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.

REPLY IN SUPPORT OF MOTION TO DISMISS

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INTRODUCTION

In its response brief, GBP doubles down on its sweeping claim that the FDA's imposition of additional safety restrictions on particularly dangerous drugs (like mifepristone) preempts the states' traditional authority to regulate for health and safety, and delegates to an agency the authority to mandate nationwide abortion access. GBP also continues to claim its financial interest in selling more drugs outweighs West Virginia's interest in protecting unborn life and maternal health. GBP's claims fail for four reasons.

First, GBP fails to meet the most basic Article III requirements of injury-in-fact and redressability. The pharmaceutical company does not allege that it has ever sold its chemical abortion drug in West Virginia, nor does it describe any plan to do so. GBP's "someday" harms are insufficient to satisfy the constitutional standing threshold.

Second, GBP does not (and could not) claim that abortion is not an issue of major political and social significance. Under separation of powers and federalism principles, GBP must point to clear congressional authorization empowering the FDA to do the things that GBP alleges it has done, namely deciding matters of medical practice and even mandating nationwide abortion. The best GBP can do is point to the 2007 FDCAAA amendments, but those amendments imposed additional requirements on drugs too dangerous to be approved without safety guardrails. Those guardrails do not amount to a clear statement from Congress taking away health and safety matters from the states, much less empowering an agency to dictate nationwide abortion access.

With respect to its preemption claims, GBP clarifies that it is not relying on the FDCA writ large but only on Congress's 2007 Amendments. Those little-used provisions, however, are particularly in apropos because they direct the FDA to impose additional restrictions (REMS) on drugs that are otherwise too dangerous to gain pre-market approval. Nothing in the text or statutory context suggests that Congress intended to displace traditional state authority or to authorize the

FDA to exercise sweeping new power over abortion. REMS are not a grant of preemptive authority, but rather place limits on the FDA's approval authority. States' Amicus Br. at 14, ECF No. 30. As the Supreme Court said in another FDA case, "Congress could not have intended to delegate" such a sweeping and consequential authority "in so cryptic a fashion." *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000).

Fourth, GBP's Commerce Clause claims fail because a decrease in a pharmaceutical company's bottom line in West Virginia does not outweigh the State's legitimate interests in protecting its most vulnerable lives. This Court should dismiss the Complaint.

ARGUMENT

I. GBP lacks standing.

GBP fails to allege an "actual or imminent, not conjectural or hypothetical" financial injury. *Spokeo, Inc. v. Robins*, 578 U.S. 330, 339 (2016). GBP acknowledges that it has never sold its chemical abortion drug in West Virginia. Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss 5, ECF No. 35 (Pl.'s Opp'n). Yet none of its cases find standing based on economic injury where the plaintiff has never participated in the given market. *See Md. Shall Issue, Inc. v. Hogan*, 971 F.3d 199, 210–11 (4th Cir. 2020) (dealer who operates several gun stores in Maryland had standing). Needless to say, a handgun dealer who sells handguns has standing to challenge a law under which the company (or its product) is directly regulated. So, too, for a plaintiff who "abandon[s] a line of business" in response to a regulation. *Nat'l Rifle Ass'n of Am. v. Magaw*, 132 F.3d 272, 282 (6th Cir. 1997). In contrast, West Virginia does not regulate GBP or mifepristone at all, and far from abandoning a "line of business," GBP has never done business in West Virginia.

GBP's "someday" intention to sell mifepristone in West Virginia is not enough. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 564 (1992) ("intent" to visit Sri Lanka and Egypt, without a plan, insufficient for injury-in-fact). So too for GBP's claim that Walgreens decided not to sell

mifepristone in West Virginia. Pl.'s Opp'n 3–4. This bare-bones allegation does not specify how any conceivable injury to Walgreens harms GBP. Perhaps anticipating this problem, GBP also alleges that it satisfies the requirements for third-party standing to assert the interests of its pharmaceutical vendees. *Id.* at 7–8. It does not. The cases cited by GBP make clear that, in order to assert the interests of a third party, a vendor plaintiff must first satisfy the requirements for Article III standing itself. *Md. Shall Issue*, 971 F.3d at 214–15 (finding third-party standing for a "[plaintiff] with standing to challenge the lawfulness of a regulation").

