UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

WHOLE WOMAN'S HEALTH ALLIANCE, *et al.*, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Case No. 3:23-cv-00019-RSB

DEFENDANTS' COMBINED MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND IN SUPPORT OF MOTION TO STAY PROCEEDINGS

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INTRODUCTION

More than twenty-two years ago, the U.S. Food and Drug Administration (FDA) approved mifepristone as safe and effective for medical termination of early pregnancy subject to certain restrictions (known since 2007 as a Risk Evaluation and Mitigation Strategy (REMS)). Over the years, in response to new evidence, FDA has approved modifications that have made those restrictions less burdensome. Most recently, on January 3, 2023, FDA approved a modification to the REMS making those restrictions less burdensome on patients and the healthcare system than they have ever been during the entire time the drug has been on the market. Plaintiffs brought this suit to challenge the January 2023 REMS modification, arguing that mifepristone should not be subject to any restrictions. But rather than seek relief from the January 2023 REMS modification, Plaintiffs seek a preliminary injunction that would *lock it in place* by prohibiting FDA "from altering the status quo with respect to the 2023 REMS in the states of Virginia, Montana, and Kansas as it relates to the availability of mifepristone during the pendency of this litigation." ECF No. 10, at 37.

There is no basis to grant that relief. *First*, the preliminary injunction that Plaintiffs request is unnecessary to prevent any ongoing or imminent irreparable harm to them. Plaintiffs fear that a Texas federal district court's order staying the approval of mifepristone might be permitted to take effect. *See All. for Hippocratic Med. v. FDA*, No. 2:22-cv-223-Z, 2023 WL 2825871 (N.D. Tex. Apr. 7, 2023) (the *Alliance* Order). But the Supreme Court has stayed that order pending the Fifth Circuit's resolution of an appeal and pending the disposition of any timely filed petition for a writ of certiorari. *See*

Danco Labs., LLC v. All. for Hippocratic Med., 143 S. Ct. 1075 (mem.) (Apr. 21, 2023). Thus, any harm from the *Alliance* Order is speculative. And even if there were any non-speculative reason to believe harm is imminent, a preliminary injunction in this case would not be an appropriate means of preventing it. Plaintiffs may not ask this Court to enter the requested preliminary injunction as a means to collaterally attack an order that might be entered by another court in another case.

Second, for similar reasons, Plaintiffs lack Article III standing to seek their requested preliminary injunction. To the extent Plaintiffs claim standing based on injuries from the January 2023 REMS modification, those injuries plainly would not be redressed by a preliminary injunction that enjoins FDA from "altering" that same January 2023 REMS modification. And to the extent Plaintiffs seek to establish standing based on injuries from the *Alliance* Order, those injuries are speculative and not fairly traceable to FDA's challenged conduct.

Third, even if Plaintiffs' requested preliminary injunction could prevent imminent irreparable harm, that relief is improper because it is not tailored to their claims or to the final agency action they challenge. Indeed, the relief sought in this motion is entirely divorced from the claims Plaintiffs assert.

Plaintiffs rely heavily on *Washington v. FDA*, No. 1:23-cv-3026-TOR, 2023 WL 2825861 (E.D. Wash. Apr. 7, 2023), which granted relief to 17 States and the District of Columbia similar to the relief Plaintiffs seek here. But this Court should not follow that decision, which entered relief that no party asked for and that the parties' briefing never

addressed.[1] Moreover, whereas the *Alliance* Order was scheduled to go into effect in seven days at the time the *Washington* district court granted relief, the *Alliance* Order is now stayed pending resolution of appellate proceedings (including possible Supreme Court review) and may never go into effect.

Even setting these problems aside, the Court should deny Plaintiffs' Motion for several more reasons. Plaintiffs are not likely to succeed on the merits because they failed to administratively exhaust their claims by filing a citizen petition with FDA, as required by agency regulations. Plaintiffs also disregard FDA's reasoned explanation for its January 2023 REMS modification and fail to show that FDA acted unreasonably or contrary to law. Moreover, the equities and public interest weigh against a preliminary injunction. And finally, even if Plaintiffs were entitled to some relief, they fail to explain why statewide relief would be necessary to redress their alleged injuries.

For all these reasons, the Court should deny Plaintiffs' Motion for Preliminary Injunction. In addition (or in the alternative to ruling on Plaintiffs' Motion at this time), the Court should grant Defendants' concurrently filed motion to stay this case pending the resolution of appellate proceedings in *Alliance*. The Court should not expend judicial resources on this matter now when the Supreme Court may resolve, narrow, or provide

[1] The plaintiffs in *Washington* asked the court to "preliminarily enjoin[] FDA from (1) enforcing or applying the 2023 REMS, and (2) taking any action to remove mifepristone from the market or otherwise cause the drug to become less available." *Washington*, No. 1:23-cv-03026, ECF No. 3, at 34. But those plaintiffs never requested an injunction requiring FDA to maintain the January 2023 REMS modification. The court fashioned that relief, without briefing from the parties, after determining that it would be inappropriate to prohibit enforcement or application of the January 2023 REMS modification. *See Washington*, 2023 WL 2825861, at *10.

guidance on issues Plaintiffs raise in their Complaint. Moreover, such a stay would avoid harm to Defendants and would not prejudice Plaintiffs.

BACKGROUND

I. Statutory and Regulatory Background

The Federal Food, Drug, and Cosmetic Act (FDCA) generally prohibits the interstate distribution of new drugs that have not received FDA approval. 21 U.S.C. § 355(a). In deciding whether to approve a new drug, FDA evaluates whether a new drug application contains scientific evidence demonstrating that the drug is safe and effective for its intended uses. *Id.* § 355(d); *see also* 21 C.F.R. §§ 314.50, 314.105(c). Similarly, when a sponsor submits a supplemental drug application proposing changes to the conditions of approval for a drug (such as changes to a drug's labeling or FDA-imposed restrictions), FDA reviews the scientific evidence submitted in support of the changes to determine whether those changes should be approved. *See* 21 C.F.R. § 314.70.

