IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
CHARLOTTESVILLE DIVISION

WHOLE WOMAN'S HEALTH ALLIANCE, *et al.*,	)	
Plaintiffs,	)	**Civil Action No.: 3:23-cv-00019**
v.	)	
UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,	)	**By: Hon. Robert S. Ballou** **United States District Judge**
Defendants.	)	

MEMORANDUM OPINION

In 2000, the United States Food and Drug Administration ("FDA") approved mifepristone as a safe and effective drug used as part of a two-drug regimen to terminate early pregnancy. In every review of mifepristone since then, FDA has reached the same conclusions about the drug's safety and effectiveness, but FDA has attached several restrictions, commonly known as REMS, which affect the prescribing and dispensing of the drug. This case challenges those restrictions and asks me to order FDA to remove all REMS on the drug. In the wake of Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228 (2022), which held that the Constitution does not provide a right to abortion and returned the authority to regulate abortion to the people's elected representatives, several states have restricted or effectively eliminated access to abortion.[1] Plaintiffs are abortion providers in Virginia, Kansas, and Montana where mifepristone remains an available FDA-approved drug for early termination of pregnancy.

[1] See Where abortion laws stand in every state a year after the Supreme Court overturned Roe, THE ASSOCIATED PRESS (June 22, 2023, 12:05 AM), https://apnews.com/article/abortion-status-list-state-protection-ban-4466aefe6141745b71c824522aac47b9.

Plaintiffs fear, however, that in a post-Dobbs climate, mifepristone soon might not be available for their patients. Plaintiffs ask me to issue a preliminary injunction to enjoin Defendants from "altering the status quo" as it relates to access to mifepristone, due to the current legal uncertainty surrounding access to the drug and abortion in general.[2] Plaintiffs' request underscores the importance of maintaining access to mifepristone, a drug deemed safe and effective by FDA for over 20 years, in those states where it can be prescribed consistent with current laws regarding abortion. However, a preliminary injunction is an extraordinary remedy with clear requirements that Plaintiffs do not currently meet. In each state in this action, mifepristone remains available to prescribe, and FDA has made no indication that it intends to limit access to mifepristone. The uncertainty at the heart of Plaintiffs' preliminary injunction request comes from circumstances unrelated to any party in this case and not because of FDA action or impending action.

I. Background

A. Statutory Background

In September 2000, FDA approved mifepristone under the brand name Mifeprex for use in medication-induced abortions. Dkt. 1 at 11. FDA specifically approved mifepristone as part of a two-drug regimen with the already approved drug misoprostol.[3] Id. FDA concluded that mifepristone was effective and safe "for the medical termination of intrauterine pregnancy through 49 days' pregnancy." Dkt. 1, Ex. A at 2. Subpart H of the FDA regulations authorized

[2] "[A] preliminary injunction is customarily granted on the basis of procedures that are less formal and evidence that is less complete than in a trial on the merits." G.G. ex rel. Grimm v. Gloucester Cty. Sch. Bd., 822 F.3d 709, 725 (4th Cir. 2016), vacated and remanded on other grounds, 137 S. Ct. 1239 (2017). "Courts are therefore permitted to consider the well-pleaded allegations of a complaint and the uncontroverted affidavits submitted in support of a motion for preliminary injunction." Boyapati v. Loudon Cty. Sch. Bd., No. 1:20-cv-01075, 2020 WL 6797365, at *3 (E.D. Va. Oct. 7, 2020) (citing Elrod v. Burns, 427 U.S. 347, 350 n. 1 (1976)).

[3] Mifepristone "interrupts early pregnancy by blocking the effect of progesterone, a hormone necessary to maintain a pregnancy." Dkt. 1 at 11. Misoprostol "causes uterine contractions that expel the pregnancy from the uterus." Id.

FDA to require that approved medications be prescribed with certain conditions "needed to assure safe use." Final Rule, 57 Fed. Reg. 58,942, 58,958 (Dec. 11, 1992) (codified at 21 C.F.R. § 314.520). The imposed conditions in 2000 on the prescription of mifepristone required: (1) in-person dispensing of mifepristone only in a clinic, medical office, or hospital by or under the supervision of a certified provider, who could only be a physician, (2) a certification by clinicians who prescribe mifepristone attesting to their clinical abilities on a signed form kept on file by the manufacturer, and agreeing with reporting and other requirements, and (3) an agreement between the prescriber and patient which contains information about the mifepristone regimen and its risks, and which requires the prescriber to provide a copy to the patient and to place a copy in the patient's medical record. Dkt. 1 at 23–24.

