that the effect of eliminating medication abortion for all patients who seek a medication abortion at Planned Parenthood is a substantial obstacle for 100% of relevant cases, which constitutes a large fraction."). But the district court used the wrong

denominator, because the court acknowledged that the elimination of drug-induced abortions will affect *all* abortion patients in South Dakota—including patients seeking surgical abortions—by reducing available appointments and increasing wait times for the remaining surgical-abortion slots. *See* Exhibit 2, at 34. The district court cannot claim that the Rule is not "relevant" to patients seeking surgical abortions and simultaneously hold that the Rule affects and unduly burdens those patients.

The district court also used the wrong numerator, because an abortion patient is not "unduly burdened" by the Rule if she remains willing and able to obtain a surgical abortion. The "undue burden" test asks whether a pregnant woman will encounter a substantial obstacle in obtaining an abortion—not whether she will encounter a substantial obstacle in obtaining her preferred method of abortion. *See Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 874 (1992) (an undue burden exists if the state imposes "a substantial obstacle to a woman's choice *to terminate her pregnancy*" (emphasis added)); *Gonzales v. Carhart*, 550 U.S. 124 (2007) (federal statute criminalizing partial-birth abortion does not impose an "undue burden"); *Whole Woman's Health v. Paxton*, 10 F.4th 430, 453 (5th Cir. 2021) (statute outlawing dismemberment abortions did not impose undue burden "[b]ecause there are safe, medically recognized alternatives to live-dismemberment-by-forceps D&E"). The district court noted that *some* abortion patients may encounter "substantial obstacles" if forced to choose between surgical abortion and continuing their pregnancy, such as patients who are contraindicated for sur-

gical abortion. *See* Exhibit 2, at 31. But the district court made no attempt to estimate or calculate this fraction of abortion patients, and the plaintiffs failed to produce evidence that would allow any court to make these estimations or calculations. *See Jegley*, 864 F.3d at 958–59 (district court must "determine" and "estimate" the number of women who would encounter substantial obstacles when conducting a "large fraction" analysis). Instead, the district court assumed that a pregnant woman has a constitutional right to choose the *method* by which she aborts her unborn child, a stance that is incompatible with *Gonzales* and the FDA's decade-long refusal to approve the use of abortion drugs in the United States. *See Benten v. Kessler*, 505 U.S. 1084, 1084 (1992).

Second, the district court concluded that *some* patients will miss or delay their follow-up appointment for misoprostol after ingesting mifeprex, putting them at risk of hemorrhage or other complications that can arise from failing to take misoprostol at the proper time. *See* Exhibit 2, at 32. But the district court made no attempt to estimate or calculate the number of patients that will miss or delay their follow-up misoprostol appointment, and it did not determine whether those patients constitute a "large fraction" of abortion patients for whom the Rule is relevant. Instead, the district court declared that *every* patient seeking a drug-abortion is at "risk" of missing or delaying their misoprostol appointment, and that this risk imposes a "substantial obstacle" on "*all* patients seeking a medication abortion." *Id.* (emphasis added).

The district court's analysis is untenable. A court cannot facially enjoin the enforcement of an abortion regulation based on a harm that will befall only a small fraction of abortion patients—and it cannot circumvent the "large fraction" requirement by claiming that every patient is at "risk" of encountering a harm that will actually affect only a small number of individuals. If this maneuver were allowed, then the partial-birth abortion ban in *Gonzales* would be facially unconstitutional, because every pregnant woman faces a "risk" that a partial-birth abortion might be necessary to preserve her health. *See Gonzales*, 550 U.S. at 166–67 (acknowledging "uncertainty" over whether partial-birth abortion might be "necessary to preserve a woman's health"). Indeed, every abortion regulation would be facially unconstitutional on the district court's view, because there is always a "risk" that an abortion regulation might cause an unexpected or unintended harm. 24-hour waiting periods, for example, impose a "risk" that the patient will be unable or unwilling to return to the clinic after providing informed consent, but a court cannot facially enjoin the enforcement of a waiting period by claiming that every abortion patient is at "risk" of encountering this obstacle. *See Casey*, 505 U.S. at 881–87 (rejecting facial challenge to Pennsylvania's 24-hour waiting period).

Third, the district court held that the Rule would increase travel costs for patients seeking drug-induced abortions. *See* Exhibit 2, at 32–33. But the district court made no attempt to determine the number or fraction of patients who would encounter "substantial obstacles" from having to make an extra

trip to the abortion clinic. Many patients can easily make the extra trip—and those patients will not be "unduly burdened" by the Rule. Other patients will switch to surgical abortion to avoid the extra travel, and those patients will not be encumbered by a "substantial obstacle." The district court must estimate the fraction of patients that will encounter substantial obstacles from requiring a separate misoprostol appointment, as well as the fraction of patients that will not encounter such obstacles. *See Jegley*, 864 F.3d at 958–59. But the plaintiffs failed to produce data or evidence that would allow these estimates to be made.

Observing that 24% of South Dakota abortion patients travel 150 miles round trip for each appointment proves nothing,[5] because many of these patients are seeking surgical abortions and will not need to make an additional trip. In addition, many patients seeking drug-induced abortions can make an extra trip without encountering a substantial obstacle, or will opt for surgical abortions if the added travel is costly or inconvenient. The district court also noted that 39% of South Dakota abortion patients are at or below 110% of the federal poverty level, but this observation is meaningless because abortion funds can defray the costs for indigent patients,[6] and the plaintiffs failed to provide data or evidence on the number of indigent patients who are incapable of obtaining aid from abortion funds or who will forgo abortion on account of the added travel costs. The district court's observation that "just

5. *See* Exhibit 2, at 32–33.
6. *See* https://abortionfunds.org

over half" of abortion patients lack a college degree, and its claim that these patients therefore "have a low degree of flexibility to leave work,"[7] is nothing but rank speculation. And its claim that the 22% of patients who had drug-induced abortions at 10 weeks will encounter a "risk" that the separate-appointment requirement will "push them past 11 weeks LMP when medication abortion is safest"[8] fails to account for the fact that those patients can obtain surgical abortions or seek drug-induced abortions earlier in their pregnancy.

Finally, the district court held that the Rule will unduly burden patients seeking *any* type of abortion in South Dakota by reducing available appointments. *See* Exhibit 2, at 34. But the district court made no attempt to estimate or determine the number or fraction of patients that would encounter substantial obstacles on account of this reduced availability. Instead, the district court declared that all patients will encounter an "added risk" of delayed services, and that this *risk* imposes a "substantial obstacle for a large fraction of abortion services." *Id.* But the plaintiffs must show that the reduced appointments *will* impose substantial obstacles on a large fraction abortion patients, not that they *might* impose such an obstacle. And the district court cannot remedy the plaintiffs' evidentiary shortcomings by allowing the mere "risk" of a delayed appointment to qualify as an undue bur-

7. Exhibit 2, at 33.
8. Exhibit 2, at 33.

den—and then claiming that this "risk" imposes a substantial obstacle on every abortion patient in the state.

3. The District Court's Equal-Protection Holding Is Untenable

The district court purported to apply the "undue burden" test to the plaintiffs' equal-protection claim. *See* Exhibit 2, at 38 ("'The standard of review for regulations that 'touch upon the right to an abortion' is the undue burden standard."). But then the district court did exactly what Chief Justice Roberts's concurrence in *June Medical* said *not* to do: It considered the medical necessity of the Rule along with its burdens and obstacles. *See id.* at 38 ("[T]he third trip and mandatory delay are *medically unnecessary*, they increase health risks for medication abortions patients, and they impose substantial obstacles for medication abortion patients and all abortion patients." (emphasis added)); *id.* ("[T]he Rule is an unnecessary regulation."); *id.* ("Applying the undue burden standard, the court finds that the third appointment and mandatory delay required by the Rule are *unnecessary regulations* and constitute an undue burden on a patient's right to choose an abortion." (emphasis added)). Medical necessity is irrelevant when applying the undue-burden standard—so long as the Rule passes the threshold requirement of having a "reasonable relation" to a "legitimate state interest." *See June Medical*, 140 S. Ct. at 2138 (Roberts, C.J., concurring in the judgment) ("So long as that [threshold] showing is made, the *only* question for a court is whether a law has the 'effect of placing a substantial obstacle in the path of a

woman seeking an abortion of a nonviable fetus.'" (emphasis added) (citation omitted)). Federal courts are not to serve as country's "*ex officio* medical board with powers to approve or disapprove medical and operative practices and standards throughout the United States." *Gonzales*, 550 U.S. at 164 (citations and internal quotation marks omitted).

The district court also held that the Rule fails rational-basis review because "the record clearly shows that misoprostol is safer when taken in the context of medication abortion than when taken for other medical purposes." Exhibit 2, at 39. But a regulation does not fail rational-basis review because it is underinclusive, and South Dakota may choose to impose safety regulations only on abortion-related uses of misoprostol—even if non-abortion uses of misoprostol present similar or greater dangers. *See Dandridge v. Williams*, 397 U.S. 471, 486–87 (1970) ("[T]he Equal Protection Clause does not require that a State must choose between attacking every aspect of a problem or not attacking the problem at all."); *id.* ("The problems of government are practical ones and may justify, if they do not require, rough accommodations—illogical, it may be, and unscientific." (citation and internal quotation marks omitted)); *Vance v. Bradley*, 440 U.S. 93, 108 (1979) ("Even if the classification involved here is to some extent both underinclusive and overinclusive, and hence the line drawn by Congress is imperfect, it is nevertheless the rule that in a case like this perfection is by no means required") (citation and internal quotation marks omitted). More importantly, the Rule's distinction between abortion and non-abortion uses of misoprostol "is not subject to court-

room fact-finding" and "may be based on rational speculation unsupported by evidence or empirical data." *FCC v. Beach Communications, Inc.*, 508 U.S. 307, 315 (1993). It is rational to believe that the Rule might improve safety for some abortion patients. *See* Harrison Decl., ECF No. 19-2, at ¶¶ 31–34. That patient safety might also be enhanced (or further enhanced) by extending the Rule's requirements to non-abortion uses of misoprostol does nothing to defeat the rationality of the Rule.

