IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

GENBIOPRO, INC.,

***Plaintiff*,**

v.

MARK A. SORSAIA*, in his official capacity as Prosecuting Attorney of Putnam County* **AND PATRICK MORRISEY, *in his official capacity as Attorney General of West Virginia*,**

Defendants.

Civil Action No.: 3:23-cv-00058
(Hon. Robert C. Chambers)

PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION FOR STAY

TABLE OF CONTENTS

INTRODUCTION

In their two-page brief in support of their motion to stay this litigation, Defendants Mark A. Sorsaia and Patrick Morrisey fail to meet their heavy burden of demonstrating that a stay is warranted. Defendants do not cite a single case from this Circuit in support of their Motion, much less explain how they satisfy the Court's three-part test for discretionary stays. Had they attempted to make the required showings, they would have failed. No factor of that test counsels in favor of a stay where a district court in another jurisdiction has issued a preliminary, non-final order concerning different claims and implicating different parties.

Regardless of what happens in the Texas litigation on which Defendants base their Motion, Plaintiff GenBioPro, Inc. ("GenBioPro") will continue to have standing to litigate its claims that West Virginia's abortion ban and restrictions are unconstitutional. The Texas court's order references generic mifepristone's approval only briefly, incorrectly presuming that the withdrawal of branded mifepristone requires the withdrawal of the generic. But generic drugs often remain on the market long after their branded counterpart is withdrawn. And the Fifth Circuit has preliminarily ordered the challenge to branded mifepristone's approval untimely.

The Motion is also overbroad. Even assuming a decision in *All. for Hippocratic Med. v. FDA*, No. 2:22-cv-00223-Z (N.D. Tex. Nov. 18, 2022) ("*AHM*") could affect FDA's 2019 approval for generic mifepristone, it would not affect GenBioPro's ability to vindicate its right to sell generic mifepristone in another federal forum, or seek re-approval of its generic in future.

GenBioPro filed this action on January 25, 2023 challenging West Virginia's abortion restrictions as unconstitutional and preempted by federal law. Since then, the parties briefed two motions to dismiss, and this Court set a hearing on those motions for Monday, April 24, 2023.

The motions to dismiss are ripe for decision, and a preliminary order from a Texas district court should not prevent this Court from ruling on them.

PROCEDURAL BACKGROUND

The U.S. Food and Drug Administration ("FDA") first approved mifepristone, one drug in a two-drug regimen indicated for medication abortion, 23 years ago. The history of Congress and FDA's repeated actions to reaffirm this approval and regulate mifepristone under a tightly controlled federal regime are set forth in Plaintiff's Complaint and in its oppositions to Defendants' motions to dismiss. Compl., ECF No. 1; Pls.' Opp'n to Def. Mark A. Sorsaia's Mot. to Dismiss, ECF No. 31; Pls.' Opp'n to Def. Patrick Morrisey's Mot. to Dismiss, ECF No. 35.

In November 2022, anti-abortion advocacy groups and doctors sued FDA in federal court for the Northern District of Texas challenging the 23-year-old approval of branded mifepristone ("Mifeprex"), as well as other changes FDA made to Mifeprex's dosing regime, administration, and dispensing between 2016 and 2021. Compl., *All. for Hippocratic Med. v. FDA*, No. 2:22-cv-00223-Z (N.D. Tex. Nov. 18, 2022) ("*AHM*"), ECF No. 1. On April 7, 2023, the Texas district court issued an order granting the plaintiffs' motion for preliminary relief in part and purporting to "stay[] the effective date of FDA's September 28, 2000, Approval of mifepristone" and subsequent actions that the plaintiffs challenged, including FDA's 2019 approval of GenBioPro's generic mifepristone. Mem. Op. and Order at 67, *AHM* (Apr. 7, 2023), ECF No. 137. The court's ruling as to the 2019 generic approval was premised only on the court's preliminary finding that plaintiffs were likely to succeed on their claim that mifepristone's original approval in 2000 was flawed. *See id.* at 60 ("Plaintiffs argue the 2019 Approval was unlawful because

FDA relied on the unlawful 2000 Approval . . . when approving generic mifepristone. . . . [T]he Court is inclined to agree with Plaintiffs . . . .").

