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

GENBIOPRO, INC.,

Plaintiff,

v. Civil Action No. 3:23-cv-00058

MARK A. SORSAIA, in his official capacity, AND PATRICK MORRISEY, in his official capacity,

Hon. Robert C. Chambers

Defendants.

DEFENDANTS' REPLY IN SUPPORT OF MOTION FOR STAY

INTRODUCTION

GenBioPro opposes a stay even though current court decisions stay the effective date of its generic approval nationwide. Specifically, the U.S. Court of Appeals for the Fifth Circuit recently upheld a stay of the effective date of GenBioPro's 2019 generic mifepristone approval—the same approval that GenBioPro argues preempts West Virginia's law in this case. The U.S. Supreme Court is currently considering, on expedited briefing, whether to grant FDA a stay of that order pending appeal. Currently, this means that GenBioPro may not market its drug anywhere in the United States, including West Virginia, because its generic approval has been stayed. Meanwhile, the Fifth Circuit has directed expedited briefing of whether, among other things, GenBioPro's 2019 generic drug approval should be stayed. Because these proceedings may well prove outcome determinative in this case, the Attorney General requests that the Court stay this case pending final resolution of the FDA lawsuit. And because this stay would serve the interests of judicial economy and impose no harm on GenBioPro (which, per its own filings, has never marketed its product in West Virginia), the Court should grant Defendants' motion.

ARGUMENT

Defendants have shown that a stay is justified here because the effective date of GenBioPro's generic mifepristone is currently stayed by order of the Fifth Circuit and pending litigation at the U.S. Supreme Court may establish that GenBioPro has no standing and render this case moot. *See Food & Drug Admin. v. All. for Hippocratic*

Med., No. 22A902 (U.S.). A "party seeking a stay must justify it by clear and convincing circumstances outweighing potential harm to the party against whom it is operative." *Williford v. Armstrong World Indus., Inc.*, 715 F.2d 124, 127 (4th Cir. 1983). Here, GenBioPro will suffer *no* harm from a stay in this case if the Supreme Court leaves the Fifth Circuit's order in place, because that order prevents GenBioPro from selling mifepristone anywhere in the United States, including West Virginia. But even if the Supreme Court stays the Fifth Circuit's decision for now, the underlying litigation will continue, potentially resulting in GenBioPro's removal from the market within a matter of weeks.

"When analyzing a motion to stay, a 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 v. Walmart Inc.*, No. CV 3:21-0460, 2022 WL 193729, at *2 (S.D.W. Va. Jan. 20, 2022). Here, these factors weigh in favor of a stay.

I. A stay is in the interest of judicial economy.

A stay of this case would serve the interests of judicial economy by delaying further briefing and argument until resolution of whether GenBioPro retains FDA authorization to market generic mifepristone. "A district court ordinarily has discretion to delay proceedings when a higher court will issue a decision that may affect the outcome of the pending case." *Carlton & Harris Chiropractic, Inc. v. PDR Network, LLC*, No. CV 3:15-14887, 2018 WL 11412001, at *2 (S.D.W. Va. Apr. 30, 2018). If the Supreme Court affirms the district court's stay (as modified by the Fifth Circuit) in the FDA case, that decision will dictate the outcome in this case.

First, GenBioPro argues that "it is unlikely that any decision in the Texas court will permanently affect the legal status of GenBioPro's product." Pl.'s Opp'n 6, ECF No. 50. But the Fifth Circuit's decision clearly leaves in place the district court's stay against the FDA's 2019 generic approval of mifepristone. *See All. for Hippocratic Med. v. Food & Drug Admin.*, No. 23-10362, 2023 WL 2913725, at *16 (5th Cir. Apr. 12, 2023). As long as that ruling remains in place, GenBioPro may not market mifepristone nationwide, obviously inclusive of West Virginia. It matters not that GenBioPro is not a party to that litigation, indeed GenBioPro's name-brand competitor intervened in that lawsuit while GenBioPro chose to wait out the proceedings involving its generic approval as a spectator rather than as a participant. In any event, FDA is a party to that lawsuit and the Fifth Circuit's order unambiguously stays the FDA's approval of GenBioPro's mifepristone product. If GenBioPro disagrees with that decision, its remedy is to intervene in that case, not to request advisory opinions from this Court on whether West Virginia law infringes on GenBioPro's right to market its product in the event that an appellate court overrule the district court's decision and it retains FDA approval.