4. The Defendants Are Likely To Succeed On Their Appeal Of The Remaining Preliminary-Injunction Factors

The district court's analysis of the remaining preliminary-injunction factors depends on its untenable conclusion that the Rule is facially unconstitutional. The plaintiffs cannot show that their patients will suffer irreparable harm absent a showing that the Rule is unconstitutional under Chief Justice Roberts's *June Medical* concurrence. And they cannot show that the balance of equities or the public interest tilts in their favor unless the Rule is unconstitutional. Because the plaintiffs are likely to prevail on their appeal of the district court's constitutional ruling, the district court's analysis of the remaining preliminary-injunction factors are equally unlikely to survive appeal.

B. The Remaining Factors Favor A Stay

The defendants will suffer irreparable injury absent a stay because the injunction prevents the State from enforcing a duly enacted law. *See Maryland v. King*, 567 U.S. 1301 (2012) (Roberts, C.J., in chambers). A stay pending

appeal is also in the public interest, as the Rule reflects the will of South Dakota's elected officials and "is in itself a declaration of the public interest." *Virginian Ry. Co. v. Sys. Fed'n No. 40*, 300 U.S. 515, 552 (1937). And the plaintiffs will not suffer substantial injury from a stay because they can still perform surgical abortions after the rule takes effect, and they have not shown or even alleged that compliance with the rule will cause them "substantial" harm of the sort that counsels against a stay. They have not alleged that their business will close or that their livelihoods will be threatened, or even that they will lose revenue that they cannot recover at the end of trial on account of sovereign immunity. *See Philip Morris USA Inc. v. Scott*, 561 U.S. 1301, 1034 (2010) (Scalia, J., in chambers).

II. The Court Should Expedite This Appeal

The defendants respectfully request expedited consideration of this appeal, regardless of whether the Court grants or denies the motion for a stay. This Court has granted expedited consideration when courts have thwarted state officials from enforcing the State's duly enacted laws. *See, e.g.*, *Craig v. Simon*, 978 F.3d 1043, 1051 (8th Cir. 2020); *Fargo Women's Health Organization v. Schafer*, 18 F.3d 526, 537 (8th Cir. 1994); *Quinn v. Missouri*, 839 F.2d 425, 426 (8th Cir. 1988); *Munson v. Gilliam*, 543 F.2d 48, 50 (8th Cir. 1976). The issues in this case are equally important and worthy of expedited review.

CONCLUSION

The motion to stay the preliminary injunction pending appeal should be granted.

Respectfully submitted.

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CERTIFICATE OF COMPLIANCE

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1. This brief complies with the type-volume limitation of Fed. R. App. P. 27(a)(2)(A) because it contains 5,185 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

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3. This brief and accompanying addendum have been scanned for viruses and are virus-free.

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Dated: February 18, 2022

CERTIFICATE OF CONFERENCE

On February 17, 2022, counsel for the plaintiffs indicated by way of e-mail that they oppose this motion and intend to file a brief in opposition.

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CERTIFICATE OF SERVICE

I certify that on February 18, 2022, this document was electronically filed with the clerk of the court for the U.S. Court of Appeals for the Eighth Circuit and served through CM/ECF upon:

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44:67:04:13. Mifepristone and Misoprostol administration for medical abortion. For the purpose of inducing a medical abortion, a pregnant woman may only take the medications Mifepristone or Misoprostol up to nine weeks after conception. Mifepristone and Misoprostol must be prescribed and dispensed by a licensed physician in a licensed abortion facility consistent with SDCL chapter 34-23A and in compliance with the applicable requirements in SDCL chapter 36-4. A pregnant woman may only take Mifepristone at a licensed abortion facility and only after informed consent has been obtained pursuant to SDCL 34-23A-l0.1 and consistent with SDCL 34-23A-56. Before dispensing Mifepristone. a physician shall provide the notice required by SDCL 34-23A-l0.l(l)(h) and 34-23A-l0.1(3) ensuring that the pregnant woman has notice that if she changes her mind about the medical abortion and decides to carry the baby to term, it is possible to reverse the effects of Mifepristone. After taking Mifepristone and undergoing an observation period in the abortion facility, the pregnant woman may return home. Between 24-72 hours after taking Mifepristone, if the pregnant woman decides to continue with the medical abortion, the pregnant woman must return to the licensed abortion facility to receive the proper amount of Misoprostol. A licensed physician shall dispense the Misoprostol to the pregnant woman in the same manner as required for Mifepristone under this section. Neither Mifepristone nor Misoprostol may be dispensed for the purpose of inducing a medical abortion in any manner contrary to this section. The abortion facility staff shall monitor the pregnant woman for complications for a medically necessary period following each administration of the abortion-inducing medications and report the following information to the Department of Health:

(1) Any complication that requires medical follow-up;
(2) The medical follow-up that was required resulting from any complication;
(3) The facility where the medical follow-up was performed; and
(4) If the pregnant woman was sex trafficked.

The abortion facility staff shall schedule a follow-up appointment with the pregnant woman to return to the abortion facility on the 14th day after taking the medication to confirm that the fetus, placenta, and membranes have been fully expelled.

For the purposes of this section, the term, medical abortion, means a procedure that uses medication to end a pregnancy.

Source: 48 SDR 75, effective January 27, 2022.
General Authority: SDCL 34-23A-51(7)(10)(11).
Law Implemented: SDCL 34-23A-10.1(3), 34-23A-19, 34-23A-56.

UNITED STATES DISTRICT COURT

DISTRICT OF SOUTH DAKOTA

SOUTHERN DIVISION

PLANNED PARENTHOOD MINNESOTA, NORTH DAKOTA, SOUTH DAKOTA and SARAH A. TRAXLER, M.D., Plaintiffs, vs. KRISTI NOEM, Governor, in official capacity; JOAN ADAM, Interim Secretary of Health, Department of Health, in official capacity; PHILIP MEYER, D.O.; President, South Dakota Board of Medical and Osteopathic Examiners, in official capacity, Defendants.	4:22-CV-04009-KES MEMORANDUM OPINION AND ORDER GRANTING PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Plaintiffs, Planned Parenthood Minnesota, North Dakota, South Dakota and Sarah A. Traxler, M.D. (jointly referred to as Planned Parenthood), move under Federal Rule of Civil Procedure 65 for a temporary restraining order and preliminary injunction enjoining defendants, Kristi Noem, Joan Adam, and Philip Meyer, D.O. (jointly referring to as state defendants), from enforcing portions of South Dakota Administrative Rule 44:67:04:13. Docket 3. The court granted the motion for a temporary restraining order on January 26, 2022, and held an evidentiary hearing on the motion for preliminary injunction on February 1, 2022. Docket 18; Docket 20. The state defendants resist Planned

Parenthood's motion. Docket 19. For the following reasons, the court grants Planned Parenthood's motion for a preliminary injunction.

BACKGROUND

I. Abortion Under the Status Quo in South Dakota

Planned Parenthood is a non-profit organization that operates a clinic in Sioux Falls, South Dakota, where it offers a broad range of reproductive health services, including medication and procedural abortions. Docket 1 ¶ 18. Its Sioux Falls clinic is the only generally available abortion provider in the state. Docket 5 ¶ 13. The clinic provides medication abortion through 11 weeks since a patient's last menstrual period (LMP) and procedural abortions through 13.6 weeks LMP. *Id.* ¶ 12. In 2021, Planned Parenthood performed 190 abortions at its Sioux Falls clinic, about 40% of which were medication abortions. *Id.* ¶ 13. And in 2020, of the 125 abortions performed at the clinic, 39.2% were medication abortions. Docket 19-1 at 13.

South Dakota Department of Health's 2020 Report of Induced Abortions provides relevant insight on abortion patients in the state. *See generally id.* Of the patients who received abortions in South Dakota in 2020, 44% reside outside the two counties—Minnehaha and Lincoln—that comprise and surround Sioux Falls. *See id.* at 5. Eighty-six percent of patients were not married; a high school degree or less was the highest educational attainment for 56% of patients. *Id.* at 7. Nearly two-thirds of patients already had one or more living children. *See id.* at 9. Seventy-nine percent of patients had an abortion through 11 weeks LMP. *See id.* at 11. Fifty percent reported that they

"could not afford the child" as a reason for abortion; 17.6% reported that the patient's "emotional health was at risk" as a reason for abortion. *Id.* at 15.