Finally, GBP's "credible threat of enforcement" claim fails for an even more fundamental reason. There is zero chance West Virginia's law will be enforced against GBP because it is not a regulated entity under the challenged laws. *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 160 (2014) and *Virginia v. American Booksellers Association*, 484 U.S. 383 (1988), are inapposite, where, as here, plaintiffs could have no actual fear that the challenged law "will be enforced against them." 484 U.S. at 393.

For similar reasons, GBP's alleged injuries are not redressable. They depend on independent third-party action. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398 (2013). And GBP's business model is illegal under federal law.[1] *See* 18 U.S.C. §§ 1461, 1462 (criminalizing using the mail and common carriers to move abortion drugs across state lines).[2]

[1] The plain text of these laws applies to pharmaceuticals because they are designed and intended to cause abortions. 18 U.S.C. §§ 1461, 1462. It is GBP's claim that a 2007 congressional amendment silently "ratified" a 2023 update to the FDA's REMS websites and somehow rendered other federal laws unenforceable that is "nonsensical." Pl.'s Opp'n 6.

[2] GBP has no standing to challenge §§ 16-2I-2 and 16-2I-9 unless a reviewing court first eliminates UCPA. *California v. Texas*, 141 S. Ct. 2104, 2116 (2021) (unenforceable statutory provision is incapable of meeting the redressability requirement).

II. Congress did not delegate the ability to set nationwide abortion policy or displace state laws regulating medical practice.

A. FDA does not have the authority to set national abortion policy.

GBP does not dispute that abortion is a major political and social issue or that there are "profound moral and spiritual implications of terminating a pregnancy, even in its earliest stage." *Planned Parenthood of Se. Penn. v. Casey*, 505 U.S. 833, 850 (1992). Instead, GBP claims—without a single citation—that the major questions doctrine does not apply here because "Congress considered the issue" by "including mifepristone in the group of drugs it deemed to have a REMS." Pl.'s Opp'n 20, 21. But the relevant question is: *which issue did Congress consider?*

Here, West Virginia does not quibble with the FDA's authority to determine whether a drug manufacturer has demonstrated that its drug is safe and effective.[3] But whether Congress has delegated to a federal agency the authority to mandate nationwide abortion access is another matter entirely.

The sole statutory authorization GBP identifies is Congress's 2007 Amendments to the FDCA (the "FDCAAA") "deeming" mifepristone and sixteen other drugs to have temporary restrictions (i.e. REMS) on their use. Pl.'s Opp'n 10–11. This language does not authorize, much less create, a federal abortion mandate; it certainly does not cede to FDA the authority to determine as a policy matter whether or when it is appropriate to abort a pregnancy. It is instead a stop-gap measure focused on certain dangerous drugs—not just mifepristone—ensuring that all of those drugs would continue to be *restricted* as the agency transitioned to its new REMS regulatory scheme.

GBP's attempts to distinguish the major-questions cases is unavailing. *West Virginia v. Env't Prot. Agency*, 142 S. Ct. 2587 (2022), in particular, is on all fours. In that case, the agency had

[3] *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, No. 2:22-cv-00223 (N.D. Tex.).

congressional authority to regulate the emission of certain pollutants from existing sources. *West Virginia*, 142 S. Ct. at 2609. But that limited authority did not encompass the much greater authority to impose cap-and-trade regulation on the entire nation. *Id.* And as in *West Virginia v. EPA*, Congress has repeatedly chosen not to enact legislation delegating the authority asserted here. Similarly, GBP's claim that the REMS provisions establish both a federal floor and ceiling that preempts complementary state regulation represents a "transformative expansion in [FDA's] regulatory authority." *Id.* at 2610 (citing *Util. Air Regul. Grp. v. Env't Prot. Agency*, 573 U.S. 302, 324 (2014). Under *West Virginia v. EPA* and other cases, GBP must—but cannot—point to "clear congressional authorization" for the authority it claims for the FDA. *West Virginia*, 142 S. Ct. at 2609.

