IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
NORTHERN DIVISION

GENBIOPRO, INC. PLAINTIFF

VS. CIVIL ACTION NO. 3:20-CV-652-HTW-LGI

DR. DANIEL EDNEY,* STATE HEALTH OFFICER
OF THE MISSISSIPPI DEPARTMENT OF HEALTH,
IN HIS OFFICIAL CAPACITY DEFENDANT

DEFENDANT'S MEMORANDUM IN OPPOSITION TO PLAINTIFF'S MOTION FOR LEAVE TO FILE AMENDED COMPLAINT

INTRODUCTION

This Court should deny GenBioPro's (GBP) motion to amend the complaint (Doc. 41) because the proposed amendment would be futile.

First, GBP's proposed amended complaint—like its operative complaint—fails to state a claim on which relief may be granted. The proposed amended complaint does not state a preemption claim against any of the State's laws. Mississippi's trigger law—the lead law challenged in the proposed amended complaint—is lawful under Supreme Court caselaw decided just weeks ago. *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2284 (2022) ("The Constitution does not prohibit the citizens of each State from . . . prohibiting abortion."). The trigger law does not conflict with or frustrate any federal law, policy, or objective on the safety or efficacy of GBP's drug. The trigger law instead

* Effective August 1, 2022, Dr. Daniel Edney succeeded Dr. Thomas E. Dobbs as the State Health Officer. Dr. Edney is automatically substituted as an official-capacity defendant in Dr. Dobbs' place under Fed. R. Civ. P. 25(d).

validly prohibits a swath of primary conduct (performing abortions) and respects any federal policy judgments on mifepristone's safety and efficacy. And the other challenged state laws regulating abortions accord with and complement federal law by promoting the safe use of what federal actors themselves deem a risky drug. Indeed, it is impossible for this Court to hold that Mississippi state law obstructs any federal policy on access to abortion drugs when federal law broadly criminalizes distributing those drugs. *See* 18 U.S.C. §§ 1461, 1462.

The proposed amended complaint also does not state a Commerce Clause claim. Congress has prohibited the commerce in which GBP seeks to engage, *see* 18 U.S.C. §§ 1461 & 1462, so dormant Commerce Clause principles pose no barrier to the challenged Mississippi laws. And even if the dormant Commerce Clause applied, GBP's Commerce Clause claim would still fail. GBP's proposed complaint fails to plausibly allege that the modest burdens on interstate commerce imposed by the challenged laws exceed the substantial local benefits they provide—benefits that the U.S. Supreme Court endorsed just weeks ago in *Dobbs*.

Second, and alternatively, GBP's proposed amended complaint—like its operative complaint—fails to establish Article III standing. GBP has never attempted to sell its drug in Mississippi, and it only speculates that it would be able to do so if the challenged laws were enjoined. GBP thus fails to adequately plead an injury in fact, that any such injury is fairly traceable to the challenged laws, or that a favorable decision would redress its claimed injury. GBP cannot satisfy traceability or redressability for the further independent reason that federal law criminalizes distributing abortion drugs—

effectively foreclosing GBP's ability to sell its drug for abortions in Mississippi. GBP's proposed amended complaint does not challenge those federal laws. Its injury is thus not traceable to Mississippi's laws and would not be redressed by relief against those laws.

The Court should deny leave to amend and should dismiss this case, for these reasons and for reasons the State has given in its prior motion-to-dismiss briefing.

BACKGROUND

GBP, the manufacturer of the generic version of the abortion drug mifepristone, filed this lawsuit in 2020. Doc. 1 at 1, 5. GBP's original, operative complaint seeks to enjoin enforcement of the Mississippi Women's Health Defense Act of 2013 (MWHDA), Miss. Code Ann. §§ 41-41-101 *et seq.*, which regulates the administering of abortion-inducing drugs to pregnant women, *id.* § 41-41-107. *See* Doc. 1 at 18-21. That complaint also seeks injunctive relief against other abortion laws and regulations that apply to medication abortions, including the 24-hour waiting period and informed-consent law, the fetal-ultrasound law, and the Minimum Standards of Operation for Abortion Facilities. Doc. 1 at 21–23. GBP claims that these laws and regulations are preempted by the Food and Drug Administration's (FDA) Risk Evaluation and Mitigation Strategy (REMS) for mifepristone, which imposes restrictions on dispensing the drug to promote patient safety. Doc. 1 at 2 ¶ 2. GBP contends that, by "impos[ing] a number of additional requirements before mifepristone can be dispensed," the State has "improperly displaced the FDA's judgment concerning the necessary precautions . . . and patient safety protections for safe use of mifepristone." Doc. 1 at 2 ¶ 3. GBP also claims that the challenged laws and regulations violate the "dormant" Commerce Clause by imposing a burden on interstate commerce that clearly exceeds their local benefits. Doc. 1 at 28–29.

The State moved to dismiss the lawsuit on the grounds that GBP lacks Article III standing and fails to state claim on which relief may be granted. Docs. 8, 9, 15. That motion remains pending.

On June 24, 2022, the U.S. Supreme Court overruled *Roe v. Wade*, 410 U.S. 113 (1973), and *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992). *See Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2284 (2022). The Court held that "[t]he Constitution does not prohibit the citizens of each State from regulating or prohibiting abortion" and thus "return[ed] that authority to the people and their elected representatives." *Id.* The Court explained that "[t]he Constitution makes no reference to abortion, and no such right is implicitly protected by any constitutional provision." *Id.* at 2242.