Planned Parenthood provides additional statistics about its abortion patients in Sioux Falls. Specific to medication abortion patients, about 24% travel more than 150 miles round trip to reach the clinic and return home, and 11% travel more than 300 miles round trip. Docket 5 ¶ 41. These distances and associated costs are doubled under the state's existing two-appointment requirement. *Id.* Many of Planned Parenthood's patients rely on public transportation, ride-sharing, or a borrowed car to reach the Sioux Falls clinic. *Id.* ¶ 42. Thirty-one percent of medication abortion patients and 39% of all abortion patients at the Sioux Falls clinic have income below 110% of the federal poverty level.[1] *Id.* ¶ 45. Many abortion patients experience domestic violence, and some are unable to access healthcare without an abusive partner's interference. Docket 6 ¶ 33.

The most common method of medication abortion, and the method used by Planned Parenthood, requires a two-drug regimen: first, mifepristone, and second, misoprostol. Docket 5 ¶ 14; Docket 6 ¶ 11. This method causes a patient to expel their pregnancy in a manner similar to miscarriage. Docket 5 ¶ 14. Under existing South Dakota law, a person who wishes to receive a medication abortion first must meet with a physician at the clinic to begin the informed consent process. Docket 1 ¶ 28; *see* SDCL § 34-23A-56. This is the

[1] "[I]n 2021, 110% of the [federal poverty level] for a family of one was an annual income of $14,168, and $29,150 for a family of four." Docket 5 ¶ 45.

patient's "first appointment." At least 72 hours later, the person must return to the clinic for the "second appointment" where the physician—the same physician who met with the patient during the first appointment—dispenses and administers mifepristone while the patient is at the clinic. Docket 5 ¶¶ 31-32. During the second appointment, the physician also dispenses the second drug, misoprostol, and instructs the person to self-administer it 24 to 48 hours later at a location of their choosing. *Id.* ¶¶ 32, 34. The state defendants note that the current FDA protocol calls for misoprostol to be administered 24 to 48 hours after mifepristone. Docket 19-2 ¶ 7. Medication abortion is safe for most women through 11 weeks LMP. Docket 6 ¶ 25.

At the first appointment, medication abortion patients are given detailed information about the medication abortion method, how and when they would take the two medications, and what to expect in the process. Docket 5 ¶ 29. They are also given the Mifeprex Medication Guide as required by the FDA. *Id.* At the second appointment, the physician confirms that the patient wishes to proceed with the abortion, the physician reviews what was discussed at the first appointment, and the patient and physician finalize a follow-up plan that is documented in the patient's medical record. *Id.* ¶ 31.

At both appointments and throughout the medication abortion process, physicians counsel patients about what effects may normally occur and what symptoms may indicate a complication. Docket 6 ¶ 23. Patients are given the chance to ask questions of their physician, and they are provided with

information to reach a medical professional at any hour of any day. Docket 5 ¶ 30; Docket 6 ¶ 23. Planned Parenthood states:

> In the overwhelming majority of instances, providers can assess patient concerns by phone, reassure them when they are experiencing normal effects (such as cramping and bleeding), help them manage these effects (e.g. with medications or interventions to reduce pain), and as needed prescribe additional medications to help them complete the process or schedule them for follow-up care.

Docket 6 ¶ 24. And in "extremely rare circumstances, providers refer patients to the nearest hospital where emergency care is available." *Id.* The state defendants also note the availability of follow-up medical care that patients avail themselves of when necessary. Docket 19-2 ¶¶ 25, 27, 28.

II. Abortion Under the New Regulation in South Dakota

The Department of Health promulgated Rule 44:67:04:13 regarding the induction of medication abortions. This Rule was to take effect January 27, 2022. The Rule, discussed in greater detail below, requires a patient seeking a medication abortion to attend 4 appointments at specific, regulated time intervals: first, for informed consent; second, at least 72 hours later for administration of mifepristone; third, 24 to 72 hours later for administration of misoprostol; and fourth, "a follow-up appointment . . . on the 14th day after taking the misoprostol[.]" S.D. Admin. R. 44:67:04:13 (2022). The third and fourth clinic appointments are new, additional requirements to existing South Dakota law.

III. Medication Abortion

Since receiving FDA-approval in 2000, over 4 million people in the United States have completed a medication abortion. Docket 5 ¶ 17. Medication

abortion is preferable to a procedural abortion for some people because it is less invasive and offers flexibility in terms of the timing and location for administering the second medication and ultimately completing the abortion. Docket 1 ¶ 30; Docket 5 ¶ 15. Regardless of a patient's preference, a medication abortion is safer and medically indicated for some patients. Docket 5 ¶ 50. For patients with certain conditions, including cervical stenosis, uterine fibroids, or obesity, a medication abortion presents fewer risks than a procedural abortion. *Id.* ¶ 66. For patients with vulvodynia or vaginismus, a procedural abortion is more painful. *Id.* Patients who have experienced rape or other sexual violence may choose a medication abortion to feel more in control and avoid having instruments placed in their vagina. *Id.*; Docket 6 ¶ 29.

As an alternative to a medication abortion, a patient may seek a procedural abortion. In South Dakota, procedural abortion becomes the only option for a patient seeking an abortion after 11 weeks LMP. Docket 6 ¶ 25. A procedural abortion during the first trimester is performed by vacuum aspiration; it requires that the patient's cervix be dilated while a tube is inserted through the vagina and cervix and into the uterus. *Id.* Suction is then applied through the tube to empty the uterus. *Id.* A procedural abortion patient typically receives sedation and/or local anesthesia. *Id.* In 2020 in South Dakota, 58% of patients were under local anesthetic while 2.4% were under general anesthetic. *See* Docket 19-1 at 14. As gestational age advances, procedural abortion becomes more invasive, requiring increased dilation and

possibly the use of forceps. Docket 6 ¶ 25. Many patients consider medication abortion less invasive than procedural abortion. *Id.* ¶ 28.

Planned Parenthood and the state defendants dispute the safety of medication abortion. Planned Parenthood argues that medication abortion is "one of the safest procedures in contemporary medical practice, comparable in safety to over-the-counter medications like ibuprofen and to antibiotics." *Id.* ¶ 12; *see also* Docket 5 ¶ 16. According to the FDA, medication abortion has a 97.4% success rate, and complications are "extremely rare." Docket 5 ¶ 16. For the 2.6% of patients who require intervention following medication abortion, the intervention is typically not urgent. Docket 5-2 at 2. Planned Parenthood points to "[m]ultiple studies [that] have confirmed that far less than one percent of patients experience serious complications from medication abortion—a number that is significantly lower than the rate of serious complications experienced by people who deliver a child." Docket 5 ¶ 16.

The state defendants assert that "[m]edication abortions commonly lead to complications, and at a rate higher than surgical abortions." Docket 19-2 ¶ 15. They point to a 2014 American College of Obstetricians and Gynocologists bulletin that states "[c]ompared with surgical abortions, medica[tion] abortion takes longer to complete, requires more active patient participation, and is associated with higher rates of bleeding and cramping." *Id.* ¶ 22 (first alteration in original). According to the FDA, "[a]bout 85% of patients report at least one adverse reaction following administration of [mifepristone] and misoprostol, and many can be expected to report more than one such

reaction;" these adverse reactions include vomiting, headache, uterine hemorrhage, viral infections, and pelvic inflammatory disease. *Id.* ¶ 23. Of the 4 million medication abortions that have taken place in the United States since 2000, over 4000 patients—or 0.1%—have experienced "adverse events" following the use of mifepristone, including 24 deaths (0.0006%), 1,042 hospitalizations (0.026%), 599 blood transfusions (0.015%), and 412 infections (0.0103%). Docket 19-2 ¶ 25. The state defendants assert that the FDA's data is not reliable due to underreporting, and they estimate a "30-fold" underestimation of "adverse events." *Id.* ¶ 27. If that were the case, the adverse events would total 120,000, or 3% of 4 million. *See id* ¶ 25.

In support of their position, the state defendants point to a 2011 Australian study that found that 3.3% of patients who used mifepristone in their first trimester required emergency room care, compared with 2.2% of procedural abortion patients. *Id.* ¶ 17. In the same study, 5.7% of medication abortion patients were admitted to a hospital following the abortion, compared with 0.4% for procedural abortion patients. *Id.* The state defendants also rely on a 2009 study in Finland that found that of women who had a medication abortion, 15.6% experienced hemorrhaging, 6.7% had incomplete abortions, and 5.9% required surgery to complete the abortion. *Id.* ¶ 18. The study "indicated that hemorrhage and incomplete abortion are more common after medical abortion" than procedural abortions. *Id.* Because mifepristone and misoprostol may depress a patient's immune system, medication abortion patients can be more susceptible to infection. *Id.* ¶ 19. According to FDA data

cited by the state defendants, medication abortion is more successful when completed earlier in pregnancy. *Id.* ¶ 21 ("comparing successful mifepristone abortions at 49 days (98.1%) to successful mifepristone abortions at 63 days (92.7%)"). The state defendants and Planned Parenthood agree that the risks that accompany abortion increase with gestational age. *Id.* ¶ 20; Docket 6 ¶ 36.

Until April 2021, an FDA Risk Evaluation and Mitigation Strategy (REMS) required that mifepristone be dispensed at a clinic. Docket 6 ¶ 18. REMS "is a drug safety program that the FDA can require for certain medications with serious safety concerns." Docket 19-2 ¶ 24 (cleaned up). The FDA suspended the in-clinic administration requirement for mifepristone in April 2021, and it eliminated the requirement in December 2021. Docket 6 ¶ 18. Still, mifepristone may not be safe for all patients, and an in-person examination by a physician is important to identify any contraindications. Docket 19-2 ¶¶ 11-13. Citing the FDA, the state defendants assert that "prudent use of medication abortion requires a follow-up in-person examination to ensure the abortion is complete, i.e., all products of conception have been removed, and to confirm the patient has not suffered serious complications." *Id.* ¶ 14.