In 1992, FDA issued regulations (the Subpart H regulations) providing for the imposition of conditions "needed to assure safe use" of certain new drugs that satisfy the other requirements for approval under the FDCA. Final Rule, 57 Fed. Reg. 58,942, 58,958 (Dec. 11, 1992) (codified at 21 C.F.R. § 314.520). In the Food and Drug Administration Amendments Act of 2007, Congress codified and expanded the Subpart H regulations by giving FDA authority to require a Risk Evaluation and Mitigation Strategy, or REMS, when it determines that restrictions are necessary to ensure that the benefits of a drug outweigh the risks. *See* Pub. L. No. 110-85, tit. IX, § 901 (codified at, *inter alia*, 21 U.S.C. § 355-1). FDA may require that a REMS include "elements to assure

safe use" if necessary to mitigate a serious health risk and if certain statutory criteria relating to ensuring safety and minimizing the burden of restrictions are satisfied. *See* 21 U.S.C. § 355-1(f)(1)-(2).

The 2007 statute expressly incorporated drugs with existing Subpart H restrictions into the new REMS framework. *See* Pub. L. No. 110-85, tit. IX, § 909 (21 U.S.C. § 331 note). Specifically, Congress "deemed" such drugs to have a REMS in effect, with the Subpart H restrictions serving as "elements to assure safe use." *Id.* § 909(b). Thereafter, application holders for such drugs were required to submit supplemental drug applications with a proposed REMS, which FDA then reviewed. *See id.*

The 2007 statute also provided standards for modifying an existing REMS. *See* 21 U.S.C. § 355-1(g)(4). As relevant here, FDA may require an applicant to "submit a proposed modification" to the REMS if the agency "determines that 1 or more goals or elements should be added, modified, or removed" from the approved REMS to "ensure the benefits of the drug outweigh the risks of the drug" or "minimize the burden on the health care delivery system of complying with the strategy." *Id.* § 355-1(g)(4)(B).

II. Factual and Procedural Background

In 2000, FDA approved the marketing of mifepristone (under the brand name Mifeprex) in a regimen with misoprostol for medical termination of early intrauterine pregnancy. At the same time, to assure mifepristone's safe use, FDA placed certain Subpart H restrictions on the distribution and use of the drug product, including requirements that (1) patients sign a Patient Agreement Form; (2) prescribers certify

(among other things) that they have the ability to accurately date pregnancies, diagnose ectopic pregnancies, and either perform surgical intervention or arrange for others to perform it if necessary; and (3) the drug be dispensed in person at a certified prescriber's office. *See* ECF No. 1-2.

Because these Subpart H restrictions were in place when the 2007 statute took effect, Mifeprex was "deemed to have in effect an approved [REMS]" that continued these restrictions as "elements to assure safe use." Pub. L. No. 110-85, § 909(b)(1); *see also* 73 Fed. Reg. 16,313 (Mar. 27, 2008). In 2011, FDA approved the Mifeprex REMS after determining that it remained "necessary … to ensure the benefits of [mifepristone] outweigh the risks of serious complications." Katzen Decl. Ex. A. When FDA approved a generic version of the drug in 2019, it approved a single, shared system REMS, known as the Mifepristone REMS Program, for both Mifeprex and the generic version. Katzen Decl. Ex. B.

FDA has since reviewed and modified the Mifepristone REMS Program.[2] As relevant here, on May 7, 2021, FDA announced that it would review elements of the Mifepristone REMS Program to determine whether those elements should be modified. Katzen Decl. Ex. C at 8. FDA's review encompassed "multiple different sources of information," including "published literature," "safety information," adverse event reports, a "REMS assessment report" submitted by the applicants, and "information provided by advocacy groups, individuals, and the [a]pplica[tion holders]." *Id.* at 10.

[2] https://perma.cc/7BQC-AJP9 (see Approval Date(s) and History, Letters, Labels, Reviews for NDA 020687).

The agency's literature review covered material published between March 29, 2016 (the date of an earlier REMS modification) and July 26, 2021, and included publications found on PubMed and Embase or provided by "advocacy groups, individuals, plaintiffs in [*Chelius v. Becerra*, No. 1:17-493-JAO-RT (D. Haw.)], and the [a]pplicat[ion holders]," as well as "healthcare providers and researchers." *Id.* at 10-11.

On December 16, 2021, FDA announced its conclusion that "the Mifepristone REMS Program continues to be necessary to ensure the benefits [of mifepristone] outweigh the risk[s]" and that "certain elements of the Mifepristone REMS Program remain necessary to assure the safe use of mifepristone." Katzen Decl. Ex. D at 6. Specifically, FDA found that the prescriber certification and Patient Agreement Form requirements continued to be necessary. *Id.* at 22. At the same time, FDA found that the REMS "must be modified to remove" the in-person dispensing requirement, so as to "allow, for example, dispensing of mifepristone by mail via certified prescribers or pharmacies." *Id.* at 35. Thus, FDA concluded based on its review that "mifepristone will remain safe and effective if the in-person dispensing requirement is removed, provided all the other requirements of the REMS are met and pharmacy certification is added." *Id.*

FDA explained its conclusions in a detailed, 49-page review memorandum. Katzen Decl. Ex. C. *First*, FDA explained its rationale for retaining the prescriber certification requirement, which allows mifepristone to be prescribed only by providers who are certified under the REMS and attest, among other things, that they can accurately date pregnancies, diagnose ectopic pregnancies, and perform or arrange for

surgical intervention for patients who experience complications. *Id.* at 12-14. FDA explained that it "continue[d] to be concerned that absent these provider qualifications, serious and potentially fatal complications associated with medical abortion, including missed ectopic pregnancy and heavy bleeding from incomplete abortion, would not be detected or appropriately managed." *Id.* at 13. FDA found "no evidence" in the relevant literature "to contradict [FDA's] previous finding that" the requirement that prescribers certify to having certain abilities is "necessary to mitigate the serious risks associated with the use of mifepristone in a regimen with misoprostol." *Id.* Thus, the agency concluded that prescriber certification "continues to be a necessary component of the REMS to ensure the benefits of mifepristone for medical abortion outweigh the risks," and that "[t]he burden of prescriber certification has been minimized to the extent possible" because each provider need only provide one certification to each of the two drug application holders for mifepristone. *Id.*

Second, FDA explained that the Patient Agreement Form "ensures that patients are informed of the risks of serious complications associated with mifepristone," "serves as an important counseling component," and "document[s] that the safe use conditions of the Mifepristone REMS Program have been satisfied." *Id.* at 14-15. In 2021, FDA concluded that "literature that focused on the informed consent process" "d[id] not provide evidence that would support removing" the Patient Agreement Form requirement. *Id.* at 16-17. Among other things, the agency found that the single-page Patient Agreement Form "is an important part of standardizing the medication information on the use of mifepristone that prescribers communicate to their patients,"

"does not impose an unreasonable burden on providers or patients," and thus "remains necessary to assure the safe use of Mifepristone." *Id.* at 18.