In short, this is a major-questions case. Were GBP correct that "deeming" a drug to have a REMS is equivalent to delegating to an agency the authority to set nationwide abortion policy, the utter lack of any intelligible principle on which to base such a freighted moral decision would clearly violate the non-delegation doctrine. *Gundy v. United States*, 139 S. Ct. 2116 (2019).

B. FDA's 2007 Amendments do not preempt state law.

On the merits, GBP's preemption claim fails. Its response brief makes clear it is relying only upon the 2007 FDCAAA Amendments. Pl.'s Opp'n at 8 ("The FDAAA preempts West Virginia's ban and restrictions."); *Id.* at 16–17. Yet nothing within those amendments indicates a congressional intent to set aside state law on a matter of historical state concern. *See Hillsborough Cnty. v. Automated Med. Laboratories*, 471 U.S. 707, 719 (1985).

1. Field preemption does not exist.

GBP says that the FDCAAA created a "framework of regulation so pervasive that Congress left no room for the States to supplement it." Pl.'s Opp'n 9 (quoting *Arizona v. United States*, 567 U.S. 387, 399 (2012)). The problem with that assertion is that Congress said the opposite. It

included an express savings clause in the FDCA providing that state law would only be invalidated upon a "direct and positive conflict." Pl.'s Opp'n 14 (citing *Wyeth v. Levine*, 555 U.S. 555, 567–8 (2009)). As a result, the FDCA cannot be found to "'wholly displace' state law in this area because it explicitly preserved state-law remedies." *Johnson v. Am. Towers, LLC*, 781 F.3d 693, 703 (4th Cir. 2015). Rather, the FDCA's express savings clause implements Congress's intent for state law to continue to play a complementary role in the field. Indeed, the presence of a savings provision "is fundamentally incompatible with complete field preemption." *Farina v. Nokia Inc.*, 625 F.3d 97, 121 (3d Cir. 2010); *Aldridge v. Miss. Dep't of Corr.*, 990 F.3d 868, 874–75 (5th Cir. 2021); *In re NOS Commc'ns*, 495 F.3d 1052, 1058 (9th Cir. 2007).

Even if GBP could avoid the express savings clause, its field preemption claim still fails the "touchstone" of preemption analysis: congressional purpose. *Wyeth v. Levine*, 555 U.S. at 565. Because regulating "health and safety matters is primarily, and historically, a matter of local concern," *Hillsborough Cnty.*, 471 U.S. at 719, GBP would need to identify a clear statement to upset the federal-state balance, *Penn. R.R. v. Puritan Coal Mining Co.*, 237 U.S. 121, 129–30 (1915). Yet GBP identifies nothing in the FDCAAA amendments to suggest that Congress meant to displace traditional state police powers.[4]

Directly contrary to the Supreme Court's holding in *Hillsborough County*, GBP cites *Wyeth* for the proposition that a presumption against preemption does not apply to state health and safety regulations. Pl.'s Opp'n 14. To be clear, that decision holds the opposite. In fact, *Wyeth* rejected

[4] Plaintiff suggests the Attorney General "waived any argument" concerning field preemption. Pl.'s Opp'n 11. But the Attorney General did address field preemption in its opening brief. Def. Morrisey's Mem. in Supp. of Mot. to Dismiss 11, ECF No. 20 (Mot. to Dismiss). And it is Plaintiff's pleadings that are insufficient. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (a court need not "accept as true a legal conclusion," and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice").