Unlike mifepristone, the FDA has never required that misoprostol be dispensed in a clinic, whether it is prescribed for medication abortion or another use. Docket 6 ¶ 19. Planned Parenthood asserts that this is because misoprostol, when used following mifepristone, can cause uterine cramping and vaginal bleeding as soon as two hours after administration, thus it is important for patients to choose a safe and comfortable environment to self-

administer misoprostol. Docket 5 ¶ 19. The original FDA-approved label for mifepristone described that a patient would return to the clinic to receive misoprostol. Docket 6 ¶ 14. But physicians prescribing the medication abortion regimen have been permitted to, and in practice have, directed patients to self-administer misoprostol at home. *Id.* The FDA altered mifepristone's label in 2016, and stated

> There is no medical rationale against permitting the woman to be given the misoprostol on the day of the initial clinic/office visit and self-administer it at a convenient time in the next 24-48 hours at home. This would avoid another visit and the time, transportation, loss of work, inconvenience, etc. that such a visit would involve. Furthermore, given the fact that 22-38% of women abort within 3 hours and 50-60% within 5 hours of [oral administration of] misoprostol, it is preferable for the woman to be in a convenient, safe place (home or at a support person's location) for the expected uterine cramping and vaginal bleeding to occur. Approximately 93% of patients at 10 weeks [LMP] . . . expel their pregnancies within 24 hours of taking misoprostol.

Id. ¶ 15 (citation omitted). The FDA has also found that "rates of treatment failure and of ongoing pregnancy were very similar regardless of whether misoprostol was taken in-clinic or at another location." Docket 5 ¶ 24. The American College of Obstetricians and Gynecologists affirms that mifepristone and misoprostol can be safely administered at home. *Id.* ¶ 25; Docket 6 ¶ 21. Planned Parenthood states "[t]here is simply no medical value in requiring the patient to return to the health center to obtain the misoprostol" and notes that "the only care that would need to be provided at this third in-person dispensing visit would be handing a patient the misoprostol." Docket 5 ¶¶ 34, 36.

In 2019, the American Association of Pro-Life Obstreticians and Gynecologists and the American College of Pediatricians petitioned the FDA to

require three clinic appointments for a medication abortion, including a separate appointment to dispense misoprostol. Docket 6 ¶ 16. The FDA denied the petition's request, noting that "studies support the efficacy of the mifepristone, in a regimen with misoprostol when taken by the patient at home. Therefore, we do not agree that an in-person visit is necessary to manage administration of misoprostol." *Id.*

Misoprostol is available at commercial pharmacies with a prescription and can be used to treat gastric ulcers, incomplete abortions, miscarriage management, postpartum hemorrhage, endometrial and cervical cancer, and difficult IUD insertion/removal. *Id.* ¶¶ 13, 19, 31; Docket 1-4 at 1; Docket 19-2 ¶ 9. Use of misoprostol to address incomplete abortion, management of postpartum hemorrhage, and miscarriage management involves a higher risk of bleeding than for use in a medication abortion. Docket 6 ¶ 31; *see also* Docket 5 ¶ 26 ("misoprostol as used in the medication-abortion regimen is at least as safe as in these other contexts"). The FDA has never required that misoprostol be dispensed at a clinic, even when used as part of a medication abortion. Docket 5 ¶ 23. The only time a person taking misoprostol would be required to have it dispensed by a physician during a separate clinic appointment is in South Dakota under Rule 44:67:04:13. *See infra*; *see also* Docket 1-1 at 3-4.

Allowing patients to take misoprostol at home is especially important for those patients who have been or are a victim of a controlling or abusive partner. *See* Docket 6 ¶ 22. At-home administration of misoprostol by the patient also reduces travel to the clinic and provides flexibility for the patient

around work, parenting, and other responsibilities. *Id.* The South Dakota State Medical Association, in comments submitted to the Department of Health, notes that requiring misoprostol to be administered during a separate clinic appointment is "unnecessary," according to safety data. Docket 1-4 at 1. The Association also states that taking mifepristone without subsequently taking misoprostol leads to a risk of hemorrhage. *Id.* at 2. The Association concludes that "the clinically unnecessary in-person dispensing requirement for Misoprostol does nothing more than create another barrier for the patient that may result in an increased risk of hemorrhage and bad outcome." *Id.*

IV. Rule 44:67:04:13

On September 7, 2021, Governor Noem signed Executive Order 2021-12. Docket 1-2 at 4. The Order sought to address "[i]mpending federal rulemaking" regarding the 2011 REMS that restricted mifepristone to in-person dispensing. *Id.* at 1; *see also id.* at 2 (referring to the REMS "for mifeprex and its approved generic, mifepristone tablets"); Docket 6 ¶ 18. The Order directed the state Department of Health:

> to begin emergency rulemaking to be implemented pursuant to the current FDA REMS, which has had a 20-year track record of helping to protect women's health with sound medical practice, to accomplish the following:
>
> a) With the proliferation of companies organizing to sell these dangerous drugs online to young women, ensure that medicines, drugs, or any other substances prescribed or dispensed with the intent of terminating the pregnancy of a woman shall only be dispensed by a physician licensed in South Dakota to a patient after examining her in-person to rule out contraindications, including but not limited to, ectopic pregnancy;

> b) Provide that no manufacturer, supplier, physician, or any other person may provide any abortion-inducing drugs directly to women in South Dakota via courier, delivery, telemedicine, or mail service;
>
> c) Ensure abortion-inducing drugs shall not be dispensed or provided in any school facility or on state grounds, including but not limited to, elementary schools, secondary schools, and institutions of higher education in this state. The abortion industry is targeting young women via social media and school bathrooms are at risk of becoming the new abortion clinics;
>
> d) Remind licensed physicians dispensing or prescribing abortion-inducing drugs they shall ensure that our state's Informed Consent laws are properly administered;
>
> e) Develop an abortion clinic license specific to the pharmaceutical nature of medical abortion in keeping with South Dakota's existing surgical abortion clinic licensing requirements (i.e. a license for "pill only" clinics).
>
> f) Collect empirical data on how often chemical abortions are performed as a percentage of all abortions, how often women experience complications that require medical follow-up (or a second abortion), where the doctor prescribing or dispensing chemical abortion is located, if she was coerced or sex trafficked and forced to take the pills, and more.
>
> g) As research shows that chemical abortion has four times greater rate of complications that surgical abortion, the state has an interest in collecting data on the rate of complications seen in our emergency rooms and other medical facilities as a result of chemical abortions. I am therefore directing the Department of Health to enhance reporting requirements for this procedure so that we know how often and how harsh the results are.

Docket 1-2 at 2-3.

During the rule making process, the Secretary of the Department of Health stated that the Rule is "required per the Governor's Executive Order 2012-12." Docket 5-2 at 1. A state rule making form asked the Secretary "Why is the rule[] needed?" The Secretary responded:

> To protect the health and safety of women that is at-risk due to the expected FDA lifting of additional safety protocols regarding the use of mifepristone and misoprostol. The rule requires the mifepristone and misoprostol used for a medical abortion may only be prescribed and dispensed by a licensed physician and administered in person in a licensed abortion facility consistent with SDCL 34-23A, and to require reporting of certain information.

S.D. Dep't of Health, Form 14 Small Business Impact Statement Form 1 (Nov. 8, 2021), https://rules.sd.gov/Uploads/684_BusinessImpact Statement.pdf (cited at Docket 5-2 at 1).

Following the rule making process, the Department of Health promulgated Rule 44:67:04:13, which took effect on January 27, 2022, though this court's temporary restraining order enjoined its enforcement until February 9, 2022. Docket 18 at 8. The Rule, in its entirety, states:

> For the purpose of inducing a medical abortion, a pregnant woman may only take the medications Mifepristone or Misoprostol up to nine weeks after conception. Mifepristone and Misoprostol must be prescribed and dispensed by a licensed physician in a licensed abortion facility consistent with SDCL chapter 34-23A and in compliance with the applicable requirements in SDCL chapter 36-4. A pregnant woman may only take Mifepristone at a licensed abortion facility and only after informed consent has been obtained pursuant to SDCL 34-23A-l0.1 and consistent with SDCL 34-23A-56. Before dispensing Mifepristone. a physician shall provide the notice required by SDCL 34-23A-l0.l(l)(h) and 34-23A-l0.1(3) ensuring that the pregnant woman has notice that if she changes her mind about the medical abortion and decides to carry the baby to term, it is possible to reverse the effects of Mifepristone. After taking Mifepristone and undergoing an observation period in the abortion facility, the pregnant woman may return home. Between 24-72 hours after taking Mifepristone, if the pregnant woman decides to continue with the medical abortion, the pregnant woman must return to the licensed abortion facility to receive the proper amount of Misoprostol. A licensed physician shall dispense the Misoprostol to the pregnant woman in the same manner as required for Mifepristone under this section. Neither Mifepristone nor Misoprostol may be dispensed for the purpose of inducing a medical abortion in any manner contrary to this section. The abortion facility

> staff shall monitor the pregnant woman for complications for a medically necessary period following each administration of the abortion-inducing medications and report the following information to the Department of Health:
>
> (1) Any complication that requires medical follow-up;
>
> (2) The medical follow-up that was required resulting from any complication;
>
> (3) The facility where the medical follow-up was performed; and
>
> (4) If the pregnant woman was sex trafficked.
>
> The abortion facility staff shall schedule a follow-up appointment with the pregnant woman to return to the abortion facility on the 14th day after taking the medication to confirm that the fetus, placenta, and membranes have been fully expelled.
>
> For the purposes of this section, the term, medical abortion, means a procedure that uses medication to end a pregnancy.

