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

WHOLE WOMAN'S HEALTH ALLIANCE, on behalf of itself, its staff, and its patients; et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; et al., Defendants.	Case No. 3:23-cv-00019-RSB

PLAINTIFFS' SURREPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Once more, the Government fails to counter the tremendous harm that Plaintiffs and their patients face. Once more, the Government cannot refute that such harm will be prevented if this Court enters an injunction like that issued in *Washington v. U.S. Food and Drug Administration*, No. 1:23-cv-3026-TOR, 2023 WL 2825861 (E.D. Wash. Apr. 7, 2023) (the "*Washington* Case")—an injunction to which the Government has effectively acquiesced by not filing a timely appeal. Plaintiffs' motion should be granted.

I. Plaintiffs and their patients face dramatic irreparable harm that is not self-inflicted and far outweighs any challenges facing the Government.

Plaintiffs will not belabor how they are experiencing irreparable injury given that the Government's latest brief merely recycles arguments already refuted.[1] Plaintiffs will, however, point out what continues to be missing from the Government's response to Plaintiffs' injuries—that Plaintiffs *cannot withstand* another round of attempts to remove mifepristone from the market. Thus, it is not simply that Plaintiffs face uncertainty around their provision of mifepristone, contrary to the Government's assertions, *see* Gov't Opp'n/Reply at 5-8—it is that another round of rollbacks on mifepristone will result in their patients being denied mifepristone or denied abortion altogether. This injury is *not* speculative or abstract.[2] The Government would require Plaintiffs' patients to be unable to use essential healthcare before they can seek relief. But, the

[1] The case on which the Government continues to rely to suggest Plaintiffs' irreparable harm is too speculative is particularly inapposite to this case. *See* ECF 40, Government's Combined Opp'n/Reply ("Gov't Opp'n/Reply") at 6. In *Direx Israel, Limited v. Breakthrough Medical Corporation*, the product defendants allegedly developed with plaintiffs' trade secrets was not even competing with the plaintiffs' product—thus, there was no imminent harm whatsoever. 952 F.2d 802, 815 (4th Cir. 1991). It is also unclear to what extent the irreparable harm analysis in *Direx* remains good law because it partly applied the "hardship balancing test" announced in *Blackwelder Furniture Company v. Seilig Manufacturing Company*, 550 F.2d 189 (4th Cir. 1977), which was abrogated by *Winter v. Natural Resources Defense Council*, 555 U.S. 7, 20 (2008). *See Stinnie v. Holcomb*, 37 F.4th 977, 982 (4th Cir. 2022), *reh'g en banc granted*, No. 21-1756, 2022 WL 3210714 (4th Cir. Aug. 9, 2022) (recognizing abrogation).

[2] Plaintiffs' expectations unfortunately align with the reality of a Fifth Circuit Court of Appeals and Supreme Court that recently rejected *Roe v. Wade* and allowed vigilante laws like Texas S.B. 8 to take effect. Mifepristone will be threatened again, and as Plaintiffs have emphasized, healthcare cannot simply turn on and off.

Government does not dispute that being denied access to mifepristone or access to abortion entirely is a most acute form of irreparable injury, particularly considering that abortion remains accessible in Virginia and is constitutionally protected in Kansas and Montana. Nor does it explain why Plaintiffs and their patients should live under this guillotine when providers in 17 states and the District of Columbia do not. This is a dramatically inequitable outcome.

Plaintiffs should not have to run to court upon the expiration of the Supreme Court stay or any other development in *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*, No. 2:22-cv-223-Z, 2023 WL 2825871 (N.D. Tex. Apr. 7, 2023) (the "*Alliance* Case"), 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. That tremendous irreparable harm vastly outweighs the Government's interest in not litigating this case, which will require minimal resources given that it raises many of the same issues as in the *Washington* Case. And, contrary to the Government's suggestion, the Supreme Court is not "poised to act" on a fundamental question of law that "may change the legal landscape" for this case on an interlocutory appeal of a preliminary injunction order for which no certiorari petition has yet been filed.[3] *Cf. Benisek v. Lamone*, 266 F. Supp. 3d 799, 808 (D. Md. 2017) (staying proceedings where the Supreme Court had granted certiorari in a case with the potential to alter the analysis for justiciability that would control the case at bar).

Further, the Government's assertion that Plaintiffs are self-inflicting their injuries misses the mark. *See* Gov't Opp'n/Reply at 6-7. None of the cases on which the Government relies for this point are relevant to the situation here, where external circumstances have forced and will likely again force Plaintiffs to make drastic operational changes in order to withstand sudden,

[3] The government accuses Plaintiffs of "delay" in bringing this case, Gov't Opp'n/Reply at 14, but Plaintiffs moved expeditiously, filing this case on May 8 after reeling from the *Alliance* orders entered in April.

immediate, and grave harm to their practices and the health and lives of their patients. *See Safari Club Int'l v. Jewell*, 47 F. Supp. 3d 29, 35 (D.D.C. 2014) (finding some harm likely self-inflicted where safari-goers chose to rearrange or cancel their trips); *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 418 (2013) (finding some harm likely self-inflicted where plaintiffs were "subjective[ly]" chilled through anticipating hypothetical future surveillance); *Buchanan v. Consol. Stores Corp.*, 125 F. Supp. 2d 730, 738 (D. Md. 2001) (finding harm likely self-inflicted where anti-discrimination civil rights organization alleged diversion of resources to investigate potential discrimination but could not point to significant impact on programs or efforts).