Third, based on an extensive review of the REMS assessment reports submitted by the application holders, postmarketing safety data (including adverse event data), and the published literature, *id.* at 18-40, FDA concluded that the in-person dispensing requirement was no longer necessary. For much of the COVID-19 public health emergency, FDA had not enforced the in-person dispensing requirement.[3] Based on that experience, FDA found that "there does not appear to be a difference in adverse events between periods during the COVID-19 [public health emergency] when the in-person dispensing requirement was being enforced and periods when the in-person dispensing requirement was not being enforced." *Id.* at 38. Moreover, postmarketing data did not show any new safety concerns with use of the drug. *Id.* The agency therefore concluded that "mifepristone will remain safe and effective for medical abortion if the in-person dispensing requirement is removed, provided all the other requirements of the REMS are met, and pharmacy certification is added." *Id.* at 39.

The pharmacy certification requirement permits pharmacies to dispense mifepristone if they become certified by agreeing to follow applicable REMS

[3] In July 2020, a district court preliminarily enjoined enforcement of that requirement in light of the pandemic. *Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183, 233 (D. Md. 2020). Although the Supreme Court eventually stayed that preliminary injunction in January 2021, *see FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 478, 578 (2021) (mem.), FDA announced in April 2021 that it would exercise enforcement discretion with respect to the in-person dispensing requirement during the public health emergency. *See* ECF No. 1-11.

requirements. FDA expressly tied the addition of the pharmacy certification requirement to the removal of the in-person dispensing requirement. *See id.* at 40 ("Given this modification to the dispensing requirements in the REMS, it is necessary to add a requirement for certification of pharmacies ...."). Adding this requirement would "incorporate[] pharmacies into the REMS, ensur[ing] that [they] are aware of and agree to follow applicable REMS requirements, and … that mifepristone is only dispensed pursuant to prescriptions that are written by certified prescribers." *Id.* "Without pharmacy certification," FDA explained, "a pharmacy might dispense product that was not prescribed by a certified prescriber." *Id.* Consequently, to "ensure the benefits of mifepristone for medical abortion outweigh the risks while minimizing the burden imposed by the REMS on healthcare providers and patients," FDA determined that the Mifepristone REMS Program must be modified to "remov[e] the in-person dispensing requirement" and add the "requirement for pharmacy certification." *Id.* at 41.

FDA directed the drugs' application holders to submit supplemental applications proposing these modifications to the REMS. Katzen Decl. Exs. E & F. The application holders submitted their supplemental applications in 2022, and FDA approved them on January 3, 2023, consistent with its December 16, 2021, determination that mifepristone will remain safe and effective for its approved use if the in-person dispensing requirement is removed, provided all the other REMS requirements are met and the pharmacy certification requirement is added. Katzen Decl. Exs. G at 9-15 & K.

III. *Alliance* and *Washington* Cases

On November 18, 2022, several physicians and physician groups brought suit in the U.S. District Court for the Northern District of Texas challenging FDA's 2000 approval of mifepristone, as well as subsequent actions by FDA, including approval of modifications to the drug's REMS and other conditions of use. *See Alliance*, No. 2:22-cv-00223-Z, ECF No. 1 (N.D. Tex. Nov. 18, 2022). The *Alliance* plaintiffs sought a preliminary injunction requiring FDA to withdraw or suspend the approval of the drug and the other challenged actions. *See Alliance*, No. 2:22-cv-00223-Z, ECF No. 6 (N.D. Tex. Nov. 18, 2022).

While the motion for a preliminary injunction was pending in *Alliance*, a coalition of States sued FDA in the U.S. District Court for the Eastern District of Washington challenging the January 2023 REMS modification. *See Washington v. FDA*, No. 1:23-cv-3206, ECF No. 1 (E.D. Wash. Feb. 23, 2023). The *Washington* plaintiffs sought a preliminary injunction prohibiting FDA from (1) applying or enforcing the REMS and (2) taking any action to remove mifepristone from the market or otherwise cause the drug to become less available. *See Washington*, No. 1:23-cv-3026, ECF No. 3 at 34 (E.D. Wash. Feb. 24, 2023).

On April 7, 2023, the *Alliance* and *Washington* courts decided their respective preliminary injunction motions within minutes of each other. In *Alliance*, the court did not order FDA to take any action to withdraw or suspend approval of mifepristone, but instead "stayed" FDA's 2000 approval of the drug "and all subsequent actions related to that approval"—an order that would have effectively halted the approval without any

action by FDA. *Alliance*, 2023 WL 2825871, at *32. The *Alliance* court stayed its order for seven days to give FDA time to seek emergency relief from the U.S. Court of Appeals for the Fifth Circuit. *Id.*

Shortly thereafter, the *Washington* court entered a preliminary injunction. The *Washington* court declined to enjoin FDA from enforcing or applying the January 2023 REMS modification, explaining that doing so would have the effect of "eliminat[ing] the ability of pharmacies to provide the drug, thereby reducing its availability." *Washington*, 2023 WL 2825861, at *10. Instead, it preliminarily enjoined FDA from "altering the status quo and rights as it relates to the availability of Mifepristone under the current operative January 2023 Risk Evaluation and Mitigation Strategy under 21 U.S.C. § 355-1 in Plaintiff States." *Id.* at *11. The court subsequently clarified that its order "must be followed" "irrespective" of the *Alliance* Order. *Washington*, No. 1:23-cv-03026, ECF No. 91, at 5, 6 (E.D. Wash. Apr. 13, 2023).

FDA and Danco Laboratories, the Mifeprex application holder, appealed the *Alliance* Order and sought an emergency stay of that order. *All. for Hippocratic Med. v. FDA*, No. 23-10362, ECF No. 20 (5th Cir. Apr. 10, 2023). On April 12, the Fifth Circuit stayed the district court's order as to the 2000 approval of mifepristone but not as to subsequent modifications to the conditions of use, including the January 2023 REMS modification. *All. for Hippocratic Med. v. FDA*, No. 23-10362, 2023 WL 2913725 (5th Cir. Apr. 12, 2023).