S.D. Admin. R. 44:67:04:13 (2022). Rule 44:67:04:13 has an effective date of January 27, 2022. *Id.* Violating a rule is a basis for revoking Planned Parenthood's license. S.D. Admin R. 44:67:01:05(1) (2006).

V. Effects of the Rule

Planned Parenthood points to several studies showing that when a law requires multiple clinic appointments to obtain an abortion, patients face delayed care or are prevented from obtaining an abortion. Docket 6 ¶¶ 53-54. During the evidentiary hearing before this court, Planned Parenthood stated that it was not aware of any other states that presently require three or more clinic appointments to obtain a medication abortion. Planned Parenthood states that "the Rule will harm [its] patients in numerous and unprecedented ways, and will severely restrict access to abortion services in South Dakota, if not end medication abortion entirely in the state." Docket 5 ¶ 37. In her affidavit, Dr. Traxler states that "[b]ased on the available evidence, I also believe that the mandatory delay and extra trip for misoprostol required by this

Rule will likely put patients at risk." *Id.* ¶ 38. She points to a "recent double-blind, placebo-controlled, randomized trial indicat[ing] that patients who interrupt the medication-abortion regimen partway through—by taking mifepristone but not following it with misoprostol within the recommended 24-to-48-hour time frame—may be at increased risk of significant hemorrhage." *Id.*; *see also* Docket 6 ¶ 46. An interrupted regimen could also lead to an incomplete abortion requiring follow-up medical care or a delay causing the pregnancy to continue beyond the 13.6 weeks LMP when abortion is available at the clinic. *See* Docket 6 ¶¶ 49-50. Dr. Traxler concludes that the mandatory delay and separate third appointment required under the Rule thus increase the likelihood that a patient will not be able to make it back to the clinic within the recommended time-frame, if at all, for administration of misoprostol and thus suffer the consequences of an interrupted regimen discussed above. Docket 5 ¶ 39. Planned Parenthood also notes that because misoprostol should ideally be administered within 48 hours after mifepristone, the period of time during which a patient should return for the third appointment is actually shorter than the 72 hours provided under the Rule. Docket 6 ¶ 44.

Planned Parenthood asserts that the mandatory delay and travel necessitated by the third appointment will create obstacles for medication abortion patients. *See* Docket 5 ¶¶ 39-40. Planned Parenthood asserts that "most abortion patients are parents, most have low incomes, and many work inflexible minimum-wage jobs." *Id.* ¶ 40. Planned Parenthood asserts that the cost of travel is an obstacle for patients given that many have low income and

do not have personal transportation. *Id.* ¶ 45; *see supra*. Planned Parenthood also states that the cost of travel is in addition to the cost of the abortion itself, including for those who have health coverage through the Affordable Care Act or Medicaid, neither of which cover abortion expenses except when the patient's life is in danger. Docket 5 ¶ 45. And each trip results in additional costs for missing work, school, and childcare. *Id.* ¶ 46. Planned Parenthood also states that each trip imposes an obstacle for patients who are trying to keep their abortion private. *Id.* ¶ 47. This is particularly true, they note, for survivors of abuse and sexual assault, who live under the watchful eye of their abuser. *Id.* ¶ 48. Additional obstacles related to travel are unforeseen circumstances, like unpredictable weather, that can delay travel or make it impossible for a patient to arrive at the right appointment interval and for their appointment time. *See id.* ¶ 44.

Planned Parenthood states that the third appointment would be "effectively impossible to comply with an as operational matter." *Id.* ¶ 51. It argues that because of its clinic schedule and attending physicians' availability, it would not be able to comply with the additional appointments and the regulated time intervals under the Rule. *Id.* ¶¶ 53-60. There are currently two abortion providers who live out of state and travel to Sioux Falls so that the clinic can provide abortion services two or three times each month. *Id.* ¶¶ 53-54, 57-58. Planned Parenthood plans to add two additional physicians in 2022. *Id.* ¶ 55. The clinic currently schedules abortions four weeks out. *Id.* ¶ 58. Planned Parenthood states that the personal and

professional obligations of their physicians preclude them from traveling back for a third appointment within 24 to 72 hours under the Rule. *Id.* ¶¶ 59-60. For these reasons, Planned Parenthood states that the Rule would force the organization to stop providing medication abortions and deprive patients of this option. *Id.* ¶ 62.

Planned Parenthood states that it will have to reduce appointments by 30% if the Rule is enforced by the state defendants. *Id.* ¶ 68. This will lead to delays for all patients seeking an abortion at the clinic, and the delay will preclude some patients from seeking an abortion altogether because they will be past 13.6 weeks LMP. *Id.* The delay in services is compounded by the existing 4-week scheduling delay. *Id.* For those who are still able to complete an abortion before 13.6 weeks LMP, Planned Parenthood notes that health risks increase as the gestational age increases. *Id.* ¶ 69. Planned Parenthood concludes that "[d]elays caused by the Rule will ultimately harm these patients." *Id.*

Planned Parenthood states that even if it was able to offer medication abortions under the Rule, delays caused by a third appointment and physician availability could push some patients past the 11 weeks LMP cut-off for a safe medication abortion. *Id.* ¶ 74. It notes that in 2021, approximately 22% of medication abortions at the clinic occurred at 10 weeks LMP, "which means for a significant percentage of [] patients any further delays could push them out of reach for a medication abortion." *Id.* ¶ 74; *see also* Docket 6 ¶ 25.

Planned Parenthood moves the court to enjoin "the Rule's mandatory delay and separate visit requirements for the dispensing of misoprostol." Docket 1 at 26.

LEGAL STANDARD

The "purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held." *Little Rock Fam. Plan. Servs. v. Rutledge*, 984 F.3d 682, 690 (8th Cir. 2021) (quoting *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981)); *see also Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 113 (8th Cir. 1981) (en banc) (a preliminary injunction "preserve[s] the status quo until the merits are determined."). When ruling on a motion for a preliminary injunction, the court must consider (1) the threat of irreparable harm to the moving party; (2) balancing this harm with any injury an injunction would inflict on other parties; (3) the likelihood of success on the merits; and (4) the public interest. *Dataphase Sys., Inc.*, 640 F.2d at 113. "While no single factor is determinative, the probability of success factor is the most significant." *Carson v. Simon*, 978 F.3d 1051, 1059 (8th Cir. 2020) (cleaned up). The movant has the burden of persuasion on a motion for preliminary injunction and must do so by a "clear showing." *Planned Parenthood Minn., N.D., S.D. v. Rounds*, 530 F.3d 724, 736 (8th Cir. 2008) (en banc) (citing *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (per curiam)).

DISCUSSION

I. Undue Burden Claim

A. Undue Burden Claim Under 42 U.S.C. § 1983

The state defendants argue that Planned Parenthood "cannot invoke 42 U.S.C. § 1983 to assert [] third-party rights, because the cause of action in section 1983 allows litigants to assert only their *own* rights, and not the rights of third parties." Docket 19 at 11. At oral argument and in their brief, the state defendants concede that Planned Parenthood has Article III standing. *See id.* The issue is "whether the plaintiffs have identified a *cause of action* that authorizes their lawsuit." *Id.*; *see Davis v. Passman*, 442 U.S. 228, 239 n.18 (1979) ("*cause of action* is a question of whether a particular plaintiff is a member of the class of litigants that may, as a matter of law, appropriately invoke the power of the court." (emphasis in original)).

The Eighth Circuit in *Pediatric Specialty Care, Inc. v. Arkansas Department of Human Services*, 293 F.3d 472 (8th Cir. 2002), recognized that third-party plaintiffs can bring a claim under § 1983. *Id.* at 478 ("[t]he provider plaintiffs in this case have standing to assert the rights of their [] patients"). The Seventh Circuit in *Planned Parenthood of Wisconsin, Inc. v. Van Hollen*, 738 F.3d 786 (7th Cir. 2013), came to the same conclusion in the context of abortion litigation. There, the court identified numerous cases, including *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 903-04 (1992) and *Planned Parenthood of Central Missouri v. Danforth*, 428 U.S. 52, 62 (1976), where "doctors and abortion clinics were found to have had standing

. . . pursuant to section 1983." *Van Hollen*, 738 F.3d at 795. Thus, the court concluded that the "justiciability of such cases is not in question." *Id.* Finally, a district court in the Eighth Circuit, addressing the same issue, relied on the analysis in *Van Hollen* when it concluded that the "Supreme Court has repeatedly allowed abortion providers to raise the rights of their patients in cases brought under § 1983[.]" *Little Rock Fam. Plan. Servs. v. Rutledge*, 397 F. Supp. 3d 1213, 1264 (E.D. Ark. 2019) (citing *Whole Woman's Health v. Hellerstedt*, 579 U.S. 582 (2016); *Gonzales v. Carhart*, 550 U.S. 124 (2007); *Ayotte v. Planned Parenthood of N. New Eng.*, 546 U.S. 320 (2006); *Bellotti v. Baird*, 428 U.S. 132 (1976)).