This Order has not gone into effect. The district court stayed its Order for seven days to allow FDA to seek emergency relief from the Fifth Circuit. *Id.* at 67; *see* Emergency Mot. Under Circuit Rule 27.3 for a Stay Pending Appeal, *All. for Hippocratic Med. v. FDA*, No. 23-10362 (5th Cir. Apr. 10, 2023), ECF No. 20. Before those seven days expired, the Fifth Circuit granted a partial stay pending appeal. Unpublished Order at 2, *All. for Hippocratic Med. v. FDA*, No. 23-10362 (5th Cir. Apr. 12, 2023), ECF No. 183-2. The Fifth Circuit Order stayed the district court's purported stay of Mifeprex's 2000 approval, holding that the statute of limitations period had run on the plaintiffs' twenty-three-year-old claims. *Id*. But it declined to stay the effect of the district court's ruling on all other actions, including GenBioPro's 2019 generic approval—even though the district court purported to stay the 2019 generic approval *only* because of flaws it found in the 2000 approval. *See id.* at 2, 42.

Following a stay request to the U.S. Supreme Court supported by fifteen amici, Justice Alito granted an administrative stay through Wednesday, April 19, and later extended it through Friday, April 21. Order, *FDA v. All. for Hippocratic Med.*, No. 22A902 (U.S. Apr. 14, 2023).

Even if the district court's Order on preliminary relief is allowed to take effect, nothing about that order purports to make a permanent change to mifepristone's status. The court's purported "stay" of certain FDA actions—premised on the mistaken idea that a court can take a drug off the market on its own—would still have to be litigated to finality, which could take years.

Moreover, on April 19, GenBioPro filed a complaint against FDA and the U.S. Department of Health and Human Services ("HHS") in the District of Maryland, asking the court

to enjoin FDA from withdrawing GenBioPro's generic approval for mifepristone without affording GenBioPro procedural due process and the procedural rights that the Federal Food Drug and Cosmetic Act ("FDCA") and its implementing regulations afford drug makers.. *See* Compl., *GenBioPro, Inc. v. FDA*, No. 1:23-cv-01057-SAG (D. Md. Apr. 19, 2023), ECF No. 1 (attached as Exhibit A).

STANDARD FOR GRANTING A DISCRETIONARY STAY

A party seeking a stay bears the burden of demonstrating "by clear and convincing circumstances" that its interest in obtaining a stay outweighs the potential harm against the non-moving party. *Williford v. Armstrong World Indus., Inc.*, 715 F.2d 124, 127 (4th Cir. 1983). The "movant 'must make out a clear case of hardship or inequity in being required to go forward, if there is even a fair possibility that the stay for which he prays will work damage to someone else.'" *Willard Bays v. Walmart Inc.*, 2022 WL 193729, at *2 (S.D.W. Va. Jan. 20, 2022) (Chambers, J.) (quoting *Armstrong World Indus.*, 715 F.2d at 127). Courts in this district have described this as a "heavy burden." *Graham v. Dhar*, 2020 WL 8184344, at *1 (S.D.W. Va. Aug. 28, 2020).

In determining whether a stay applicant has satisfied this heavy burden, a district court "must consider: (1) whether a stay is in the interest of judicial economy, (2) the degree of hardship and equity to the moving party absent a stay, and (3) potential prejudice to the non-moving party." *Willard Bays*, 2022 WL 193729, at *2. "Overarching this balance is the court's paramount obligation to exercise jurisdiction timely in cases properly before it." *Sunbeam Prods., Inc. v. Hamilton Beach Brands, Inc.*, 2010 WL 1946262, at *2 (E.D. Va. May 10, 2010) (quoting *Cherokee Nation of Okla. v. United States*, 124 F.3d 1413, 1416 (Fed. Cir. 1997)). "In seeking a stay, a litigant argues in the shadow of 'the virtually unflagging obligation of the

federal courts to exercise the jurisdiction given them.'" *Conley v. Paitsel*, 2021 WL 5772455, at *1 (S.D.W. Va. Dec. 6, 2021) (quoting *Colo. River Water Conservation Dist. v. United States*, 424 U.S. 800, 817 (1976)).