Second, GenBioPro argues that "the Texas case implicates issues unrelated to this litigation" and that GenBioPro will have standing in this case "regardless of the Texas litigation's outcome." Pl.'s Opp'n 6, 8. Not so. The Fifth Circuit held unlawful the FDA's approval of GenBioPro's generic drug. *See All. for Hippocratic Med. v. Food & Drug Admin.*, No. 23-10362, 2023 WL 2913725 (5th Cir. Apr. 12, 2023). The Texas case thus bears directly on and supersedes every issue in this case. It is impossible

for a generic drug approval that has been held invalid to preempt a state law that protects the health and safety of West Virginia citizens. *See* Compl. ¶¶ 93–101, ECF No. 1. Indeed, that FDA's approval of generic mifepristone has been held invalid renders any opinion from this Court on whether that approval preempts West Virginia law advisory. *See United Pub. Workers of Am. (C.I.O.) v. Mitchell*, 330 U.S. 75, 89 (1947) ("[T]he federal courts established pursuant to Article III of the Constitution do not render advisory opinions.").

GenBioPro argues that "[c]ourts deny stay applications premised on a litigant's identification of a 'different case that may or may not affect the Court's proceedings.'" Pl.'s Opp'n 7 (quoting C*arlton & Harris Chiropractic, Inc. v. PDR Network, LLC*, 2018 WL 11412001, at *2 (S.D.W. Va. Apr. 30, 2018) (Chambers, J.) (collecting cases)). But here Defendants identify a different case that in its present posture removes the very federal approval that Plaintiffs say preempts West Virginia's law and allows marketing the product underlying all of its challenges here.

Third, GenBioPro argues that Defendants' "motion does not contemplate that GenBioPro *could* prevail in its litigation in Maryland against FDA which would ensure its product remains available to customers nationwide, or that GenBioPro might seek re-approval of its generic, or that the Texas case will ultimately be dismissed for lack of standing." Pl.'s Opp'n 7–8 (emphasis added). These someday events only highlight that judicial economy will be conserved by a stay in this case. GenBioPro did not file its late-breaking Maryland litigation until April 19, 2023—a day after Defendants' motion to stay. Regardless, neither the possibility of GenBioPro

prevailing in Maryland (an unknowable prognostication though the odds seem long) nor it seeking re-approval of its generic at some unknown future date are sufficiently definite to give it standing to challenge West Virginia's laws *now*. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 401 (2013) (holding that "future injury is too speculative to satisfy the well-established requirement that threatened injury must be 'certainly impending'"). And the Fifth Circuit has already held that Plaintiffs in the Texas case have standing to challenge the 2019 generic approval of mifepristone regardless of whether they have standing to challenge the FDA's original 2000 approval. *See All. for Hippocratic Med.,* 2023 WL 2913725 at *11.

Finally, GenBioPro misunderstands the administrative stay issued by the Northern District of Texas and upheld by the Fifth Circuit. GenBioPro argues that, even if upheld by the Supreme Court, this order "would not affect GenBioPro's ability to vindicate its right to sell generic mifepristone in another federal forum." But as the Eastern District of Washington recently recognized—and FDA has not contested—the effect of invalidating an agency approval is to render that drug unapproved nationwide. *See* Defs.' Mot. For Clarification at 2, *Washington v. Food & Drug Admin.*, No. 23-cv-3026 (E.D. Wash. Apr. 10, 2023), ECF No. 81, Attached as Exhibit A (acknowledging that the Texas district court's "order would—of its own force and without any further action by FDA—stay the effectiveness of FDA's prior approvals").

GenBioPro also argues "the parties in Texas are years from finality." Pl.'s Opp'n 9. Again, nothing prevents GenBioPro from intervening in that preexisting lawsuit. But this temporal finality assertion is also incorrect. The Fifth Circuit has

issued expedited briefing on the issue of whether the FDA must stay approval of generic mifepristone (after upholding the district court's stay) with oral argument to occur in less than one month. And the Supreme Court may weigh in as soon as today. In short, judicial economy weighs decisively in favor of granting the stay.

II. West Virginia will suffer hardship absent a stay.

West Virginia law at issue in this case serves the State's legitimate interests in "respect for and preservation of prenatal life at all stages of development," "the protection of maternal health and safety," and "the elimination of particularly gruesome or barbaric medical procedures." *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2284 (2022). Under the Constitution, "the regulation of health and safety matters is primarily and historically a matter of local concern." *Hillsborough Cnty., Fla. v. Automated Med. Laboratories, Inc.*, 471 U.S. 707, 719 (1985). West Virginia has an interest in seeing that its laws are followed and would suffer concrete harms to its resources if this lawsuit charges forward, notwithstanding that GenBioPro has significant standing and merits hurdles in a case that is currently moot under an order upheld by the Fifth Circuit. Consequently, the Court should stay this case and allow West Virginia's duly enacted law to remain in place until the Texas case reaches a final resolution on whether the FDA's approval of generic mifepristone was valid.