Here, the court finds the state defendants' analysis of § 1983 ignores multiple instances where the Eighth Circuit and the Supreme Court have recognized a cause of action under § 1983 brought by abortion providers on their own behalf and on behalf of their patients. *See, e.g., Little Rock Fam. Plan. Servs.*, 984 F.3d 682. Thus, Planned Parenthood's undue burden claim is properly brought under 42 U.S.C. § 1983.

B. Likelihood of Success on the Merits

"Success on the merits has been referred to as the most important of the four factors." *Roudachevski v. All-Am. Care Ctrs., Inc.*, 648 F.3d 701, 706 (8th Cir. 2011). When a challenged law was "implemented through legislation or regulation[] developed through presumptively reasoned democratic processes," the court analyzes whether the movant is *likely* to succeed on the merits. *Rounds*, 530 F.3d at 732 (quoting *Able v. United States*, 44 F.3d 128, 131 (2d

Cir. 1995) (per curium)) (noting that "likelihood of success" is a higher standard than a "fair chance" of success). Because the Rule is a state regulation promulgated under South Dakota's rule making process, the court will apply the likelihood of success standard.[2] At the preliminary injunction stage, "the speculative nature" of the likelihood of success inquiry "militates against any wooden or mathematical application of the test." *United Indus. Corp. v. Clorox Co.*, 140 F.3d 1175, 1179 (8th Cir. 1998).

"[A] state cannot 'impose an undue burden on the woman's ability to obtain an abortion.' " *Hopkins v. Jegley*, 968 F.3d 912, 914 (8th Cir. 2020) (quoting *June Med. Servs. L.L.C. v. Russo*, 140 S. Ct. 2103, 2135 (2020) (Roberts, C.J., concurring)). The "threshold requirement [is] that the State have a 'legitimate purpose' and that the law be 'reasonably related to that

[2] The Eighth Circuit has not indicated whether the "likelihood of success" standard applies to a state regulation promulgated by the executive branch at the direction of an executive order. In *Rounds*, the Court relied on the Second Circuit's reasoning in *Able*: the likelihood of success standard applies when "a party seeks to stay government action taken in the public interest pursuant to a statutory or *regulatory scheme*[.]" 530 F.3d at 731 (emphasis added) (quoting *Able*, 44 F.3d at 131). In *Richland/Wilkin Joint Powers Authority v. U.S. Army Corps of Engineers*, 826 F.3d 1030 (8th Cir. 2016), the Eighth Circuit affirmed the district court's finding that the lower "fair chance of prevailing" standard applied when plaintiffs sought to enjoin a construction project "authoriz[ed] . . . pursuant to expert agency recommendation." *Id.* at 1040-41. Here, Planned Parenthood seeks to enjoin an administrative rule that was "required" by executive order to be promulgated. *See supra* at 13. Whether this process is akin to "adopting a complex statute through fulsome debate" is an open question. *See Richard/Wilkin Joint Powers Auth.*, 826 F.3d at 1040. Relying on the word "regulation" in *Rounds* and *Able*, the court here applies the "likelihood of success" standard.

goal.' " *June Medical*, 140 S. Ct. at 2138. "So long as that showing is made, the only question for a court is whether a law has the 'effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus.' " *Id.* (quoting *Casey*, 505 U.S. at 877).

1. Whether the Rule is reasonably related to a legitimate purpose

Planned Parenthood argues that the Rule lacks a legitimate purpose regarding the Rule's mandatory third appointment for dispensing misoprostol; and, even if there is a legitimate purpose, the Rule is not reasonably related to that purpose. *See* Docket 4 at 11-14. The state defendants argue that rational basis review applies to this issue. Docket 19 at 20. And under rational basis, the state defendants conclude that the Rule is reasonably related to three purported purposes that they identify and explain in their brief. *Id.* at 20-23. The state defendants urge the court to apply the rational basis standard articulated in *Heller v. Doe*, 509 U.S. 312 (1993):

> A statute is presumed constitutional and "[t]he burden is on the one attacking the legislative arrangement to negative every conceivable basis which might support it," whether or not the basis has foundation in the record. Finally, courts are compelled under rational-basis review to accept a legislature's generalizations even when there is an imperfect fit between means and ends.

Id. at 320 (cleaned up) (quoting *Lehnhausen v. Lake Shore Auto Parts Co.*, 410 U.S. 356, 364 (1973); *see also* Docket 19 at 20.

But in *Casey*, the Supreme Court stated that "a statute which, while furthering . . . [a] valid state interest, has the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible

means of serving its legitimate ends." 505 U.S. at 877. And in *Hellerstedt*, the Supreme Court held that it "is wrong to equate the judicial review applicable to the regulation of a constitutionally protected personal liberty with the less strict review applicable where, for example, economic legislation is at issue." *Hellerstedt*, 136 S. Ct. at 2309. That standard of "less strict review," rational basis, is well-established: that a law will be upheld "if there is any reasonably conceivable state of facts that could provide a rational basis for the classification" in the law. *TCF Nat'l Bank v. Bernanke*, 643 F.3d 1158, 1165 (8th Cir. 2011) (quoting *FCC v. Beach Commc'ns, Inc.*, 508 U.S. 307, 313 (1993)).

Declining to use rational basis, the Supreme Court in *Hellerstedt* explained:

> [I]n *Gonzales* the Court, while pointing out that we must review legislative "factfinding under a deferential standard," added that we must not "place dispositive weight" on those "findings." *Gonzalez* went on to point out that the "Court retains an independent constitutional duty to review factual findings where constitutional rights are at stake."

Hellerstedt, 136 S. Ct. at 2310 (emphasis omitted) (internal citations omitted) (quoting *Gonzales*, 550 U.S. at 165). In *Gonzales*, the Court looked to the "recitals" of the challenged law to determine its purpose. 550 U.S. at 156. Without similar recitals or legislative findings accompanying the challenged law in *Hellerstedt*, the Court "infer[red] that the legislature sought to further a constitutionally acceptable objective[.]" 136 S. Ct. at 2310. But there, the Court also looked to the "great weight of the evidence" in front of the district court

and its review of the benefits of the law to determine its purpose. *Id.* at 2311; *see also June Medical*, 140 S. Ct. at 2138 (Roberts, C.J., concurring) ("*Casey* discussed benefits in considering the threshold requirement that the State have a "legitimate purpose" and that the law be "reasonably related to that goal.").

Here, the court finds that the Rule regulates a constitutionally protected personal liberty, a person's right to seek an abortion. *See Hellerstedt*, 136 S. Ct. at 2309-10. Thus, the court will not apply rational basis review and will apply the Supreme Court's analysis in *Hellerstedt* and *Gonzales* to this threshold issue.

The South Dakota Secretary of Health stated that the Rule was promulgated because it was "required per the Governor's Executive Order 2021-12." Docket 5-2 at 1. Several purposes are readily apparent in the recitals and directives in the Executive Order: (1) respond to FDA rulemaking lifting the 2011 REMS restricting mifepristone to in-person dispensing; (2) ensure that mifepristone and misoprostol are dispensed in-person to medication abortion patients by a physician after an in-person examination to rule out contraindications; (3) restrict where abortion medications are dispensed and bar telemedicine medication abortions; (4) reinforce the state's informed consent procedure; (5) collect empirical data on medication abortions; and (6) enhance reporting requirements for medication abortions. Docket 1-2 at 2-3. The Secretary's subsequent summary of the Rule's purposes is consistent with the objectives identified in the Executive Order: respond to "the expected FDA

lifting of additional safety protocols regarding the use of mifepristone and misoprostol" to ensure that mifepristone and misoprostol are only "prescribed and dispensed by a licensed physician and administered in-person in a licensed abortion facility consistent with SDCL 34-23A, and to require reporting of certain information." S.D. Dep't of Health, Form 14 Small Business Impact Statement Form 1 (Nov. 8, 2021), https://rules.sd.gov/Uploads/684_BusinessImpactStatement.pdf (cited at Docket 5-2 at 1). Because Planned Parenthood seeks an injunction of the mandatory third appointment and accompanying delay period, the court focuses on the first three purposes, as identified above, that relate to the administration of misoprostol in the Governor's Executive Order.

First, Planned Parenthood argues that the Department's stated purpose of responding to FDA changes regarding both mifepristone and misoprostol is misguided because the FDA has not recently taken action with regard to misoprostol. Docket 4 at 12. Here, the record indicates that in 2021 the FDA suspended, and later eliminated, the REMS that required in-person administration of mifepristone. But the FDA, which has never required in-person administration of misoprostol, has not recently made any change regarding misoprostol. While the Executive Order did not incorrectly refer to FDA changes regarding misoprostol, the Secretary's explanation of the Rule did. Thus, to the extent the Rule seeks to respond to FDA changes regarding misoprostol, the Rule lacks a legitimate purpose.

Second, Planned Parenthood argues that the purposes of banning telemedicine abortions and requiring in-person dispensing of mifepristone and misoprostol following an examination for counterindications are moot, because existing state law requires two clinic appointments, including an examination, before mifepristone and misoprostol are dispensed in-person. *Id.* at 13. Here, Planned Parenthood has only established that these purposes are redundant with existing law, not that they are illegitimate. Planned Parenthood states that at-home administration of mifepristone is safe, but it does not argue that a ban on telemedicine or requiring in-person dispensing (as opposed to administration) are undue burdens on patients. Thus, the courts finds that the second and third purposes are legitimate.