FDA and Danco then sought a further stay of the district court's order from the Supreme Court. The Supreme Court granted that request, staying the *Alliance* Order

"pending disposition of the appeal in the United States Court of Appeals for the Fifth Circuit and disposition of a petition for writ of certiorari." *Danco Labs.*, 143 S. Ct. 1075 (mem.). After expedited briefing on the merits, the Fifth Circuit heard oral argument on the appeal from the *Alliance* Order on May 17.

IV. The Present Litigation

On May 8, Plaintiffs, who are abortion providers in Virginia, Montana, and Kansas, filed suit in this Court, asserting essentially the same claims as the plaintiffs in *Washington*. That same day, Plaintiffs moved for a preliminary injunction. But unlike the plaintiffs in *Washington*, Plaintiffs here do not seek to preliminarily enjoin FDA's enforcement or application of the REMS. Instead, they ask for the relief that the *Washington* court entered, and to apply that relief throughout Plaintiffs' States.

STANDARD OF REVIEW

A preliminary injunction is an "extraordinary and drastic" remedy that "may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. NRDC, Inc.*, 555 U.S. 7, 20-23 (2008); *Munaf v. Geren*, 553 U.S. 674, 689-90 (2008). The party seeking such relief must "demonstrate that (1) it is 'likely to succeed on the merits'; (2) 'irreparable harm' is 'likely' 'in the absence of preliminary relief'; (3) 'the balance of equities tips in [its] favor'; and (4) 'an injunction is in the public interest.'" *Henderson for NLRB v. Bluefield Hosp. Co.*, 902 F.3d 432, 439 (4th Cir. 2018) (quoting *Winter*, 555 U.S. at 20). The third and fourth factors "merge" when the federal government is the defendant. *Nken v. Holder*, 556 U.S. 418, 435 (2009).

ARGUMENT

I. There Is No Basis To Grant A Preliminary Injunction Against Speculative Harms That Do Not Arise From The Challenged Agency Action.

Plaintiffs ask this Court to enter a preliminary injunction that would freeze in place the sole final agency action that they challenge, the January 2023 REMS modification,[4] on the theory that "a host of threats ha[s] encircled the provision of medication abortion, including pending federal litigations to which Plaintiffs are not a party." ECF No. 10, at 1. But Plaintiffs have not shown that the harms they fear will ever come to pass, much less that they will do so imminently. Even if the harms were concrete and imminent, moreover, a preliminary injunction in this case would be an improper means of preventing them.

A. Plaintiffs Fail To Show Their Requested Relief Would Prevent Irreparable Harm

To obtain a preliminary injunction, a plaintiff must make a "clear showing" that, absent such relief, it will suffer irreparable harm that is "neither remote nor speculative, but actual and imminent." *Direx Israel, Ltd. v. Breakthrough Med. Corp.*, 952 F.2d 802, 812 (4th Cir. 1991). A plaintiff fails to make that showing when its allegations of irreparable

[4] While Plaintiffs assert that "they have also demonstrated that an injunction blocking the imposition of the 2023 REMS is appropriate," ECF No. 10, at 20, they do not ask for a *preliminary* injunction blocking the January 2023 REMS modification, as the rest of their Motion confirms. *See* ECF No. 8, at 2 ("In this motion, Plaintiffs seek narrow preliminary relief enjoining Defendants from deviating from the status quo of provision of mifepristone under the 2023 REMS during the pendency of this litigation."); ECF No. 8-1 (similar); ECF No. 10, at 37 (similar). Nor do they explain how preliminarily enjoining the January 2023 REMS modification would redress any alleged harm. *Cf. Washington*, 2023 WL 2825861 at *10 (rejecting such relief because it "would eliminate the ability of pharmacies to provide the drug, thereby reducing its availability").

harm are "conditioned on possible future events." *Id.* at 816. That is true of the harms that Plaintiffs fear here.

As noted, Plaintiffs do not seek a preliminary injunction against enforcement or application of the January 2023 REMS modification. They assert no irreparable harm from that challenged action, *see* ECF No. 10, at 33-35, and any such harm would not be redressed by a preliminary injunction requiring FDA to maintain that very same action. Instead, Plaintiffs argue that they would be harmed if the *Alliance* Order were to take effect in whole or in part by various downstream effects of that order. *See id.*; *see also id.* at 35 (seeking "legal protection from the havoc that might ensue from any orders affecting the availability of mifepristone as a result of" the *Alliance* Order). But as discussed above, the Supreme Court has stayed that order pending the Fifth Circuit's resolution of an appeal and any Supreme Court proceedings that may follow, *Danco Labs.*, 143 S. Ct. 1075 (mem.), and thus it is entirely speculative whether that order will ever take effect, what form it would it take, and how it would affect Plaintiffs. And because there is certainly no prospect of that order taking effect anytime soon, Plaintiffs face no "actual and imminent" harm, *Direx*, 952 F.2d at 812, from the *Alliance* Order.[5]

Even if Plaintiffs had identified any ongoing or imminent irreparable harm, any such harm could not properly be prevented by a preliminary injunction issued in this

[5] In passing, Plaintiffs also refer to "a new citizen petition to FDA seeking to have mifepristone's approval revoked." ECF No. 10, at 1. That citizen petition asks FDA to consider an issue not implicated by any of Plaintiffs' claims, namely whether the agency should "revoke its actions to approve Mifepristone and modify the associated regimen (including the REMS) until the agency conducts the required consultation with the

case. Plaintiffs' theory, in essence, is that if the Fifth Circuit and/or (assuming that a party seeks certiorari) the Supreme Court decline to disturb the district court's order in *Alliance*, then *this* Court should try to counteract its effects by imposing a contrary order. But "federal district courts lack the power to void or otherwise alter other courts' orders through a collateral attack." *McNeil v. Brown*, No. 17-cv-2602, 2019 WL 1003583, at *4 (D.D.C. Feb. 28, 2019). And in any event, the Court could not shield Plaintiffs from a harm imposed *by another court* through an injunction *against FDA*, which would not be the source of that harm. *See Vapor Tech. Ass'n v. FDA*, 977 F.3d 496, 501 (6th Cir. 2020) ("The Maryland court's injunction was not an action by the FDA—it was an action taken by the court itself. The Maryland court is an independent third party that is not part of the present suit. Vapor Stockroom cannot sue the FDA to attack the Maryland court's decision.").[6]

B. Plaintiffs Lack Standing To Seek Their Requested Preliminary Injunction

For similar reasons, Plaintiffs lack standing to seek the form of relief they request in their Motion for Preliminary Injunction. To meet the "irreducible constitutional minimum of standing," *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992), a plaintiff must "allege personal injury fairly traceable to the defendant's allegedly unlawful conduct

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United States Fish and Wildlife Service ('FWS') and National Marine Fisheries Service ('NMFS') … as compelled by the [Endangered Species Act of 1973]." Katzen Decl. Ex. L. FDA has not decided the citizen petition, and Plaintiffs do not claim that the citizen petition poses an imminent risk of injury. *See* ECF No. 10, at 33-35. Moreover, Plaintiffs cite no authority for the proposition that the mere *submission* of a citizen petition by a third party is enough to establish irreparable harm and standing.