The Food and Drug Administration Amendments Act of 2007 removed Subpart H but gave FDA the authority to require a Risk Evaluation and Mitigation Strategy ("REMS") when "necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. 355-1(a)(1). The 2007 statute also authorized FDA to require that any REMS included as part of a drug authorization include "elements to assure safe use" ("ETASU") if medically necessary due to a drug's "inherent toxicity or potential harmfulness[.]" Id. at 355-1(f)(1). For a drug to have ETASU, the Secretary of the FDA must determine that the drug is associated with "a serious adverse drug experience," which includes death, immediate risk of death, and inpatient hospitalization. Id. at 355-1(f)(1)(A), (b)(4). The ETASU must "not be unduly burdensome on patient access to the drug" and must "minimize the burden on the health care delivery system[.]" Id. at 355-1(f)(2). All drugs approved with restrictions under Subpart H, like mifepristone, were deemed to have a REMS in effect, with the Subpart H restrictions serving as ETASU. Pub. L. No. 110-85, tit. IX, § 909(b). Thus, the original restrictions attached to mifepristone under

Subpart H became REMS affecting the prescribing and dispensing of the drug. FDA may also require an applicant to submit proposed modifications for existing REMS if the agency "determines that 1 or more goals or elements should be added, modified, or removed" from the current REMS to "ensure the benefits of the drug outweigh the risks of the drug" or to "minimize the burden on the health care delivery system of complying with the strategy." 21 U.S.C. § 355-1(g)(4)(B).

B. REMS Placed on Mifepristone

Since 2007, FDA has reevaluated the mifepristone REMS, including in 2016, 2019, 2021, and 2023. Dkt. 1 at 24. "During FDA's 2016 review of the REMS, dozens of medical experts and their organizations asked FDA to eliminate the REMS because of the harms it imposed on patients and providers without any medical benefits."[4] Id. Thirty organizations submitted a letter to FDA during the 2016 review asking that it lift the REMS and extend the gestational age indicated on mifepristone's labeling from 49 to 70 days. Dkt. 1, Ex. K, at 1–2. They argued that "[e]xtensive scientific and clinical evidence of mifepristone's safety and efficacy, and the ever-increasing burden on patient access to abortion care, clearly demonstrate that mifepristone's REMS program is not needed to protect patients." Id. at 6. The organizations asked FDA to consider this burden "[i]n light of the FDA's statutory mandate from Congress to consider the burden caused to patients by REMS, and the agency's own stated commitment to ensuring that drug restrictions do not unduly burden patient access." Id.

The conclusions from FDA in its 2016 review included (1) that Mifeprix "has been increasingly used as its efficacy and safety have become well-established by both research and experience, and serious complications have proven to be extremely rare;" (2) that "[g]iven that

[4] These organizations included the American College of Obstetricians and Gynecologists ("ACOG"), the American Public Health Association ("APHA"), and the Society of Family Planning ("SFP"). Dkt. 1 at 24.

the numbers of . . . adverse events appear to be stable or decreased over time, it is likely that . . . serious adverse events will remain acceptably low[,]" and (3) that the risk of death from mifepristone is 0.00000232%.[5] Dkt. 1, Ex. E at 14, 49; see also Dkt. 1, Ex. I; Dkt. 1 at 14. FDA updated the mifepristone REMS to allow a broader set of healthcare providers other than physicians to prescribe mifepristone and increased the indicated gestational age limit from 49 to 70 days. Dkt. 1 at 15; Dkt. 1, Ex. F at 10.

FDA received a citizen petition[6] in 2020 from 21 state attorneys general asking that because of the COVID-19 pandemic, FDA remove the REMS which are "unnecessary, undue burdens in accessing safe and time-sensitive, essential medical care." Dkt. 1, Ex. Q at 4. In the alternative, the attorneys general asked FDA to allow certified prescribers to use telehealth to prescribe mifepristone. Id. In July 2020, the District of Maryland temporarily enjoined FDA from enforcing the in-person dispensation requirements under the REMS during the COVID-19 pandemic. Am. Coll. of Obstetricians & Gynecologists v. U.S. Food and Drug Admin., 472 F. Supp. 3d 183, 233 (D. Md. 2020). In April 2021, FDA found that safety concerns regarding the use of mifepristone had not increased after the court enjoined in-person prescription requirements. FDA then suspended the in-person dispensing requirement during the COVID-19 public health emergency, Dkt. 1, Ex. J at 1–2, and in January 2023, amended the REMS to remove the in-person dispensing requirement permanently, but it imposed a pharmacy certification requirement in its place. Dkt. 1 at 16, 27.

[5] "Penicillin has a mortality rate three times greater than mifepristone. Viagra has a mortality rate more than six times greater than mifepristone. Tylenol overdose is one of the *most common* causes of liver transplantation in the U.S.—it leads to 56,000 emergency department visits, 2,600 hospitalizations, and 500 deaths per year in the United States. No REMS applies to any of these drugs." Dkt. 1 at 34 (emphasis in original).

[6] A citizen petition allows for an individual or an organization to petition FDA to issue, amend, or revoke a regulation or order or to take or refrain from taking any other form of administrative action. 21 C.F.R. § 10.25.