II. A preliminary injunction against FDA, as was issued in the *Washington* Case, would prevent irreparable harm to Plaintiffs and their patients.

Despite their arguments that Plaintiffs are not entitled to the injunction they seek due to standing and redressability in particular, *see* Gov't Opp'n/Reply at 6-8, the Government does not dispute that because of the *Washington* injunction, they must maintain the status quo of access to mifepristone in 17 states and the District of Columbia "irrespective" of orders from the district court or the Fifth Circuit in the *Alliance* Case.[4] *See Washington v. U.S. Food and Drug Administration*, No. 1:23-cv-3026-TOR, 2023 WL 2941567, at *2 (E.D. Wash. Apr. 13, 2023). They have, therefore, conceded that such an order, *which runs against FDA*, does prevent the irreparable harm Plaintiffs are experiencing because it insulates providers from the continued fallout from the *Alliance* Case.[5] It may be that the parties cannot point to another case like

[4] The Government complains that Plaintiffs should not rely on the Government's role in asserting that the Fifth Circuit ruling in the *Alliance* Case operated as a total prohibition on using mifepristone, *see* Gov't Opp'n/Reply at 5 & n.2, but this side-steps the point. Plaintiffs are merely pointing out that the Government has the role of implementing any orders from the *Alliance* Case, underscoring how an order running against FDA provides the relief Plaintiffs are seeking.

[5] The Government now disclaims its argument that Plaintiffs are collaterally attacking the *Alliance* orders—asserting just that an injunction would be targeted at "relief from another district court's order." *See* Gov't Opp'n/Reply at 3. The doctrine employed to determine whether that is the case *is* collateral estoppel, and that standard is clearly not met.

Washington, *see* Gov't Opp'n/Reply at 9, but the *Washington* injunction remains in effect, has not been appealed, and, if extended, would prevent Plaintiffs and their patients from being irreparably harmed.

The Government also strikes out again in its search for authority to support its creation of a separate standing analysis for seeking a preliminary injunction. *See* Gov't Opp'n/Reply at 7-8. Plaintiffs are not asserting that there is a preliminary injunction exception to the standing inquiry—just that Article III standing and the test for a preliminary injunction are distinct. They are no less distinct because standing is a jurisdictional requisite that may be addressed at any stage of a litigation. The cases cited by the Government are somewhat muddy, but they ultimately only reinforce that the inquiries are distinct. *See Waskul v. Washtenaw Cnty. Cmty. Mental Health*, 900 F.3d 250, 255-56 (6th Cir. 2018) (affirming district court ruling that organization had no likelihood of success on the merits of its request for injunctive relief because it was not experiencing any injury given that it had already received the administrative hearings and notices it sought through an injunction); *Suzhou Angela Online Game Tech. Co. v. Snail Games USA, Inc.*, No. 22-55137, 2022 WL 5240656, at *1 (9th Cir. 2022) (addressing first whether a plaintiff had standing to pursue its challenge at the preliminary injunction stage and then applying the four-factor test to determine if the plaintiff was entitled to a preliminary injunction); *City of Los Angeles v. Lyons*, 461 U.S. 95, 105 (1983) (concluding that plaintiff presented no case or controversy and thus lacked standing to maintain any challenge, including seeking injunctive relief, against a chokehold policy that was subject to a moratorium). Plaintiffs have standing to challenge the REMS, and the Government has never contended otherwise.

III. The Government's opposition to Plaintiffs' merits arguments still falls flat.

FDA has again failed to show that it likely engaged in the requisite *analysis* for reimposing the REMS.[6]

FDA's conclusory assertion that the REMS is appropriate, *see* Gov't Opp'n/Reply at 10, is an utter *failure to explain* how mifepristone meets the stringent criteria for imposing a REMS. Neither in briefing nor at argument has the Government pointed to anything in the administrative record showing such an analysis of how the mifepristone REMS is "commensurate with a specific serious risk" and not "'unduly burdensome on patient access to the drug[,]" and how it "'minimize[s] the burden on the healthcare delivery system[.]'" *See* ECF 27, June 5, 2023 Response Brief (quoting 21 U.S.C. § 355-1).

Further, the Government inappropriately attempts to narrow *Mayor of Baltimore*. *See* Gov't Opp'n/Reply at 11. That case holds that if the "medical community finds [a regulation] to be repugnant," an agency cannot articulate a satisfactory explanation under the APA by simply "announcing" that it "merely 'disagrees' with every major medical organization in the country." *Mayor of Baltimore v. Azar*, 973 F.3d 258, 278 (4th Cir. 2020). Here, the agency has not "announced" any disagreement with the medical consensus; rather, FDA has simply ignored it. This is plainly insufficient under *Mayor of Baltimore*.

[6] The Government incorrectly characterizes these two arguments as "new merits arguments," *see* Gov't Opp'n/Reply at 10. These arguments have been addressed in Plaintiffs' prior briefing. *See, e.g.*, ECF 10, Mem. Supp. Pls.' Mot. for Prelim. Inj. at 21-24, 27-33 (explaining how the imposition of the REMS is contrary to the FDCA and how FDA has never explained why it continues to be necessary); *id.* at 25-27 (explaining how FDA has not addressed why it has deviated from the medical consensus).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of July 2023, I filed the foregoing document with the Clerk of Court using the CM/ECF system.

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