[6] Plaintiffs could have sought to intervene in *Alliance* to protect any interests of theirs, but they did not.

and likely to be redressed by the requested relief." *California v. Texas*, 141 S. Ct. 2104, 2113 (2021) (quoting *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 (2006)). Because a plaintiff must demonstrate standing for "each form of relief that is sought," *Carolina Youth Action Project v. Wilson*, 60 F.4th 770, 778 (4th Cir. 2023) (quoting *Town of Chester v. Laroe Estates, Inc.*, 581 U.S. 433, 439 (2017)), Plaintiffs must demonstrate standing to seek their requested relief, specifically a preliminary injunction prohibiting FDA from altering "the current operative January 2023 [REMS]." *See* ECF Nos. 8, 8-1, 10.[7]

Plaintiffs cannot meet that burden. Any alleged injuries fairly traceable to the January 2023 REMS modification—the only "allegedly unlawful conduct" of Defendants at issue in this case, *see California*, 141 S. Ct. at 2113—could not possibly be redressed by a preliminary injunction requiring FDA to *maintain* the January 2023 REMS modification. And injuries that are *not* fairly traceable to the January 2023 REMS modification—such as injuries that would spring from the *Alliance* Order taking effect—cannot establish Plaintiffs' standing. *See Lujan*, 504 U.S. at 560 (holding that an injury is not "fairly traceable" to challenged agency conduct if it is "the result of the independent action of some third party not before the court"); *Vapor Tech.*, 977 F.3d at 501 (holding that a plaintiff lacked standing to sue FDA based on injuries caused by another court

[7] Plaintiffs claim to bring this suit partly on behalf of their staff and patients. *See, e.g.*, Compl. ¶ 18. But third-party standing "does not relieve plaintiffs of the need to independently establish their *own* Article III standing." *Ass'n of Am. Physicians & Surgeons v. FDA*, 13 F.4th 531, 547 (6th Cir. 2021) (emphasis added). In any event, the alleged injuries to Plaintiffs' staff and patients are no more imminent, fairly traceable to FDA action, or redressable by the relief sought than Plaintiffs' own alleged injuries.

order because those injuries were not "fairly traceable" to FDA since the other court was "an independent third party").

Moreover, Plaintiffs' fears that mifepristone will become less available absent an injunction fail to establish standing for the same reasons they fail to establish irreparable harm. To satisfy the first element of standing, a plaintiff must allege an injury that is "actual" or "certainly impending," *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013), not "conjectural" or "hypothetical," *Lujan*, 504 U.S. at 560. "'[A]llegations of possible future injury' are not sufficient." *Clapper*, 568 U.S. at 409 (quoting *Lujan*, 504 U.S. at 565 n.2). But Plaintiffs have not alleged any imminent plans by FDA to impose new restrictions on access to mifepristone or to otherwise alter the REMS that FDA approved modifications to only a few months ago. Although the *Alliance* Order would alter the legal status of mifepristone, as explained above, the Supreme Court fully stayed that order through completion of the appeal, including any proceedings in the Supreme Court. As discussed, moreover, it would be improper for this Court to enter an injunction with the intent of blocking the order of a different district court.[8]

[8] Plaintiffs suggest that the REMS "stigmatize[s]" mifepristone, thus allowing "antiabortion activists and hostile enforcers" to "weaponiz[e]" the REMS in their efforts to ban or restrict abortion. ECF No. 10, at 20. But "antiabortion activists and hostile enforcers" are independent third parties not before the Court, and the results of their actions are not fairly traceable to FDA. *Lujan*, 504 U.S. at 560. Courts have consistently rejected similarly attenuated theories of indirect stigmatic injury, *see, e.g.*, *Allen v. Wright*, 468 U.S. 737, 755-56 (1984); *Malkan v. Am. Bar Ass'n*, No. 18-cv-7810, 2019 WL 2024346, at *4 (N.D. Ill. May 8, 2019); *Bishop v. United States ex rel. Holder*, 962 F. Supp. 2d 1252, 1268 (N.D. Okla. 2014), and Plaintiffs cite no case adopting anything like the theory they propose.

C. Plaintiffs' Requested Relief Is Not Tailored To Their Claims

Additionally, the Court should deny Plaintiffs' Motion because Plaintiffs' requested preliminary injunction bears no relation to their claims and does not provide relief from the final agency action that they challenge.

"Our legal system is built on the foundational principle that remedies are a means of redressing wrongs." *Bacon v. City of Richmond, Va.*, 475 F.3d 633, 638 (4th Cir. 2007). What "determines the scope of the remedy" is "the nature of the violation" that the plaintiff establishes. *Swann v. Charlotte-Mecklenburg Bd. of Ed.*, 402 U.S. 1, 16 (1971); *see also Bacon*, 475 F.3d at 638 ("Remedies, in other words, do not exist in the abstract; rather, they flow from and are the consequence of some wrong."). Thus, where a plaintiff challenges discrete final agency action under the APA, *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 891 (1990), the proper remedy aside from remand to the agency—even in the context of a preliminary injunction—is "limited only to vacating the unlawful action, not precluding future agency decisionmaking." *Hill Dermaceuticals, Inc. v. FDA*, 709 F.3d 44, 46 n.1 (D.C. Cir. 2013); *see also, e.g.*, *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 65 (2004) ("The [APA's] limitation to *required* agency action rules out judicial direction of even discrete agency action that is not demanded by law.").

Plaintiffs' requested relief violates this principle. Again, Plaintiffs do not allege that FDA is on the verge of taking some action to add new restrictions on mifepristone or make it less available than it is under the existing REMS. Rather, the sole "wrong" they challenge is a discrete final agency action: the January 2023 REMS modification. The aim of their lawsuit is to remove all restrictions on mifepristone and set aside the

January 2023 REMS modification. But the preliminary relief they ask for would require FDA to maintain that challenged action, rather than set it aside. Because such a "remedy" is neither tailored to Plaintiffs' claims nor authorized by the APA, the Court should deny Plaintiffs' Motion.