In 2022, a citizen petition consisting of 49 organizations requested that FDA "ask Danco Laboratories, LLC ("Danco") – the holder of the approved new drug application for Mifeprex (mifepristone) – to submit a Supplemental New Drug Application (sNDA) that seeks to add miscarriage management as an indication to the drug's label and to eliminate or modify mifepristone's [REMS] . . . so that it is not unduly burdensome for that use." Dkt. 1, Ex. O at 1. FDA denied the citizen petition and noted that FDA could not order Danco to submit a sNDA but that if Danco submitted a sNDA, FDA "will review such application consistent with the [Food, Drug, and Cosmetic Act], FDA regulations, and [the] standard process for sNDAs." Dkt. 1, Ex. P at 3. FDA also denied the citizen petition's request for review of mifepristone's REMS and noted that because it had not approved mifepristone for miscarriage management, reviewing the burdens of the REMS Program for that purpose would be premature. Id. at 3.

C. Legal Challenges to Mifepristone Use

Legal challenges to FDA's approval and regulation of mifepristone are ongoing since the Supreme Court's decision in Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228 (2022), which held that the Constitution does not provide a right to abortion and returned the authority to regulate abortion to the people's elected representatives. In the Eastern District of Washington, 17 states[7] and the District of Columbia, on behalf of themselves and as parens patriae on behalf of their residents, asked the court to declare that the mifepristone REMS violate the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551-59, and the United States Constitution and to enjoin FDA from enforcing or applying the mifepristone REMS or from taking any action

[7] The states included in the lawsuit are Washington, Oregon, Arizona, Colorado, Connecticut, Delaware, Illinois, Michigan, Nevada, Mexico, Rhode Island, Vermont, Hawaii, Maine, Maryland, Minnesota, and Pennsylvania.

to remove mifepristone from the market or reduce its availability ("the Washington case").[8] Washington v. U.S. Food and Drug Admin., No. 1:23-cv-3026, Dkt. 35 at 90 (E.D. Wash. Mar. 9, 2023). In April 2023, the Washington Court granted the plaintiffs' motion for a preliminarily injunction and enjoined FDA from "altering the status quo and rights as it relates to the availability of Mifepristone under the current operative January 2023 [REMS] . . . in Plaintiff States." Washington v. U.S. Food and Drug Admin., No. 1:23-cv-3026, 2023 WL 2825861, at *11 (E.D. Wash. Apr. 7, 2023) (internal quotation marks omitted).

In the Northern District of Texas, doctors and national medical associations that provide healthcare for pregnant and post-abortion[9] patients asked the court to order FDA to "withdraw mifepristone and misoprostol as FDA-approved chemical abortion drugs" and to "hold unlawful, set aside, and vacate" FDA's 2000 approval of mifepristone ("the Alliance case").[10] Alliance for Hippocratic Med. v. U.S. Food and Drug Admin., No. 2:22-cv-223, Dkt. 1 at 110 (N.D. Tex. Nov. 18, 2022). In April 2023, the court granted the plaintiffs' motion for a preliminary injunction and stayed "the effective date of FDA's September 28, 2000, Approval of mifepristone and all subsequent challenged actions related to that approval – *i.e.*, the 2016

[8] The plaintiffs argue that "(1) FDA acknowledges that serious adverse events are exceedingly rare, (2) mifepristone's associated fatality rate is .00005% . . . , (3) all the data shows th[at] mifepristone is among the safest drugs in the world . . . , and (4) there is no reasoned scientific basis for subjecting it to additional burdens that are not applied to other, riskier medications." Washington v. U.S. Food and Drug Admin., No. 1:23-cv-3026, 2023 WL 2825861, at *7 (E.D. Wash. Apr. 7, 2023) (internal quotation marks omitted)

[9] The plaintiffs are Alliance for Hippocratic Medicine, American Association of Pro-Life Obstetricians and Gynecologists, American College of Pediatricians, Christian Medical & Dental Associations, Shaun Jester, D.O., Regina Frost-Clark, M.D., Tyler Johnson, D.O., and George Delgado, M.D.

[10] The plaintiffs argue that FDA never had the authority to approve mifepristone and misoprostol for sale and that "FDA has not only continued to keep chemical abortion drugs on the market, but the agency has also eliminated the few safeguards it initially established to protect women and girls who go through the chemical abortion drug regimen." Alliance, No. 2:22-cv-223, Dkt. 1 at 15–16. The issues in the Alliance case relating to FDA authority to approve mifepristone and modify the REMS are not before me. The only evidence in the record here is that FDA has consistently found mifepristone safe and an important medication for health care professionals to manage patients during early pregnancy termination.

Changes, the 2019 Generic Approval, and the 2021 Actions." Alliance for Hippocratic Med. v. U.S. Food and Drug Admin., No. 2:22-cv-223, 2023 WL 2825871, at *32 (N.D. Tex. Apr. 7, 2023). The Alliance Court imposed its injunction nationwide, but stayed its order for seven days to allow FDA to seek emergency relief from the Fifth Circuit. Id. On appeal to the Fifth Circuit, FDA and Danco[11] moved for a stay of the case pending appeal to the Supreme Court. The Fifth Circuit granted the stay as it related to FDA's 2000 approval of mifepristone and denied the stay as it related to the plaintiffs' "arguments challenging FDA's 2016 Major REMS Changes and all subsequent actions[,]" effectively reinstating pre-2016 restrictions on mifepristone. Alliance for Hippocratic Med. v. U.S. Food and Drug Admin., No. 23-10362, 2023 WL 2913725, at *21 (5th Cir. Apr. 12, 2023). On appeal to the Supreme Court, the Supreme Court granted the plaintiffs' motion for stay. Danco Labs., LLC v. Alliance for Hippocratic Med., 143 S. Ct. 1075, 1075 (2023). The Supreme Court stayed the Northern District of Texas's order "pending disposition of the appeal in the United States Court of Appeals for the Fifth Circuit and disposition of a petition for a writ of certiorari, if such a writ is timely sought." Id. The stay order provides that if the Supreme Court denies certiorari, the stay will terminate automatically, but if it grants certiorari, the stay will terminate after the Supreme Court enters its judgment. Id.