ARGUMENT

Defendants have not, and cannot, satisfy the criteria for a discretionary stay – nor did they even try to do so in their motion (and therefore have waived any arguments for a stay at this time). In 2007, Congress determined that only FDA should restrict access to mifepristone. *See* Compl. ¶¶ 6-15. Nevertheless, West Virginia imposed laws improperly restricting access to this essential medication by banning abortion in almost all cases. *See id.* ¶¶ 11-13 (describing the abortion ban and prior restrictions on abortion access). Those laws make it nearly impossible for GenBioPro to market, promote, and sell its product, generic mifepristone, for its indicated use. *Id.* ¶ 16.

Staying this case will harm GenBioPro by continuing to hamper its ability to sell its product in the State. It also will harm the nearly two million West Virginians living under an unconstitutional regime preventing them from accessing it, as well as GenBioPro's customers, the healthcare providers and pharmacies that prescribe and dispense mifepristone. Because a stay would "work damage," Defendants must justify it by "clear and convincing circumstances." *Willard Bays*, 2022 WL 193729, at *2 (internal quotation marks & citation omitted). Their two-page motion fails to do so.

I. A Stay Will Not Serve Judicial Economy

Defendants cannot show that a stay is in the interest of judicial economy. They cite no law supporting their position that delaying resolution in this case serves judicial economy. They argue only (at 2) that pending litigation in the Fifth Circuit (involving none of the parties or claims that are before this Court) "directly impacts this case," and therefore that "judicial

economy" warrants a stay "until a final decision is reached in" Texas. This unsupported statement fails for several reasons.

First, it is unlikely that any decision in the Texas court will permanently affect the legal status of GenBioPro's product. The court's preliminary order purporting to "stay" a 23-year-old drug approval and the subsequent approval of a generic version is unprecedented, untenable, and will likely be overturned. The court in Texas developed no record on the generic product made by GenBioPro, and GenBioPro was not a party to that litigation. Additionally, Defendants argue (at 2) that the district court's interpretation of the Comstock Act will prohibit GenBioPro from shipping its product to West Virginia. But the Fifth Circuit declined to affirm the parts of the district court's (preliminary) decision based on the Comstock Act, meaning that there is no active ruling on the law one way or the other that could affect GenBioPro. See Unpublished Order at 42, *All. for Hippocratic Med. v. FDA*, No. 23-10362 (5th Cir. Apr. 12, 2023), ECF 183-2 ("[W]e need not definitively interpret the Comstock Act to resolve this stay application."). Even if there were, any decision of the Northern District of Texas or Fifth Circuit is not binding on this Court, and the Court could order relief that conflicts with those decisions, just as the district court did in Washington.

Second, the Texas case implicates issues unrelated to this litigation. The plaintiffs in Texas did not challenge—nor did the court mention—the 2023 mifepristone REMS, the preemptive effects of the FDAAA, or the dormant Commerce Clause, which are the bases for the instant case. In fact, the Texas court barely mentioned GenBioPro or its product; it referred to generic mifepristone only when presuming, incorrectly, that withdrawing branded Mifeprex from the market would necessarily result in generic mifepristone's withdrawal as well. *See* Mem. Op. and Order at 60, *AHM* (Apr. 7, 2023), ECF No. 137; *see also* Compl., *All. for Hippocratic Med.*

v. FDA, No. 2:22-cv-00223-Z (N.D. Tex. Nov. 18, 2022), ECF No. 1 at ¶¶ 87-88; Pls.' Br. in Supp. of Their Mot. for Prelim. Inj. at 5, 21–23*, All. for Hippocratic Med. v. FDA*, No. 2:22-cv-00223-Z (N.D. Tex. Nov. 18, 2022), ECF No. 7.[1] Courts deny stay applications premised on a litigant's identification of a "different case that may or may not affect the Court's proceedings." *Carlton & Harris Chiropractic, Inc. v. PDR Network, LLC*, 2018 WL 11412001, at *2 (S.D.W. Va. Apr. 30, 2018) (Chambers, J.) (collecting cases).