Alternatively and additionally, Planned Parenthood claims that the Rule's mandatory third appointment for the administration of misoprostol, and the accompanying delay period, are not reasonably related to the Rule's stated purposes. *Id.* at 12-13. They argue that any further restriction on misoprostol has no reasonable relation to anything in the Executive Order. *See id.* Specifically, they point out that misoprostol is already dispensed by a physician in the clinic; the Executive Order makes no mention of the need for an additional appointment or a mandatory time delay. *See id.* And Planned Parenthood argues that the Rule's third appointment and time delay actually put patients at greater risk and impose an undue burden. *Id.* at 14.

Here, the third appointment and mandatory time delay appear for the first time in the Rule. Nothing in the Executive Order indicates a change in

FDA regulations regarding misoprostol. And as the court discusses below, the third appointment and time delay for misoprostol increase the risks to patients' health. Thus, the court finds that the portion of the Rule sought to be enjoined is not reasonably related to the purposes as stated by the executive branch. Because the part of the rule challenged by Planned Parenthood fails to meet this threshold requirement, that part of the Rule should be enjoined on this basis alone. But to fully address the parties' arguments regarding Planned Parenthood's facial and as-applied challenges to the Rule, the court proceeds with the undue burden analysis.

2. Whether the Rule imposes an undue burden

To establish an undue burden, Planned Parenthood must demonstrate that "in a large fraction of the cases in which [the Rule] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion." *Planned Parenthood of Ark. & E. Okla. v. Jegley*, 864 F.3d 953, 958 (8th Cir. 2017) (quoting *Casey*, 505 U.S. at 895). "The Supreme Court has clarified that "cases in which the provision at issue is relevant" is a narrower category than "all women," "pregnant women," or even "women seeking abortions identified by the State." *Id.* (emphasis omitted) (quoting *Hellerstedt*, 136 S. Ct. at 2320); *see also Casey*, 505 U.S. at 894-95. In *Jegley*, the Eighth Circuit found that "because the contract-physician requirement only applies to medication-abortion providers, the 'relevant denominator' here is women seeking medication abortions in Arkansas." *Id.* There are three issues that must be resolved in order to determine whether Planned Parenthood has met their

burden: (1) in what cases is the Rule "relevant"; (2) does the Rule create a "substantial obstacle to a woman's choice to undergo an abortion" in those cases in which the Rule is "relevant"; and (3) is the substantial obstacle present in a "large fraction" of the "relevant" cases. *See, e.g.*, *Planned Parenthood Minn., N.D., S.D. v. Daugaard*, 799 F. Supp. 2d 1048, 1060 (D.S.D. 2011) ("the relevant cases are those that involve a woman who has chosen to undergo an abortion and would otherwise not consult with a pregnancy help center"); *Casey*, 505 U.S. at 895 (limiting the relevant cases to "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").

Planned Parenthood claims that the Rule is relevant only to patients seeking a medication abortion in South Dakota. Docket 24 at 15. They argue that the Rule is an "actual restriction" only for medication abortion patients, and not all of its abortion patients. *Id.* (citing *Hellerstedt*, 136 S. Ct. at 2320). The state defendants argue that the denominator should include all people seeking an abortion at Planned Parenthood because Planned Parenthood's undue burden argument rests on the effects the Rule would have on that group. Docket 19 at 14.

Under *Jegley* and *Casey*, the court finds that the relevant cases, or denominator, are limited to Planned Parenthood's medication abortion patients. But because part of Planned Parenthood's undue burden argument rests on effects on all its abortion patients, the court finds that the Rule is also relevant

to that group as well. Thus, the court analyzes whether the Rule imposes a substantial obstacle on a large fraction of patients in both groups.

The next step is to determine whether the Rule creates "a substantial obstacle to a woman's choice to undergo an abortion" for a "large fraction" of relevant cases. *See Daugaard*, 799 F. Supp. 2d at 1060. The Supreme Court "has made clear that a State may promote but not endanger a woman's health when it regulates the methods of abortion." *Stenberg v. Carhart*, 530 U.S. 914, 931 (2000) (citations omitted). "As with any medical procedure, the State may enact regulations to further the health or safety of a woman seeking an abortion. Unnecessary health regulations that have the purpose or effect of presenting a substantial obstacle to a woman seeking an abortion impose an undue burden on the right." *Casey*, 505 U.S. at 878.

Concerning what constitutes a large fraction, the Supreme Court in *Casey* addressed the constitutionality of, among other provisions, a "spousal notification requirement." *Id.* at 893. The relevant cases in *Casey* with regard to that requirement were "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." *Id.* at 895. The Court held that the requirement was unconstitutional under the "large fraction" test after it found that the requirement was "likely to prevent a significant number of [those] women from obtaining an abortion." *Id.* at 893-94. This language and reasoning indicates that the term "large fraction" should not be construed as some numerical threshold that must be established. *See id.* The Eighth Circuit

has recognized that 18% can constitute a "large fraction," though it has not set that number, or any number, as a brightline minimum. *See Planned Parenthood, Sioux Falls Clinic v. Miller*, 63 F.3d 1452, 1462 & n.10 (8th Cir. 1995).

Planned Parenthood argues that the third appointment for dispensing misoprostol, and the accompanying 24 to 72 hour delay for the third appointment, impose substantial obstacles for medication abortion patients. Docket 4 at 15-23. First, they argue that the Rule would eliminate access to medication abortion. *Id.* at 15; Docket 24 at 15. On this point, the record indicates that Planned Parenthood would not be able to comply with the Rule's third appointment and 24 to 72 hour delay requirements based on physician availability. This result would affect 100% of Planned Parenthood's medication abortion patients. Medication abortion is safer for some patients than a procedural abortion. A medication abortion is medically indicated for some patients. And for those who are victims of domestic violence or rape, medication abortion is preferable. The alternative, procedural abortion, is more invasive—a fact that imposes an obstacle for patients who prefer the flexible timing and lesser degree of bodily invasion of a medication abortion. Thus, the court finds that the effect of eliminating medication abortion for all patients who seek a medication abortion at Planned Parenthood is a substantial obstacle for 100% of relevant cases, which constitutes a large fraction.

Second, Planned Parenthood argues that the third appointment for dispensing misoprostol, and the accompanying 24 to 72 hour delay, for the

third appointment, impose substantial obstacles for medication abortion patients because, even if Planned Parenthood could implement the Rule, the Rule is an unnecessary regulation. Docket 4 at 15-23. The record shows that the FDA—an entity that both Planned Parenthood and the state defendants point to as authoritative—does not require misoprostol to be administered by a physician in a clinic. The FDA allows self-administration of misoprostol at a location of the patient's choosing. And the FDA recommends that it be administered 24 to 48 hours after mifepristone, not 24 to 72 hours as is permitted under the Rule. Specifically, the FDA has found that there is no medical rationale against permitting self-administration of misoprostol. But there is medical rationale for not requiring a separate clinic appointment for the administration of misoprostol. The requirement of a third appointment necessarily puts all medication abortion patients at greater risk of hemorrhage or other complications because it requires an unnecessary trip to the clinic that could be missed or delayed, thus interrupting the medication regimen. Those unnecessary risks are burdens in themselves. The court finds that the third appointment and mandatory delay are an unnecessary regulation and thus a substantial obstacle for all patients seeking a medication abortion.

Planned Parenthood argues that even if it could comply, the Rule would impose substantial travel and logistical obstacles on abortion patients, 40% of whom are mediation abortion patients. Docket 4 at 20. Forty-four percent of patients would have to travel to the Sioux Falls clinic from somewhere outside the clinic's two-county area. Twenty-four percent of patients would travel 150

miles round trip, or 450 miles total for the three appointments required under the Rule. For the many patients who rely on public transportation, ride-sharing, or a borrowed vehicle, the likelihood that they could successfully return for a third appointment time within the 24 to 72 hour delay period is low. And because 39% of all patients are at or below 110% of the federal poverty level, the third appointment adds to the already substantial financial obstacles of travel. Patients' travel obstacles are compounded by the fact that just over half of patients have a high school degree or less education—a fact that indicates patients have a low degree of flexibility to leave work. Nearly-two thirds needs to arrange care for their other child or children, especially the 86% who are unmarried. In addition to these many obstacles to traveling to their third appointment, patients face the obstacle of increased risk to health if they are unable to timely return for the third appointment and receive misoprostol to complete the abortion. For the 22% of patients who had a medication abortion at 10 weeks LMP in 2021, the Rule imposes an obstacle by risking that the third appointment will push them past 11 weeks LMP when medication abortion is safest and available at Planned Parenthood. Because people seeking an abortion in South Dakota must already travel to the Sioux Falls clinic twice, requiring a third appointment at a specific time would further compound patients' financial, logistical, and health obstacles. The court finds these requirements do "not merely make abortions a little more difficult or expensive to obtain," but rather amount to substantial obstacles for a large fraction of medication abortion patients. *See Casey*, 505 U.S. at 893.