The Fifth Circuit heard argument again from the parties, this time on "the ultimate question of whether the district court erred in issuing the stay order." Alliance for Hippocratic Med. v. U.S. Food and Drug Admin., No. 23-10362, 2023 WL 5266026, at *6 (5th Cir. Aug. 16, 2023). The Fifth Circuit vacated that portion of the district court's order that stayed the effective date of mifepristone's 2000 approval and the 2019 generic approval. The court, however, affirmed that portion of the district court's order that stayed the 2016 amendments to the REMS.

[11] Danco Laboratories, LLC, the exclusive manufacturer, marketer, and distributor of Mifeprex in the United States, intervened in the action.

Id. at *32. The Fifth Circuit maintained that mifepristone will remain available under the pre-2016 REMS in both its name brand and generic form but recognized that "all of this relief is subject to the Supreme Court's prior order, which stays the district court's order until the disposition of any petition for certiorari." Id. To be clear, the Supreme Court stay keeps mifepristone available in whatever states it can be legally prescribed subject to the 2023 REMS at least through the final determination of the litigation in the Alliance case.

D. Preliminary Injunction Motion

The REMS approved in 2023 require that mifepristone be prescribed by a certified clinician and be dispensed by a certified pharmacy, and that the prescriber and patient sign a form patient agreement. FDA has concluded that the REMS "remain necessary to assure the safe use of mifepristone for medical termination of intrauterine pregnancy through 70 days gestation; and therefore, the Mifepristone REMS Program continues to be necessary to ensure the benefits outweigh the risk." Dkt. 27, Ex. D at 6. Plaintiffs challenge the need for the REMS in this lawsuit alleging that "[c]ontinued enforcement of the REMS perpetuates harmful and unnecessary barriers that make it more difficult to access essential healthcare and interferes with this decision-making." Dkt. 1 at 22. Plaintiffs contend that mifepristone's REMS violate the APA and the United States Constitution because they are arbitrary and capricious and in direct opposition to the recommendations of medical experts. Id. at 41–43. Plaintiffs ask the Court to enter a permanent injunction to enjoin Defendants from enforcing or applying the mifepristone REMS. Id. at 44.

Of immediate interest, Plaintiffs seek a preliminary injunction not to remove the REMS during the pendency of this lawsuit, but to prevent "defendants and any person in active concert or participation with them from altering the status quo as it relates to the availability of

mifepristone under the 2023 REMS in Virginia, Montana, and Kansas, where Plaintiffs operate." Dkt. 10 at 37. Plaintiffs are asking me to keep in place the exact REMS that they seek to remove in their Complaint. Defendants oppose Plaintiffs' motion and argue that Plaintiffs do not have standing, have failed to exhaust their administrative remedies, and have not alleged irreparable harm in the absence of the preliminary injunction. Dkt. 27.

II. Standing

Article III of the United States Constitution limits the jurisdiction of federal courts to certain "Cases" and "Controversies." U.S. Const. art. III, § 2. "One element of the case-or-controversy requirement is that plaintiffs must establish that they have standing to sue." Clapper v. Amnesty Int'l USA, 568 U.S. 398, 408 (2013) (internal quotation marks and citations omitted). "Thus, Article III standing is a 'subject matter jurisdiction issue.'" Mejico v. Alba Web Designs, LLC, 515 F. Supp. 3d 424, 430 (W.D. Va. 2021) (quoting Beyond Sys., Inc. v. Kraft Foods, Inc., 777 F.3d 712, 715 (4th Cir. 2015)).

To establish constitutional standing to sue, "a plaintiff must show (i) that [they] suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief." TransUnion LLC v. Ramirez, 141 S. Ct. 2190, 2203 (2021). An injury-in-fact is "an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." Lujan v. Defs. of Wildlife, 504 U.S. 555, 560 (1992) (internal quotation marks and citations omitted). "Further, the injury must be causally connected to the conduct complained of and it must be likely, not just speculative, that the injury will be redressed by a favorable decision from the court." Oryn Treadway Sheffield, Jr., Trust v. Consolidation Coal Co., 819 F. Supp. 2d 625, 628 (W.D. Va. 2011). Plaintiffs must "demonstrate

standing separately for each form of relief sought." Friends of the Earth, Inc. v. Laidlaw Envt'l Servs. (TOC), Inc., 528 U.S. 167, 185 (2000). "The same principle applies when there are multiple plaintiffs. At least one plaintiff must have standing to seek each form of relief requested in the complaint." Town of Chester, N.Y. v. Laroe Estates, Inc., 581 U.S. 433, 439 (2017). "While the proof required to establish standing increases as the suit proceeds, the standing inquiry remains focused on whether the party invoking jurisdiction had the requisite stake in the outcome when the suit was filed." Davis v. Fed. Election Comm'n, 554 U.S. 724, 734 (2008).