In keeping with these jurisprudential principles, other courts have continued to litigate questions involving mifepristone's availability, notwithstanding the Texas litigation. A federal court in the Eastern District of Washington preliminarily enjoined FDA from altering the "status quo" of mifepristone's availability as laid out in FDA's 2023 Risk Evaluation and Mitigation Strategy ("REMS") in 17 states and the District of Columbia. Order Granting in Part Pls.' Mot. for Prelim. Inj. at 30, *Washington v. FDA*, No. 1:23-cv-3026-TOR (E.D. Wash. Apr. 7, 2023), ECF No. 80. That court noted that its injunction applies "irrespective of the Northern District of Texas Court ruling." Order Granting Mot. for Clarification at 5-6, *Washington v. FDA*, No. 1:23-cv-3026-TOR (E.D. Wash. Apr. 13, 2023), ECF No. 91.

Even assuming a court could unilaterally "stay" a drug approval that a federal agency granted 23 years ago, Defendants' motion fails to take into account any number of intervening actions that might ensure GenBioPro's standing. For example, the motion does not contemplate that GenBioPro could prevail in its litigation in Maryland against FDA which would ensure its

[1] The FDA has a comprehensive process for addressing suspension or withdrawal of drugs. *E.g.* 21 U.S.C. § 355(e), 21 C.F.R. §§ 314.150, 314.200, 314.530. It has not undertaken that process as to mifepristone and, indeed, has argued that such action would be unwarranted given the significant data and "decades of experience" that "conclusively demonstrate[] the drug's safety." Appl. to Stay the Order Entered by the U.S. Dist. Ct. for the N. Dist. of Tex. and for an Administrative Stay at 2*, FDA v. All. For Hippocratic Medicine* (U.S. Apr. 14, 2023).

product remains available to customers nationwide, or that GenBioPro might seek re-approval of its generic[2], or that the Texas case will ultimately be dismissed for lack of standing.

For these reasons, regardless of the Texas litigation's outcome, GenBioPro has standing to litigate the harms West Virginia's unconstitutional laws imposes on its ability to market and provide mifepristone in the state. *See 303 Creative LLC v. Elenis*, 6 F.4th 1160, 1173 (10th Cir. 2021) ("Assuming Appellants offer wedding-related services to the public as they say they will, there is no reason to then conclude that Appellants will fail to attract customers. . . . [W]e find nothing 'imaginary or speculative' about Appellants' apprehensions that they may violate CADA if they offer wedding-based services in the manner that they intend.") (quoting *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 165 (2014)), *cert. granted in non-relevant part*, 142 S. Ct. 1106 (2022). The prospective interference with GenBioPro's interests is sufficient to uphold standing and to warrant the declaratory judgment that it seeks. *Ezell v. City of Chicago*, 651 F.3d 684, 695-96 (7th Cir. 2011) (upholding standing for pre-enforcement challenge by firing range facility operator that had not yet set up facilities in Chicago) (cited with approval in *Maryland Shall Issue, Inc. v. Hogan*, 971 F.3d 199, 211 (4th Cir. 2020) ("Action Target, as a supplier of firing-range facilities, is harmed by the firing-range ban.")). The State's unconstitutional overreach obstructs GenBioPro's ability to not only market its current product, but also to make its future product plans. This conduct is causing harm now and unrelated legal proceedings do not change that harm.

[2] The Fifth Circuit has, in a preliminary order, held that the challenge to the 2000 approval of mifepristone untimely, *see* Unpublished Order at 2, 23-24, *All. for Hippocratic Med. v. FDA*, No. 23-10362 (5th Cir. Apr. 12, 2023), thereby permitting sales of branded mifepristone to proceed. And the approval process for a generic bioequivalent of the brand medication is a relatively straightforward process, *see* 21 U.S.C. § 355(j).