the same claim made here: "that the presumption against preemption should not apply . . . because the Federal Government has regulated drug labeling for more than a century." *Wyeth*, 555 U.S. at 565 n.3. As the Court held in *Wyeth*, "That argument misunderstands the principle: [The Supreme Court] rel[ies] on the presumption because respect for the States as 'independent sovereigns in our federal system' leads us to assume that 'Congress does not cavalierly pre-empt state-law causes of action.'" *Id.* (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). As a result, "[t]he presumption … does not rely on the absence of federal regulation." *Id.* Rather, where, as here, "the field that Congress is said to have pre-empted has been traditionally occupied by the States 'we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

GBP also uses Congress's inclusion of an express savings clause to argue for broader preemption. Pl.'s Opp'n 14 (arguing that the FDCA preserved only state regulation that did not pose a "direct and positive conflict" with federal law). That argument seeks to turn the idea of the savings clause on its head, pushing a conclusion contrary to the clause's manifest intent. And again, *Wyeth* says differently: "The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them." *Wyeth*, 555 U.S. at 575.

2. The UCPA does not conflict with the FDCAAA.

GBP claims that the UCPA "conflict[s] with Congress's determination" that FDA alone may regulate mifepristone. Pl.'s Opp'n 13. But there never was such a determination. *See Wyeth*, 555 U.S. at 575 (rejecting argument that FDCA assigned the FDA "precise balancing of risks and

benefits" leaving "no room for different state-law judgments"). In fact, Congress expressly preserved additional state regulation. *Id.*

Further, there is no conflict between federal and state law because the FDCA and West Virginia "regulate different actors engaging in different conduct in different parts of the drug market." States' Amicus Br. 4–5. The FDCA regulates drug manufacturers, requiring them to prove the safety and effectiveness of their product, whereas West Virginia prohibits abortion, with certain exceptions.

These different regulatory purposes preclude finding preemption. In *Nat'l Meat Ass'n v. Harris*, for instance, the Supreme Court suggested that a federal law regulating livestock slaughter methods did not preempt the state-law determination that horses should not be slaughtered for human consumption. 565 U.S. 452, 457 (2012); *Oneok Inc. v. Learjet, Inc.*, 575 U.S. 373, 374 (2015) (preemption not possible where state laws targeted "all businesses in the marketplace" rather than wholesale gas prices). That West Virginia law may have an indirect effect on GBP's bottom line does not a preemption claim make. *See Va. Uranium, Inc. v. Warren*, 139 S. Ct. 1894, 1900-02 (2019).

At the end of the day, GBP is left with its financially-motivated market-access claim. GBP says that West Virginia's regulation of a drug "earmarked for 'access' frustrates Congress's purpose." Pl.'s Opp'n 14. But West Virginia's Unborn Child Protection Act does not regulate any drug; rather, it seeks to advance the state's legitimate and undeniable interests in protecting unborn life and promoting maternal health. The UCPA does not question or challenge FDA's safety and efficacy determination; indeed, mifepristone's use as an abortifacient is not prohibited for those circumstances when an abortion is permitted within the Act's exceptions.

Virginia Uranium puts a fine point on it. The Supreme Court in that case refused to broadly interpret federal law to "prohibit[ ] an activity … far removed from the [agency's] historic powers." *Va. Uranium*, 139 S. Ct. at 1904–05. The FDA has no power to mandate nationwide access to any type of treatment or procedure. Full stop. To hold otherwise would represent "a serious intrusion into state sovereignty." *Lohr*, 518 U.S. at 488 (plurality opinion).

In any event, Congress has not given FDA authority to "earmark" drugs "for access," much less one with known serious health risks like mifepristone. There is not, for example, any federal requirement that manufacturers sell approved drugs, let alone at an affordable price. States' Amicus Br. 13. The FDCA does "not give drug manufacturers an unconditional right to market their federally approved drug at all times"; it merely says they "may not market a drug without federal approval." *Wyeth*, 555 U.S. at 592 (Thomas, J., concurring).