Finally, Planned Parenthood argues that the Rule imposes a substantial burden on all abortion patients, because the Rule would require the clinic to end medication abortion services. Docket 4 at 18-19. This, in turn, would congest Planned Parenthood's already busy schedule of procedural abortions, and thus would have a negative effect on the availability of procedural abortions. Planned Parenthood asserts that, based on physician availability, it would have to reduce appointments by 30% if the Rule's third appointment and mandatory delay are not enjoined. Planned Parenthood is already scheduling abortions four weeks out. Abortions are safer and lower risk when performed earlier in gestation. Thus, the added risk associated with delayed services for all patients is a substantial obstacle for a large fraction of all patients.

At this stage, Planned Parenthood has made a clear showing that the third appointment and mandatory delay impose substantial obstacles on a large fraction of relevant cases regardless of whether the relevant cases consist of all abortions in South Dakota or the smaller subset of medication abortions only. Thus, the court finds that the Rule likely imposes an undue burden on Planned Parenthood and its patients' right to seek an abortion. And because Planned Parenthood has made a threshold showing that it is likely to succeed on the merits of its facial challenge to the Rule, the court proceeds to weigh the other *Dataphase* factors as to the undue burden claim.[3] *Rounds*, 530 F.3d at 732.

[3] Alternatively, Planned Parenthood seeks as-applied relief in its complaint. Docket 1 at 26. The state defendants do not dispute the evidence in the record

B. Threat of Irreparable Harm

"The basis of injunctive relief in the federal courts has always been irreparable harm and inadequacy of legal remedies." *Id.* at 732 n.5 (quoting *Beacon Theatres, Inc. v. Westover*, 359 U.S. 500, 506-07 (1959)). Under the second *Dataphase* factor, the movant must show it is "likely to suffer irreparable harm in the absence of preliminary relief[.]" *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). "Constitutional violations, however brief, are unquestionably irreparable." *Daugaard*, 799 F. Supp. 2d at 1076. As discussed above, Planned Parenthood has established that it is likely to succeed on the merits with regard to enjoining enforcement of the Rule's mandatory third appointment. Thus, the court finds that this factor, the threat of irreparable harm, weighs in favor of granting the preliminary injunction.

C. Balance of the Hardships

The balance of the harms factor calls for the court to balance the harms that would result in the following scenarios: (1) if the preliminary injunction was improperly denied because plaintiffs prevailed on the merits of the case; and (2) if the preliminary injunction was improperly granted because

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that medication abortion is medically and socially safer for some patients, including those who wish to conceal their abortions from abusive partners. Thus, Planned Parenthood is entitled to relief as-applied to patients for whom a medication abortion is medically indicated and to patients who are at a health or safety risk of making a return trip to the clinic for a third appointment. *See Jegley*, 508 F. Supp. 3d 361, 392 (E.D. Ark. 2020); *see also Planned Parenthood Sw. Ohio Region v. DeWine*, 696 F.3d 490, 494 (6th Cir. 2012); *Planned Parenthood Cincinnati Region v. Taft*, 444 F.3d 502, 511-12, 514 (6th Cir. 2006).

defendants prevailed on the merits of the case. *See Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 284 (4th Cir. 2002) ("[W]hile cases frequently speak in the short-hand of considering the harm to the plaintiff if the injunction is denied and the harm to the defendant if the injunction is granted, the real issue in this regard is the degree of harm that will be suffered by the plaintiff or the defendant if the injunction is *improperly* granted or denied."); *see also Hillerich & Bradsby Co. v. Christian Bros., Inc.*, 943 F. Supp. 1136, 1142 (D. Minn. 1996) (balancing the harms by looking at what the harm to the defendant would be if the injunction were "improperly granted").

If the preliminary injunction is improperly denied, many people will have been unduly burdened by the Rule, and, in effect, delayed or precluded from obtaining an abortion. The extent of the harm if the preliminary injunction turns out to have been improperly granted is that the state defendants will have been wrongly prevented from carrying out their official duties.

After balancing the harm to the parties, the court finds that all parties are potentially exposed to harm if the preliminary injunction is found to have been improperly granted or denied. But when considering the nature of the parties' interest that are at stake, the potential harm to Planned Parenthood's interests are more severe because the harms directly affect a constitutional right. Thus, the court finds that the balance of the harms weighs in favor of granting the preliminary injunction.

D. Public Interest

As discussed above, Planned Parenthood has demonstrated by a clear showing that it is likely to succeed on the merits of its undue burden claim. There is a public interest in protecting the right to choose an abortion. And the public has a clear interest in ensuring the supremacy of the United States Constitution. While the public also has an interest in the enforcement of state administrative rules, that interest is secondary to the public interest expressed above. Thus, the court finds that this factor weighs in favor of granting the preliminary injunction.

II. Equal Protection Claim

Planned Parenthood claims that the Rule's differential treatment of patients and providers using misoprostol for abortions violates the Equal Protection Clause. They argue that the Rule treats patients taking misoprostol for the purpose of terminating their pregnancy different than similarly situated patients taking it for other purposes, for example to manage miscarriage or postpartum hemorrhaging. This differential treatment "fails equal protection review under any level of scrutiny," and they cite the standard for both rational basis and strict scrutiny. Docket 4 at 23. The state defendants argue that rational basis applies, and under that standard the Rule does not violate the Equal Protection Clause. Docket 19 at 23.

Under the Fourteenth Amendment, "[n]o State shall make or enforce any law which shall . . . deny to any person within its jurisdiction the equal protection of the laws." U.S. Const. amend. XIV, § 1. And under the Equal

Protection Clause in the Amendment, "all persons similarly situated shall be treated alike." *Stevenson v. Blytheville Sch. Dist. # 5*, 800 F.3d 955, 970 (8th Cir. 2015) (quoting *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 439 (1985)). The standard of review for regulations that "touch upon the right to an abortion" is the undue burden standard. *Planned Parenthood of Mid-Missouri & E. Kan., Inc. v. Dempsey*, 167 F.3d 458, 464 (8th Cir. 1999) (citing *Casey*, 505 U.S. at 871-74, 884-85); *see also id.* ("Since *Casey*, we have applied the undue burden test in cases involving legislation that affects the right to abortion.")

Here, the Rule requires that a physician administer misoprostol to a patient at a third, separate clinic appointment only when prescribed in the context of a medication abortion. For every other use of misoprostol, a patient can self-administer the medication at a location of their choosing without a separate, third appointment. As described above, the third trip and mandatory delay are medically unnecessary, they increase health risks for medication abortions patients, and they impose substantial obstacles for medication abortion patients and all abortion patients. The record indicates that misoprostol, when used for purposes other than medication abortion, is less safe and increases the risk of bleeding, but in those contexts does not require a separate, third appointment with a licensed physician. This finding further establishes that the Rule is an unnecessary regulation. Applying the undue burden standard, the court finds that the third appointment and mandatory delay required by the Rule are unnecessary regulations and constitute an undue burden on a patient's right to choose an abortion. Thus, the Rule's

disparate treatment of misoprostol and abortion patients taking misoprostol violates the equal protection clause.

Alternatively, the court reviews Planned Parenthood's equal protection claim under the rational basis standard. The state defendants argue that the Rule's overarching purpose is patient health. *See, e.g.*, Docket 19 at 21-22. But the record clearly shows that misoprostol is safer when taken in the context of medication abortion than when taken for other medical purposes. But under the Rule, patients are allowed to self-administer misoprostol when taken for purposes other than medication abortion. The FDA, an entity the state defendants cite to as authoritative on the subject, states that there is no medical reason for a patient to return to a clinic for a separate appointment for the administration of misoprostol. Notwithstanding the relative safety of misoprostol when prescribed for a medication abortion, if the Rule were concerned with patient health, it would recommend that misoprostol be administered 24 to 48 hours after mifepristone, as the FDA recommends, and not 24 to 72 hours later as the Rule requires. Medication abortion patients are already examined for counterindications during their first two appointments, a fact that further negates the state defendants' argument in favor of patient health. The court finds no rational basis for the third appointment and mandatory delay for administration of misoprostol under the Rule. Thus, under rational basis, the Rule violates the Equal Protection Clause.

Whether under heightened scrutiny for regulations touching upon the right to an abortion, or under rational basis, Planned Parenthood has

established by a clear showing that it is likely to succeed on its equal protection claim. This is the most significant of the four preliminary injunction factors. And because this claim carries with it similar constitutional considerations as Planned Parenthood's undue burden claim, the court finds that the remaining three preliminary injunction factors weigh in favor of granting the injunction. *See supra.*

CONCLUSION

Planned Parenthood has met its burden of establishing that the four factors for a preliminary injunction weigh in its favor. Thus, it is

ORDERED that Planned Parenthood's motion for preliminary injunction (Docket 3) is granted. The state defendants are enjoined from enforcing the third appointment for the dispensing of misoprostol and the mandatory delay accompanying the third appointment. The state defendants are enjoined from enforcing the pertinent part of the Rule against Planned Parenthood. Specifically, the portion of the Rule enjoined is:

> Between 24-72 hours after taking Mifepristone, if the pregnant woman decides to continue with the medical abortion, the pregnant woman must return to the licensed abortion facility to receive the proper amount of Misoprostol. A licensed physician shall dispense the Misoprostol to the pregnant woman in the same manner as required for Mifepristone under this section.

Dated February 8, 2022.

BY THE COURT:

/s/ *Karen E. Schreier*
KAREN E. SCHREIER
UNITED STATES DISTRICT JUDGE