II. Plaintiffs' Motion For Preliminary Injunction Should Be Denied For Several Other Reasons

Plaintiffs' Motion for Preliminary Injunction should also be denied for at least four other reasons: (1) Plaintiffs are not likely to succeed on the merits because they failed to exhaust their administrative remedies, (2) Plaintiffs are not likely to succeed on the merits because the January 2023 REMS modification was lawful and reasonable, (3) Plaintiffs fail to show that the balance of equities and public interest tip in favor of a preliminary injunction, and (4) Plaintiffs are not entitled to the statewide relief they request.

A. Plaintiffs Failed To Administratively Exhaust Their Claims

The APA requires a party to exhaust any administrative remedy mandated by statute or agency rule. *See Darby v. Cisneros*, 509 U.S. 137, 153 (1993). FDA regulations set forth a detailed (and mandatory) administrative process for challenging agency action. As relevant here, "[a] request that [FDA] take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on [a citizen petition.]" 21 C.F.R. § 10.45(b); *id.* §§ 10.25(a), 10.30; *see also id.* § 10.1 (defining "administrative action" as "every act, including the refusal or failure to act, involved in the administration of any law by the Commissioner"). Moreover, a party

challenging an agency action "who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a new petition to modify the action under § 10.25(a)." *Id.* § 10.45(f). Such exhaustion requirements "serve[] to 'allow an agency the opportunity to use its discretion and expertise to resolve a dispute without premature judicial intervention and to allow courts to have the benefit of an agency's talents through a fully developed administrative record.'" *Cavalier Tel., LLC v. Va. Elec. & Power Co.*, 303 F.3d 316, 322 (4th Cir. 2002) (quoting *Thetford Props. IV Ltd. v. Dep't of Hous. & Urban Dev.*, 907 F.2d 445, 448 (4th Cir. 1990)).

Plaintiffs concede that they did not seek relief from the agency through a citizen petition but argue that doing so would be futile. ECF No. 10, at 32. As the Fourth Circuit has explained, however, "[a]bsent a clear showing that an administrative agency has taken a hard and fast position that makes an adverse ruling a certainty, a litigant's prognostication that he is likely to fail before an agency is not a sufficient reason to excuse the lack of exhaustion." *Thetford Prop. IV Ltd.*, 907 F.2d at 450. To make that "clear showing," "[m]ore than 'bare allegations of futility' must be demonstrated … as a claimant must come forward with a 'clear and positive showing' to warrant 'suspending the exhaustion requirement.'" *Wilson v. UnitedHealthcare Ins. Co.*, 27 F.4th 228, 241 (4th Cir. 2022) (quoting *Makar v. Health Care Corp. of Mid-Atlantic (CareFirst)*, 872 F.2d 80, 82 (4th Cir. 1989)).

Plaintiffs fail to meet their burden to show futility. Plaintiffs' claims involve arguments and publications that FDA has not previously considered. These include

arguments that first became available in 2022 and thus could not have been considered by the agency at the time of its 2021 REMS review—for example, Plaintiffs' arguments about how the REMS interacts with post-*Dobbs* state legislation, *see, e.g.*, Compl. ¶¶ 1, 9, 73, 74, 99, 103, and studies and other material published in 2022 and not reviewed by FDA that allegedly show the REMS is unduly burdensome and does not contribute to mifepristone's safety profile, *see, e.g., id.* ¶¶ 44 n.6, 68 n.33, 7 n.38, 120 n.66. As FDA has repeatedly demonstrated in approving modifications to the REMS and other conditions of approval over the past 22 years, the agency is committed to carefully evaluating new evidence and determining whether particular restrictions remain necessary to assure the safe use of mifepristone. There is no reason to think the agency would take a different approach to Plaintiffs' arguments and publications if Plaintiffs were to submit them to the agency as required.

Plaintiffs' arguments to the contrary are unpersuasive. Plaintiffs assert in conclusory fashion that FDA "refused similar relief to that sought here when it was requested in 2020 by 21 States and in 2022 by [the American College of Obstetricians and Gynecologists (ACOG)]." ECF No. 10, at 32 (footnotes omitted). But neither the States' 2020 letter nor the 2022 ACOG citizen petition is on point. The 2020 letter (ECF No. 1-18) was not a citizen petition—the agency's prescribed administrative remedy. It was submitted to an agency docket collecting comments on a guidance that addressed enforcement discretion during the pandemic with respect to certain types of REMS

requirements that were not relevant to the Mifepristone REMS Program.[9] The letter did not provide any supporting data, let alone the supporting data on which Plaintiffs base their challenge to the January 2023 REMS modification. Nor is there anything in FDA's response to that letter (*see* Katzen Decl. Ex. J) that suggests submitting a citizen petition would have been futile.

ACOG's 2022 citizen petition is even further afield. That citizen petition (which post-dated the 2021 REMS review) requested that FDA ask the holder of the new drug application for Mifeprex to submit an application to add miscarriage management as a new indication for mifepristone. ECF No. 1-16, at 2. FDA denied that request because it is up to the new drug application holder to decide whether to seek approval for a new indication. ECF No. 1-17, at 3. That conclusion led FDA to reject the petition's related request to eliminate or modify the REMS for mifepristone "so that it is not unduly burdensome for a miscarriage management indication." *Id.* at 4; *see also* ECF No. 1-16, at 2. The related request, FDA explained, was "premature" because miscarriage management "is not a currently approved indication for mifepristone." ECF No. 1-17, at 4. ACOG's citizen petition did not ask FDA to consider the new reasons now offered by Plaintiffs for eliminating the Mifepristone REMS Program.

Finally, the Court should reject Plaintiffs' far-reaching argument that FDA's defense of the January 2023 REMS modification in *Washington* renders exhaustion futile.

[9] The guidance can be found at https://www.regulations.gov/document/FDA-2020-D-1106-0018. The States' 2020 letter is posted with the docket number FDA-2020-D-1106-0061.

"If a litigation position is enough to show futility … then the futility exception would swallow the exhaustion doctrine." *Chorosevic v. MetLife Choices*, 600 F.3d 934, 946 (8th Cir. 2010). Plaintiffs' argument also ignores the fact that FDA argued in *Washington* that the plaintiffs there had failed to administratively exhaust their claims, and that FDA's decision should be upheld because it could not be attacked on the basis of argument and evidence that were never presented to the agency.