Defendants argue that Plaintiffs lack standing to seek the preliminary injunction. Defendants contend that Plaintiffs have not suffered any injury in fact because "Plaintiffs have not alleged 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." Dkt. 27 at 18. Defendants also argue that Plaintiffs' injuries traceable to the January 2023 REMS "could not possibly be redressed by a preliminary injunction requiring FDA to *maintain* the January 2023 REMS modification." Id. at 17. Finally, Defendants argue that any injuries that would spring from the Alliance order taking effect cannot establish standing because "it would be improper for this Court to enter an injunction with the intent of blocking the order of a different district court." Id. at 17–18.

Plaintiffs argue that they have standing to sue because they "are challenging the 2023 REMS, which they allege limit the accessibility of mifepristone by constraining the provider pool, confusing and stigmatizing patients, and making it more difficult to use mail-order pharmacies in direct-to-patient telehealth." Dkt. 33 at 4, n. 4. Further, Plaintiffs argue that "FDA's decision to continue to impose a REMS on mifepristone is part and parcel of efforts to restrict mifepristone and treat it as if it is something dangerous, which it is not." Id. Plaintiffs

contend that the relief sought against the 2023 REMS will redress the wrongs Plaintiffs allege. Id.

I find that Plaintiffs have standing to sue. Defendants conflate the constitutional requirements for standing and the requirements for a preliminary injunction and analyze whether Plaintiffs have suffered irreparable harm and whether a preliminary injunction could redress their alleged injuries. However, the standing inquiry looks only at "whether a plaintiff had the requisite stake in the outcome of a case 'at the outset of the litigation.'" Deal v. Mercer Cty. Bd. of Educ., 911 F.3d 183, 187 (4th Cir. 2018) (quoting Friends of the Earth, Inc, 528 U.S. at 167). Here, Plaintiffs have standing to bring this action asserting that FDA imposed REMS that have affected access to mifepristone which establishes a cognizable injury to their patients and business that may be remedied by removal of the REMS. Accordingly, I find that Plaintiffs meet all necessary requirements for constitutional standing.

III. Exhaustion of Administrative Remedies

The APA requires a plaintiff to exhaust available administrative remedies before bringing their grievances to federal court. 5 U.S.C. § 704. The APA does not mandate a specific process, but a plaintiff must exhaust "to the extent that it is required by statute or by agency rule as a prerequisite to judicial review." Darby v. Cisneros, 509 U.S. 137, 153 (1993).

Interested persons may challenge FDA activities and "may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action . . . in the form of a citizen petition." 21 C.F.R. § 10.25(a). "A request that the Commissioner take . . . administrative action must first be the subject of a final administrative decision based upon a petition submitted under § 10.25(a) . . . before any legal action is filed in a court complaining of the action or failure to act." 21 C.F.R. § 10.45(b).

The exhaustion requirement "provides an agency with an opportunity 'to correct its own mistakes with respect to programs it administers before it is haled into federal court.'" Volvo GM Heavy Truck Corp. v. U.S. Dep't of Labor, 118 F.3d 205, 209 (4th Cir. 1997) (quoting McCarthy v. Madigan, 503 U.S. 140, 144–45 (1992)). Exhaustion, however, has its exceptions, including situations where resorting to administrative procedures would be futile. Fares v. U.S. I.N.S., 50 F.3d 6 (Table) (4th Cir. 1995) (citing Darby v. Kemp, 957 F.2d 145, 147 (4th Cir. 1992) (overruled on other grounds)); McDonald v. Centra, Inc., 946 F.2d 1059, 1063 (4th Cir. 1991)). The Fourth Circuit requires a "clear and positive showing of futility . . . before suspending the exhaustion requirement." Makar v. Health Care Corp. of Mid–Atlantic (CareFirst), 872 F.2d 80, 83 (4th Cir. 1989).

The party claiming inadequacy or futility of the administrative remedy has the burden of showing circumstances supporting an exception. Googerdy v. N.C. Agr. and Tech. State Univ., 386 F. Supp. 2d 618, 628–29 (M.D.N.C. 2005). "The typical circumstances under which a party has been allowed to circumvent agency procedures are ones that show inherent bias on the part of the agency or where the agency has demonstrated by past actions, be it past patterns of decision making, the agency's past position on the merits of the case at issue, or agency statements, that it will not grant the relief sought by the party seeking relief in court." McDonald v. Centra, 118 B.R. 903, 923 (D. Md. 1990).