Nor can GBP read into the FDCAAA a congressional mandate that mifepristone "continue to be available." Pl.'s Opp'n 15. That amendment provided that drugs approved under SubPart H would be "deemed to have in effect an approved" REMS—a stopgap measure until FDA could convert the restrictions initially imposed on dangerous drugs approved under SubPart H into REMS. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 at 950–51; 21 U.S.C. § 355-1. Thus the requirement that covered drug manufacturers submit a "proposed risk evaluation and mitigation strategy" within 180 days. *Id.* In summary, GBP's audacious preemption arguments "rel[y] on an untenable interpretation of congressional intent and an overbroad view of an agency's power to pre-empt state law." *Wyeth*, 555 U.S at 573. [5]

[5] The presumption against preemption applies with full force to West Virginia's in-person requirements, W. VA. CODE §§ 30-1-26(b)(9), 30-3-13a(g)(5), as well as two dormant provisions of law requiring informed consent and patient counseling, *id.* §§ 16-2I-2, 16-2I-9. Pl.'s Opp'n 13. All of these provisions complement rather than frustrate the purpose of the REMS. *Id.*

III. GBP's Commerce Clause claim fails.

GBP argues that West Virginia's challenged laws violate the dormant aspect of the Commerce Clause. Compl. ¶ 17, ECF No. 1. GBP argues that West Virginia's challenged laws "violate the [dormant Commerce] Clause by imposing an undue burden on interstate commerce, by regulating extraterritorially, and by functionally banning an article of commerce." Pl.'s Opp'n 23. To begin, GBP did not raise extraterritoriality in its complaint, Compl. ¶ 104, nor does its response explain what extraterritorial impact West Virginia's laws have, Pl.'s Opp'n 26–27. Nor could it—West Virginia's laws do not purport to regulate abortion outside the State's borders.[6]

GBP claims the challenged laws ban an article of commerce and that the Attorney General failed to address this argument in his motion to dismiss. Both claims are wrong. Indeed, the Attorney General explained that West Virginia has not banned mifepristone at all. Mot. to Dismiss 19. Instead, West Virginia law regulates only primary conduct—that of abortion—and leaves mifepristone untouched for other purposes, such as treating cancer or Cushing disease, as well as for any legal abortion within one of the Act's exceptions, including medical emergencies, rape, and incest.

That leaves GBP with only its argument that the challenged laws violate the *Pike* balancing test. "Where the statute regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). GBP acknowledges that the State has a legitimate interest in "protecting unborn lives," but argues that interest is outweighed by noncommercial burdens

[6] Def. Morrisey's motion to dismiss does address extraterritoriality noting GBP does not (and could not) argue that West Virginia's challenged laws discriminate against interstate commerce—either "facially, in its practical effect, or in its purpose." Mot. to Dismiss at 18 (quoting *McBurney v. Young*, 667 F.3d 454, 468 (4th Cir. 2012)).

allegedly imposed on third parties. Pl.'s Opp'n 24–25 (discussing "the burden on West Virginians' right to access lifesaving, safe, and necessary healthcare"). But that is not how the *Pike* balancing test works. Because West Virginia's law does not prohibit GBP from manufacturing mifepristone, from selling it in other States, or even from selling it in West Virginia, it imposes no burden on interstate commerce. The challenged laws do not violate the Commerce Clause and GBP's claims should be dismissed.

CONCLUSION

For the reasons set forth herein, Defendant Patrick Morrisey, in his official capacity as the Attorney General of the State of West Virginia, requests his Motion to Dismiss this matter be granted.

Respectfully submitted this 31st day of March, 2023,

By counsel,

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CERTIFICATE OF SERVICE

I hereby certify that, on this 31st day of March, 2023, I electronically filed the foregoing "Reply in Support of Motion to Dismiss" with the Clerk of Court and all parties using the CM/ECF System.

/s/ Curtis R. A. Capehart
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