B. The January 2023 REMS Modification Was Lawful And Reasonable

Plaintiffs' claims are also unlikely to succeed on the merits because the January 2023 REMS modification was consistent with the law and reasonable.

First, Plaintiffs' claim that the January 2023 REMS modification was "in excess of statutory authority and contrary to law," Compl. ¶ 147, ECF No. 10, at 21-24, ignores the text of the statute and the history of the Mifepristone REMS Program. As described above, the restrictions on mifepristone predate the REMS statute and were originally imposed under Subpart H. When Congress established the REMS framework in 2007, it "deemed" drugs with Subpart H restrictions to have a REMS with elements to assure safe use already in effect. *See* Pub. L. No. 110-85, tit. IX, § 909 (21 U.S.C. § 331 note). It did not require FDA to determine in the first instance whether each drug that had Subpart H restrictions could independently satisfy the statutory criteria for establishing a REMS with elements to assure safe use.

During FDA's 2021 review of the Mifepristone REMS Program, the question before the agency was whether to modify the existing REMS. With respect to modifying a REMS, the statute authorizes FDA to require the sponsor to submit a proposed REMS

modification to (1) ensure the benefits of the drug outweigh the risks or (2) minimize the burden on the health care delivery system of complying with the REMS. 21 U.S.C. § 355-1(g)(4)(B). Elements to assure safe use must be commensurate with a specific serious risk and, considering such risk, "not be unduly burdensome on patient access to the drug[,] and … to the extent practicable, … minimize the burden on the healthcare delivery system[.]" *Id.* § 355-1(f)(2), *see also id*. § 355-1(f)(1). FDA's 2021 REMS review—which Plaintiffs ignore—shows that the January 2023 REMS modification was consistent with those criteria. *See supra* at 7-10; Katzen Decl. Ex. C at 14, 18, 36, 37, 39-40, 41; *see also* Katzen Decl. Ex. G.

Plaintiffs argue that the January 2023 REMS modification is "contrary to law" because mifepristone is safe and the REMS restrictions are "unrelated" to any medical risk and unduly burdensome on rural patients. *See* ECF No. 10, at 22-23. That argument misses the point. FDA has found mifepristone to be safe with the REMS requirements that Plaintiffs seek to have removed. Katzen Decl. Ex. C at 39 ("[M]ifepristone will remain safe and effective for medical abortion if the in-person dispensing requirement is removed, provided all the other requirements of the REMS are met, and pharmacy certification is added …."). And in the decision that Plaintiffs challenge, FDA considered the burdens of the REMS restrictions based on the evidence before the agency. *See supra* at 7-10. FDA explained that, although certain restrictions remained necessary to assure the safe use of the drug product, the in-person dispensing requirement was no longer necessary and its removal would render the REMS less burdensome. Were Plaintiffs to submit new evidence in a citizen petition to FDA

supporting their contention that the REMS is unnecessary to assure safe use of mifepristone and unduly burdens access to the drug (which they have not done, *see supra* at 20-24), FDA would carefully weigh that evidence, just as it has always done when evaluating the necessity of particular restrictions.

Also without merit is Plaintiffs' contention that the lack of a REMS for Korlym—a drug product for treating Cushing's syndrome[10] that has mifepristone as its active ingredient—disproves the need for a REMS for Mifeprex and its generic. ECF No. 10, at 23. Plaintiffs argue that the lack of a Korlym REMS means "FDA plainly does not consider mifepristone to be *inherently* toxic or harmful." *Id.* As an initial matter, Plaintiffs misstate the standard, which looks to whether a drug is "potential[ly]" harmful, not whether it is inherently so. *See* 21 U.S.C. § 355-1(f)(1). And "FDA's determination as to whether a REMS is necessary for a particular drug is a complex, drug-specific inquiry, reflecting an analysis of multiple, interrelated factors and of how those factors apply in a particular case." Katzen Decl. Ex. I, at 4. Thus, the fact that there is no REMS for Korlym does not compel FDA to reach the same result for Mifeprex and its generic, which have conditions of use very different from Korlym's. FDA conducted its case-specific inquiry for Korlym, explicitly considered the REMS for Mifeprex, and explained why Korlym does not require a REMS to assure safe use of the drug to treat Cushing's syndrome. *See* Katzen Decl. Ex. H.

[10] "Cushing's syndrome is a disorder that occurs when [the] body makes too much of the hormone cortisol over a long period of time." NIH, National Institute of Diabetes and Digestive and Kidney Diseases, https://perma.cc/5GCX-5UEW.

Second, Plaintiffs are incorrect to assert that the January 2023 REMS modification was "arbitrar[y] and capricious[]." *See* Compl. ¶ 151. Review under the arbitrary-and-capricious standard is "at its most deferential" with respect to an agency's scientific determinations within its area of expertise. *Balt. Gas & Elec., Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1982). In particular, "[FDA's] judgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA's expertise and merit deference from [courts]." *Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d. Cir. 1995); *see also FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 579 (2021) (Roberts, C.J., concurring) (explaining that the "significant deference" owed to FDA's judgments weighed against "compel[ling] the FDA to alter the regimen for medical abortion"); *Cytori Therapeutics, Inc. v. FDA*, 715 F.3d 922, 925 (D.C. Cir. 2013) ("In Administrative Procedure Act cases alleging arbitrary or capricious agency action, courts must be careful not to unduly second-guess an agency's scientific judgments.") (Kavanaugh, J.).

FDA's January 2023 REMS modification was a reasonable application of its expertise. FDA applied the standards governing modification of a REMS and asked whether evidence since the agency's review of the Mifepristone REMS Program in 2016 established that one or more goals or elements should be added, modified, or removed to ensure that the benefits of the drug outweigh the risks or to minimize the burden on the health care delivery system of complying with the REMS. After weighing the evidence before it, the agency concluded that the prescriber certification and Patient Agreement Form requirements must be retained; that the in-person dispensing

requirement must be removed; and that a pharmacy certification requirement must be added to permit certified pharmacies to dispense mifepristone. The agency's explanations for these conclusions exemplified reasoned decision-making. *See supra* at 7-10. The APA requires no more.

Plaintiffs disregard (indeed, do not even mention) FDA's reasoned explanation for its approval of the January 2023 modification to the Mifepristone REMS Program. Their arguments either raise issues never put before the agency or rest on disagreement with how FDA weighed the relevant factors. None of these arguments overcomes FDA's reasoned decision-making.