Plaintiffs allege that "FDA reevaluated the provisions of the mifepristone REMS in 2016, and again in 2019, 2021, and 2023, but it has continually decided to reimpose the REMS despite longstanding objections from the medical community and its own review of the data showing mifepristone's safety and efficacy." Dkt. 1 at 24. Thirty organizations petitioned FDA in 2016 to completely lift the REMS. Id. at 25. FDA's clinical review team concluded that the patient

agreement form "does not add to safe use conditions for the patient for this REMS and is a burden for patients." Dkt. 1, Ex. H at 25. However, FDA's Commissioner "concluded that continuing the REMS requirement for a signed Patient Agreement Form would not interfere with access and would provide additional assurance that the patient is aware of the nature of the procedure, its risks, and the need for appropriate follow-up care." Dkt. 1, Ex. L at 1. FDA has retained the patient agreement form requirement since. Id. Citizen petitions in 2020 and 2022 requested FDA to review and remove all mifepristone's REMS to no avail. In the Washington case, FDA stated "that its decision to maintain the REMS restrictions on mifepristone was reasonable." Dkt. 1 at 41 (internal quotation marks omitted). Plaintiffs argue that "[t]here is no prospect that FDA would take a different view if Plaintiffs were required to submit a citizen petition now." Id.

Some of the evidence and arguments cited by Plaintiffs have never been considered by FDA, specifically the status of abortion rights and access post-Dobbs because the case was not decided until 2022. Dkt. 27 at 21–22. FDA maintains that it "is committed to carefully evaluating new evidence and determining whether particular restrictions remain necessary to assure the safe use of mifepristone." Id. at 22. The citizens petitions cited by Plaintiffs are also not directly on point to the pending litigation. The 2020 citizen petition "did not provide any supporting data." Id. at 23. FDA denied a review of mifepristone's REMS after the 2022 citizen petition because the request was premature. Id. FDA opposes Plaintiffs' argument that its position in the Washington case renders exhaustion futile because that argument "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." Id. at 24.

While FDA has changed the mifepristone REMS since its approval in 2000 and it has considered whether to retain or change the REMS repeatedly throughout the last 23 years, it continues to find that the REMS remain necessary. Plaintiffs seek removal of mifepristone's REMS, just as several other organizations have before them. The 2022 citizen petition is not directly relevant to the current action, but FDA has shown through other actions, specifically through its continued approval of mifepristone's REMS, that it will not change or remove the REMS. I find that requiring administrative exhaustion is futile, as FDA has demonstrated by its past actions and prior findings that it will not grant the relief sought by Plaintiffs. See Roe v. Shanahan, 359 F. Supp. 3d 382, 403 (E.D. Va. 2019) ("Exhaustion need not be required where it would constitute an empty formality."). Both the Washington and Alliance courts found that yet another citizen petition to FDA asking that it reconsider the REMS would be futile. Washington, 2023 WL 2825861, at *6 (concluding that after prior citizen petitions filed in 2020 and 2022, and FDA's full review of the REMS in 2021, "FDA cannot credibly argue that its decision on the Mifepristone REMS Program would change upon another citizen petition."); Alliance, 2023 WL 2825871, at *15 (finding administrative exhaustion regarding FDA's mifepristone policy likely futile because "it is unlikely FDA would reverse course")

I agree with the Washington and Alliance courts and find that administrative exhaustion through a citizen petition would be futile for Plaintiffs.

IV. Motion for Preliminary Injunction

In this lawsuit, Plaintiffs seek a permanent injunction removing the REMS associated with mifepristone. In contrast, Plaintiffs seek a preliminary injunction during the pendency of this litigation to enjoin FDA "from deviating from the status quo in the states in which [Plaintiffs] provide care." Dkt. 10 at 5. That is, Plaintiffs ask the court, at least at the preliminary

injunction stage, not to remove the REMS, but "to protect [their] continued ability to prescribe and dispense mifepristone to their patients during the pendency of this litigation." Id. at 2. Plaintiffs argue that the preliminary injunction is necessary because of the pending Alliance and Washington cases to which Plaintiffs are not parties and because of a new citizen petition to FDA seeking to have mifepristone's approval revoked. Id.

Federal Rule of Civil Procedure 65 provides the basis for a court to issue a preliminary injunction. Fed. R. Civ. Proc. 65(a). A preliminary injunction is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." Roe v. Dep't Def., 947 F.3d 207, 219 (4th Cir. 2020) (quoting Winter v. Nat. Res. Def. Council, 555 U.S. 7, 22 (2008)). A party seeking a preliminary injunction must establish that (1) the movant is likely to succeed on the merits; (2) the movant is likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in the movant's favor; and (4) an injunction is in the public interest. Winter, 555 U.S. at 20. A court need not consider all four factors before denying preliminary injunctive relief. Henderson for Nat'l Labor Relations Bd. v. Bluefield Hospital Co., LLC, 902 F.3d 432, 439 (4th Cir. 2018) (citing Winter, 555 U.S. at 23 (noting that the balance of equities and public interest alone required denial of injunctive relief)). Here, I find that Plaintiffs have not adequately established irreparable harm in the absence of preliminary relief.