III. A stay will not prejudice GenBioPro.

A stay will not prejudice GenBioPro because it has no right to distribute mifepristone in West Virginia if its FDA approval is invalid. In other words, as long as the FDA's 2019 generic approval of mifepristone remains stayed, GenBioPro may

not market its products within West Virginia *regardless* of the outcome of this case. Further, a stay will not prejudice GenBioPro in the least because it has never marketed mifepristone in West Virginia nor even suggested concrete plans to do so. Thus, the Court should stay this case to avoid rendering an advisory opinion on the validity of West Virginia's laws.

As for GenBioPro's late-breaking lawsuit in Maryland—that lawsuit will not disrupt issues in the Texas case because it is based on an inaccurate understanding of basic administrative law principles. In that lawsuit, GenBioPro claims that "Congress delegated to the HHS Secretary *sole* legal authority to "suspend" a drug approval." Ex. A to Pl.'s Opp'n ¶14, ECF No. 50-1. As the Supreme Court said in *Abbott*, another FDCA case, "the Administrative Procedure Act provides specifically not only for review of '[a]gency action made reviewable by statute' but also for review of 'final agency action for which there is no other adequate remedy in a court,'" *Abbott Laboratories v. Gardner*, 387 U.S. 136, 140 (1967) (citing 5 U.S.C.A. § 704). As a result, the APA's "generous review provisions" must be given a "hospitable" interpretation. *Shaughnessy v. Pedreiro*, 349 U. S. 48, 51 (1955); *see United States v. Interstate Com. Comm'n*, 337 U. S. 426, 433–35 (1949).

Further, GenBioPro chose not to participate in the Texas litigation involving FDA and GenBioPro's generic approval. Even today, it could intervene in the Texas federal-court matter and seek relief on appeal. Its failure to pursue that readily available remedy undercuts the company's argument of prejudice here.

Respectfully submitted,

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Defendants.

CERTIFICATE OF SERVICE

I hereby certify that, on this 21st day of April, 2023, I electronically filed the foregoing "Defendants' Reply in Support of Motion for Stay" with the Clerk of Court and all parties using the CM/ECF System.

/s/ Curtis R. A. Capehart
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Exhibit A

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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, *et al.*, Plaintiffs, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	No. 1:23-cv-03026 DEFENDANTS' MOTION FOR CLARIFICATION 05/10/23 WITHOUT ORAL ARGUMENT

Plaintiffs challenge FDA's January 3, 2023, approval of modifications to the Risk Evaluation and Mitigation Strategy (REMS) for mifepristone.[1] On April 7, 2023, this Court declined to preliminarily enjoin FDA from enforcing or applying any requirement of mifepristone's REMS. Order at 26-27. But the Court preliminarily enjoined the agency 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 [(REMS)] under 21 U.S.C. § 355-1 in Plaintiff States." Order at 30.

Shortly before this Court entered its order, the United States District Court for the Northern District of Texas entered an order invoking 5 U.S.C. § 705 to stay the approval of the new drug application and abbreviated new drug application for mifepristone. *See Alliance for Hippocratic Medicine v. FDA*, 2:22-cv-00223-Z, Dkt. 137 (Apr. 7, 2023). That court stayed its order for seven days to give FDA

[1] This motion uses the term "mifepristone" to refer to drug products that are approved for medical termination of early pregnancy, in both brand name and generic form. FDA has separately approved another manufacturer's drug, Korlym, which has mifepristone as its active ingredient and is approved for the treatment of Cushing's syndrome. This litigation, including the Court's order, does not affect Korlym or its generic.

time to seek relief from the United States Court of Appeals for the Fifth Circuit, and FDA is seeking an emergency stay pending appeal. But if the Texas district court's order takes effect, the order would—of its own force and without any further action by FDA—stay the effectiveness of FDA's prior approvals of mifepristone nationwide. *See id.*

The result of that order appears to be in significant tension with this Court's order prohibiting FDA from "altering the status quo and rights as it relates to the availability of Mifepristone" in Plaintiff States. Order at 30. The Court did not address the interaction between the two orders, presumably because they were issued less than 20 minutes apart. To ensure that Defendants comply with all court orders in these unusual circumstances, Defendants respectfully request that this Court clarify their obligations under its preliminary injunction in the event that the *Alliance* order takes effect and stays the approval of mifepristone.

April 10, 2023

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CERTIFICATE OF SERVICE

I hereby certify that, on April 10, 2023, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Noah T. Katzen

NOAH T. KATZEN