Third, the parties in Texas are years from finality. A final district court decision following the production of an administrative record and summary judgment briefing will likely be appealed, first to the Fifth Circuit, and then to the Supreme Court. The Fifth Circuit has already preliminarily advised that the plaintiffs' challenge to Mifeprex's approval suffers from infirmities, including timeliness. Unpublished Order at 2, 23-24, *All. for Hippocratic Med. v. FDA*, No. 23-10362 (5th Cir. Apr. 12, 2023)**.** GenBioPro should not have to wait years to litigate the harms Defendants have caused. Indeed, the point behind a pre-enforcement challenge is to ensure that the State acts within the bounds of the Constitution and that parties may know the operative rules when doing business.

The Texas case was filed only two months before the case pending before this Court, is far from a final outcome, and likely will not affect this Court's decision on any legal issues in this case. It does not implicate GenBioPro's standing to litigate the economic harm of West Virginia's abortion ban and restrictions. Judicial economy therefore does not favor delaying GenBioPro's ability to get relief from this Court.

II. Defendants Will Suffer No Hardship In Litigating This Case

Defendants made no argument that they will suffer hardship if the action is not stayed. Nor could they. "The mere fact that this action will go forward, and that litigating it will cost money, is an insufficient reason to warrant a stay." *Sunbeam*, 2010 WL 1946262, at *4. And this case will not involve extensive—or any—discovery. It implicates only legal issues.

Moreover, Defendants have already fully briefed the motions to dismiss on which they now seek, abruptly, to defer or avoid a decision. *See Gibbs v. Plain Green, LLC*, 331 F. Supp. 3d 518, 528 (E.D. Va. 2018) (stay inappropriate when "the parties ha[d] briefed this Court on various issues" already). Defendants can point to no harm or injury from this Court ruling on the

constitutional issues presented by the Complaint so that a business like GenBioPro's can proceed free of unconstitutional constraints.

III. A Stay Will Prejudice GenBioPro

Defendants sought an indefinite, potentially years-long stay, without acknowledging that courts generally decline to stay cases when a stay would prejudice the non-movant. *Carlton*, 2018 WL 11412001, at *3. "A plaintiff's plausible allegations of ongoing harm can weigh against granting a stay because of the potential for prejudice in such a circumstance." *Gibbs*, 331 F. Supp. 3d at 528.

Even a short stay would prejudice GenBioPro. West Virginia's unconstitutional Ban and Restrictions inhibit GenBioPro from selling its product within the State, constricting the company's customer base. A delay of even a few months—much less an indefinite period of time while the Texas case winds its way up and down several layers of the judiciary—would be "significant" and "prejudicial." *Willard Bays*, 2022 WL 193729, at *2 (noting a delay of over two months may be prejudicial); *see also Fisher v. United States*, 2013 WL 6074076, at *5 (E.D. Va. Nov. 18, 2013) (denying a motion to stay where a court could not estimate an exact period of delay and could not rule out the potential that the delay might be significant).

This Court therefore should not require GenBioPro to "sit aside for an undeterminable amount of time" while suffering continuing economic harm. *Avalonbay Cmtys., Inc. v. San Jose Water Conservation Corp.*, 2007 WL 2481291, at *3 (E.D. Va. Aug. 27, 2007), *aff'd*, 325 F. App'x 217 (4th Cir. 2009).

CONCLUSION

For the reasons discussed above, this Court should deny Defendants' Motion for a stay of these proceedings.

Dated: April 20, 2023

Respectfully submitted,

/s/ Anthony J. Majestro

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CERTIFICATE OF SERVICE

I, the undersigned, counsel for Plaintiff, GenBioPro, Inc., do hereby certify that on April 20, 2023, I electronically filed and served the foregoing **PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION FOR STAY** with the Clerk of the Court and all parties using the CM/ECF system.

Respectfully submitted,

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