A. Irreparable Harm

"A plaintiff must demonstrate more than just a 'possibility' of irreparable harm." Di Biase v. SPX Corp., 872 F.3d 224, 230 (4th Cir. 2017). A finding for a plaintiff based only on a possibility of irreparable harm "is inconsistent with [the Supreme Court's] characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that

the plaintiff is entitled to relief." Winter, 555 U.S. at 22 (internal quotations omitted). The plaintiff "must make a 'clear showing' that it will suffer harm that is 'neither remote nor speculative, but actual and imminent.'" Mountain Valley Pipeline, LLC v. 6.56 Acres of Land, Owned by Sandra Townes Powell, 915 F.3d 197, 216 (4th Cir. 2019) (quoting Direx Israel, Ltd. v. Breakthrough Med. Corp., 952 F.2d 802, 812 (4th Cir. 1991)). The harm must be such that it "cannot be fully rectified by the final judgment after trial." Id. (internal quotation omitted). "Mere injuries, however substantial, in terms of money, time and energy necessarily expended in the absence of a stay are not enough. The possibility that adequate compensatory or other corrective relief will be available at a later date . . . weighs heavily against a claim of irreparable harm." Di Biase, 872 F.3d at 230 (quoting Sampson v. Murray, 415 U.S. 61, 90 (1974)).

Plaintiffs argue that they will be irreparably harmed without a preliminary injunction for at least three reasons: (1) "returning to an older regulatory scheme . . . would prevent Plaintiffs from providing direct to patient telehealth, which has had a tremendous impact on patients in rural areas or for whom in-clinic visits are difficult to access[;]" (2) "resurrecting pre-2016 restrictions would confine certified mifepristone prescribers to physicians only[;]" and (3) "the legal uncertainty surrounding mifepristone has unleashed chaos in Plaintiffs' states" with Plaintiffs "unsure from one day to the next whether they will be able to maintain their protocols and procedures, or whether they will have to upend their practices to ensure that they are complying with various court orders."[12] Dkt. 10 at 34–35. Plaintiffs note that even with the stay in the Alliance case, "it is the uncertainty about how Plaintiffs and their patients are to respond to such events that is causing irreparable harm." Dkt. 33 at 6. Plaintiffs argue that they "should not

[12] In a related argument, Plaintiffs contend that they have "expended significant resources in order to parse conflicting court orders, pivot their practices, explain the chaos to patients, and ensure that they are providing evidence-based patient care throughout." Dkt. 33 at 6. Plaintiffs note that Plaintiff Trust Women spent $20,000 on brand name mifepristone. Id.

have to run to court upon the expiration of the Supreme Court stay or any other development in Alliance . . . to receive the same relief entered in the Washington case, given that in that moment, people could be denied access to mifepristone or abortion entirely." Dkt. 41 at 2.

Defendants argue that Plaintiffs' allegations of irreparable harm are purely speculative because the Supreme Court has stayed the Alliance order pending disposition on a writ of certiorari. Defendant further contend that "it is entirely speculative whether that order will ever take effect, what form it would [sic] take, and how long it would affect Plaintiffs." Dkt. 27 at 15. Defendants also argue that Plaintiffs have not alleged that FDA is the source of any imminent, irreparable harm and that Plaintiffs' request amounts to an attempted alteration of another court's order. Id. at 16; Dkt. 40 at 5.

Plaintiffs have not clearly established that they will suffer irreparable harm because of FDA's actions in the absence of preliminary relief. Presently, mifepristone, whether in a generic or name brand form, can be marketed and prescribed by providers and used for the effective and safe termination of a pregnancy. Plaintiffs have offered no evidence that FDA intends to take action to change any of mifepristone's REMS or to restrict the access of the drug in Virginia, Kansas, or Montana. Indeed, FDA has been enjoined from changing the REMS at this time in 17 states and the District of Columbia by the Washington court. The record contains no evidence that FDA can promulgate regulations that would apply in certain states and not others, that it has ever done so, or that it intends to take such action. Thus, much of Plaintiffs' allegations of irreparable harm are not rooted in actual and imminent events or actions taken by FDA. Mountain Valley Pipeline, LLC, 915 F.3d at 216.

Finally, the harm Plaintiffs allege could result from the Alliance case is purely speculative. Because of the Supreme Court's stay in the Alliance case, mifepristone remains an

available and viable medical option for health care professionals in Virginia, Kansas, and Montana. I agree that the outcome of the Alliance case could have an impact on Plaintiffs, but it is neither necessary nor appropriate to issue a preliminary injunction in anticipation of or because of a ruling from another court.

"Any time [the government] is enjoined by a court from effectuating statutes enacted by the 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)). Here, such an extraordinary remedy is not warranted because Plaintiffs have failed to show irreparable harm caused by FDA. Because Plaintiffs cannot show that they will suffer irreparable harm, they cannot establish the necessary factors for preliminary injunctive relief. See Henderson, 902 F.3d at 439; accord In re Search Warrant Issued June 13, 2019, 942 F.3d 159, 171 (4th Cir. 2019). See also Wolfe v. Rynolds, No. 4:18-cv-01350, 2019 WL 258110, at *1–2 (D.S.C. Jan. 18, 2019) (declining to address all four factors for a preliminary injunction when at least one factor had not been met); Rullan v. Goden, No. CCB-17-3741, 2023 WL 3093406, at *3 (D. Md. Apr. 26, 2023) (same); ABC Phones of N.C., Inc. v. Yahyavi, No. 5:20-cv-0090, 2020 WL 4208923, at *8 (E.D.N.C. July 22, 2020) (same).