C. The Balance Of Equities And Public Interest Weigh Against An Injunction

Even if Plaintiffs had met their burden to show likelihood of success on the merits and irreparable harm, they fail to show that the balance of equities and public interest tip in favor of granting the requested preliminary injunction.

Plaintiffs seek this preliminary injunction with the goal of obtaining "legal protection from the havoc that might ensue from any orders affecting the availability of mifepristone as a result of" the *Alliance* Order. ECF No. 10, at 35. They argue that FDA "will not be harmed by maintaining the status quo for providers in Virginia, Montana, and Kansas when they are already required to do the same for providers in the 17 States and the District of Columbia that are parties to the *Washington* Case." ECF No. 10, at 35. But it is entirely speculative whether the *Alliance* Order will ever take effect. Entry of the requested injunction thus would provide no benefit to anyone. Conversely, "any time" the government "is enjoined by a court from effectuating statutes enacted by

representatives of its people, it suffers a form of irreparable injury." *Maryland v. King*, 567 U.S. 1301, 1303 (2012) ((quoting *New Motor Vehicle Bd. of Cal. V. Orrin W. Fox Co.*, 434 U.S. 1345, 1351 (1977)).

D. Plaintiffs Are Not Entitled To Statewide Relief

Even if Plaintiffs were entitled to their requested preliminary injunction, that injunction should be limited to the Plaintiffs themselves and not extend throughout their respective States. "The Art. III judicial power exists only to redress or otherwise to protect against injury to the complaining party, even though the court's judgment may benefit others collaterally." *Warth v. Seldin*, 422 U.S. 490, 499 (1975). "Whenever the extraordinary writ of injunction is granted, it should be tailored to restrain no more than what is reasonably required to accomplish its ends. This is particularly so when preliminary injunctive relief is granted." *S.C. Dept. of Wildlife & Marine Res. v. Marsh*, 866 F.2d 97, 100 (4th Cir. 1989) (internal quotation marks and citation omitted).

None of Plaintiffs' asserted injuries warrants statewide relief. Unlike the *Washington* plaintiffs, Plaintiffs do not assert injuries that would arise from mifepristone being less available throughout their States generally. *Cf.* 2023 WL 2825861, at *5. If the Court finds that Plaintiffs have shown that the preliminary injunction they seek would prevent imminent harm to them and their patients, that goal can and should be accomplished by limiting the injunction to Plaintiffs and not affecting the rights and obligations of non-party providers and their patients.

III. The Court Should Stay Proceedings Pending *Alliance* Appellate Proceedings

In addition to denying Plaintiffs' Motion for Preliminary Injunction—or as an alternative to ruling on that Motion at this time—the Court should stay proceedings in this matter until the resolution of appellate proceedings in *Alliance*.

"[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936). "Pausing these proceedings to await further guidance from the Supreme Court is not abdication: it is an expression of prudence, judicial restraint, and respect for the role of a district court that must scrupulously adhere to the instructions of appellate authorities." *Benisek v. Lamone*, 266 F. Supp. 3d 799, 808 (D. Md. 2017) (denying a motion for preliminary injunction and staying a case where "the Supreme Court is poised to act and in so doing may change the legal landscape"); *see also Hickey v. Baxter*, 833 F.2d 1005 (4th Cir. 1987) (per curiam) (unpublished) ("We find that the district court acted within its discretion in staying proceedings while awaiting guidance from the Supreme Court in a case that could decide relevant issues.").

Here, in the interest of judicial economy, the Court should stay proceedings pending resolution of appellate proceedings in *Alliance*. The appeal and any Supreme Court proceedings in *Alliance* may resolve, narrow, or provide guidance on some or all of the issues that this Court would have to decide were this case to move forward. For instance, if the Supreme Court ultimately grants certiorari in *Alliance*, its decision may

address (among other things) the standard under which courts should review FDA's decisions relating to mifepristone for medical termination of early pregnancy. It makes little sense for the parties and the Court to spend time and resources on further litigation of Plaintiffs' claims when pending appellate proceedings in *Alliance* may resolve, narrow, or provide guidance on the very issues to be litigated.

Nor is there a "fair possibility that [a] stay … will work damage" to Plaintiffs. *Landis*, 299 U.S. at 255. As discussed above, Plaintiffs' principal concern—the prospect that the *Alliance* Order could ultimately take effect—could not come to pass unless the Fifth Circuit and/or (assuming a party seeks certiorari from any adverse Fifth Circuit ruling) the Supreme Court decline to disturb the order. Nor are Plaintiffs injured by deferred consideration of the merits of their challenge to the January 2023 REMS modification. Two of the three REMS elements they challenge have been in place for over two decades, during which time Plaintiffs never sought to challenge them.[11] The only REMS elements that changed in January 2023 included the removal of the in-person dispensing requirement (which prevented any pharmacy from dispensing mifepristone) and the addition of the pharmacy certification requirement (which, for the first time, permitted certified pharmacies to dispense mifepristone). Because Plaintiffs are not pharmacies, they will suffer no prejudice from deferring consideration of their challenge until after resolution of the *Alliance* appellate proceedings. And even if

[11] One of the Plaintiffs, All Families Healthcare, joined ACOG's 2022 citizen petition which, as explained above, requested something different than what Plaintiffs request here. *See supra* at 23.

Plaintiffs were somehow adversely affected by a stay, that harm is clearly outweighed by the "hardship or inequity," *id.*, to Defendants of being "forced to litigate on [at least] two fronts" and being "subjected to the possibility of inconsistent rulings in the two actions." *Citizens Ins. Co. of Am. v. Chief Digit. Advisors*, No. 20-CV-1075-MMA (AGS), 2020 WL 8483913, at *2 (S.D. Cal. Dec. 22, 2020); *see Franklin v. Scripps Health*, No. 22-CV-367-MMA (MDD), 2022 WL 4389691, at *5 (S.D. Cal. Sept. 21, 2022).

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiffs' Motion for Preliminary Injunction and grant Defendants' Motion to Stay Proceedings. In the alternative, the Court should grant Defendants' Motion to Stay Proceedings and defer consideration of Plaintiffs' Motion for Preliminary Injunction until after the stay terminates.

June 5, 2023

Respectfully submitted,

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Certificate of Service

I certify that the foregoing was served on all counsel of record via ECF on June 5, 2023.

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