B. Balance of the Equities and Public Interest

Although I need not consider the balance of the equities and public interest because Plaintiffs have failed to make a clear showing regarding irreparable harm, I note that Plaintiffs have not shown that the equities weigh in their favor at this time. The balance of the equities and public interest prongs of the Winter test "merge when the Government is the opposing party." Nken v. Holder, 556 U.S. 418, 436 (2009). As it relates to the balance of the equities, a court "must balance the competing claims of injury and must consider the effect on each party of the

grant or withholding of the requested relief." Winter, 555 U.S. at 24 (internal quotation marks omitted). See also Hughes Network Sys., Inc. v. InterDigital Commc'ns Corp., 17 F.3d 691, 693 (4th Cir. 1994) (noting that the balance of the equities is "reached by comparing the relevant harms to the plaintiff and defendant"). As it relates to the public interest, a court "should pay particular regard for the public consequences in employing the extraordinary remedy of injunction." Weinberger v. Romero-Barcelo, 456 U.S. 305, 312 (1982).

Plaintiffs argue that equity favors a preliminary injunction because "Defendants 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 17 other states and the District of Columbia that are parties to the Washington case." Dkt. 10 at 35. Defendants correctly argue, however, that because "it is entirely speculative whether the Alliance Order [either the district court or Fifth Circuit decision] will ever take effect[,] [e]ntry of the requested injunction thus would provide no benefit to anyone." Dkt. 27 at 28. Plaintiffs have not shown that the balance of the equities weighs in their favor because Plaintiffs have not demonstrated a clear benefit at this time to a preliminary injunction. Because of the stay in Alliance and the preliminary injunction in Washington, mifepristone is still on the market, and FDA effectively cannot change the REMS nationwide. Accordingly, Plaintiffs have not shown that the balance of the equities weighs in their favor.

V. Motion to Stay

Defendants seek a stay in this case pending resolution of the Alliance case. The "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." Derosa v. Walsh, 541 F. App'x 250, 252 (4th Cir. 2013). In determining whether to grant a

motion to stay, the Court must "balance the various factors relevant to the expeditious and comprehensive disposition of the causes of action on the court's docket." Maryland v. Universal Elections, 729 F.3d 370, 375 (4th Cir. 2013). Courts consider the following factors: "(1) the length of the stay; (2) the hardship the movant would face if the stay were denied; (3) the burden of the stay on the nonmovant; and (4) whether the stay would promote judicial economy by avoiding duplicative litigation." City of Galax v. Purdue Pharma, L.P., No. 7:18-cv-00617, 2019 WL 653010, at *3 (W.D. Va. Feb. 14, 2019). The moving party bears the burden to show good cause for the stay. See Landis v. N. Am. Co., 299 U.S. 248, 254–55 (1936).

Defendants seek a stay, arguing that "[i]t makes little sense for the parties and the Court to spend time and resources on further litigation of Plaintiffs' claims when the pending appellate proceedings in Alliance may resolve, narrow, or provide guidance on the very issues to be litigated." Dkt. 27 at 31. Defendants further argue that they will be prejudiced by being forced to litigate on two fronts and possibly being subject to inconsistent rulings but that Plaintiffs will not be prejudiced because "[t]wo of the three REMS elements they challenge have been in place for over two decades, during which time Plaintiffs never sought to challenge them." Id. at 31–32. Plaintiffs object to a stay and argue that because the Alliance case is a challenge to the 2000 FDA approval of mifepristone, "it is not assured that the Supreme Court will say anything about whether the 2023 REMS modification was unlawful." Dkt. 33 at 15. Plaintiffs further argue that they will be prejudiced because Plaintiffs and people seeking abortions in Virginia, Montana, and Kansas "are facing unprecedented challenges in the wake of the overturning of Roe [v. Wade, 410 U.S. 113 (1973)] that ha[ve] made these [REMS] requirements intolerable." Id. at 16. Finally, Plaintiffs argue that Defendants will not experience any prejudice because they are already subject to litigating this issue on two fronts in Washington and in Alliance. Id.

I will take the motion to stay under advisement pending discussions with the parties about production of the administrative record. It is my belief that the production of the administrative record in this case will be substantially similar to the production in the Washington case. The parties are directed to schedule a status conference within thirty days after this Opinion is issued to discuss a timeline for production of the administrative record.

VI. Conclusion

Plaintiffs' Motion for Preliminary Injunction, Dkt. 8, is **DENIED**. Defendants' Motion to Stay, Dkt. 25, is **TAKEN UNDER ADVISEMENT**. The parties are **DIRECTED** to schedule a status conference within 30 days after this Opinion is issued to discuss a timeline for production of the administrative record.

Entered: August 21, 2023

Robert S. Ballou

Robert S. Ballou
United States District Judge