As a result of *Dobbs*, Mississippi's "trigger law" prohibiting most abortions, Miss. Code Ann. § 41-41-45, has taken effect. The trigger law provides that "[n]o abortion shall be performed or induced in the State of Mississippi, except . . . where necessary for the preservation of the mother's life or where the pregnancy was caused by rape." *Id.* § 41-41-45(2). *Abortion* is defined as "the use or prescription of any instrument, medicine, drug or any other substance or device to terminate the pregnancy of a woman known to be pregnant[.]" *Id.* § 41-41-45(1). Any person who performs or attempts to perform an abortion in violation of the statute commits a felony and may be subjected to 1–10 years of imprisonment. *Id.* § 41-41-45(4). The trigger law took effect on July 7, 2022. *See* 2007 Miss. Laws Ch. 441 (S.B. 2391) § 6 (trigger law takes effect ten days after publication of Attorney General's determination that *Roe v. Wade* has been overruled); Attorney

General's Determination Regarding Section 41-41-45, Miss. Code Ann., No. 26438 (June 27, 2022) (https://www.sos.ms.gov/adminsearch/ACProposed/00026438b.pdf).

After *Dobbs* was decided, this Court directed the parties to address the impact on this case of *Dobbs* and of the trigger law. GBP submitted a letter arguing that *Dobbs* has no impact on the merits of its claims. The State asserted that *Dobbs* and the activation of the trigger law required the dismissal of this lawsuit. In response, GBP emailed the Court and asked it to defer ruling on the motion to dismiss until it could move to amend its complaint to challenge the trigger law.

On the date ordered by the Court, GPB filed its motion for leave to file an amended complaint. Doc. 41. The proposed amended complaint does not assert new claims but rather adds allegations that the trigger law conflicts with the FDA-approved REMS for mifepristone and prohibits GBP from selling mifepristone in Mississippi. Doc. 42 at 3; Doc. 41-1 at 19–20, 25–27. The proposed amended complaint also "includes minor amendments to reflect changes to the FDA's approved regimen for mifepristone that the FDA has stated are forthcoming" and allegations "related to [GBP's] Prescriber Agreement with Planned Parenthood Southeast, Inc., which was previously submitted in a letter to the Court." Doc. 42 at 3. According to the proposed amended complaint, Planned Parenthood Southeast operates a clinic in Hattiesburg that "does not provide any abortion services because of the Mississippi restrictions and now ban." Doc. 41-1 at 27 ¶¶ 78, 80. Because Jackson Women's Health Organization, previously the only abortion clinic in Mississippi, closed soon after *Dobbs* was decided, GBP alleges that "there are no abortion clinics to which [it] may sell its product." *Id.*

LEGAL STANDARD

Generally, a "court should freely give" leave to amend pleadings "when justice so requires." Fed. R. Civ. P. 15(a)(2). But this "is not a mechanical absolute and the circumstances and terms upon which such leave is to be freely given is committed to" a district judge's "informed, careful judgment and discretion." *Freeman v. Cont'l Gin Co.*, 381 F.2d 459, 468 (5th Cir. 1967) (cleaned up). In determining whether to grant leave to amend, a court "may consider a variety of factors" including "futility of the amendment." *Marucci Sports, L.L.C. v. Nat'l Collegiate Athletic Ass'n*, 751 F.3d 368, 378 (5th Cir. 2014) (cleaned up). Amendment is futile if the proposed amended complaint "would fail to survive a Rule 12(b)(6) motion," *id.*, or "does not satisfy the requirements of standing," *Ayers v. Johnson*, 247 F. App'x 534, 535 (5th Cir. 2007).

ARGUMENT

This Court should deny GBP's motion for leave and grant the State's motion to dismiss, for two independent reasons. First, amendment would be futile because GBP's proposed complaint—like its existing complaint—fails to state a preemption claim or dormant Commerce Clause claim. Second, amendment would be futile because GBP lacks Article III standing to challenge the trigger law or any of the laws and regulations it challenged in its original complaint.

I. Amendment Would Be Futile Because GBP's Proposed Amended Complaint Fails to State a Claim on Which Relief May Be Granted.

A. GBP's Proposed Amended Complaint Fails to State a Preemption Claim.

GBP seeks leave to amend the complaint to claim that the trigger law prevents GBP "from selling its product in Mississippi and creates an even more stark conflict with

the FDA's approved regimen for mifepristone." Doc. 42 at 7. The proposed complaint alleges that the trigger law "directly conflicts with the FDA's statutorily-authorized REMS for mifepristone, as it prevents access to an FDA-approved medication that has been deemed safe and effective." Doc. 41-1 at 20 ¶ 61.

GBP's proposed amended preemption claim—like its operative preemption claim—fails as a matter of law. The trigger law does not conflict with or frustrate any federal law or policy. The trigger law does not impermissibly regulate the safety or efficacy of an FDA-approved drug. Rather, the trigger law prohibits primary conduct—performing abortions—that the State is constitutionally entitled to prohibit. And to the extent that any other state laws or regulations affect GBP's product, those laws are permissible health and safety regulations that do not conflict with or obstruct any federal law or policy. Allowing GBP to amend its complaint would be futile. The Court should dismiss the preemption claim.

Preemption and the Trigger Law. "The wellspring of preemption doctrine is the Constitution's Supremacy Clause[.]" *Ass'n of Taxicab Operators USA v. City of Dallas*, 720 F.3d 534, 537 (5th Cir. 2013). That Clause provides: "Th[e] Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. In deciding whether federal law preempts a state law, "the purpose of Congress is the ultimate touchstone[.]" *Wyeth v. Levine*, 555 U.S. 555, 565 (2009). A state law is preempted if it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."

Arizona v. United States, 567 U.S. 387, 406 (2012) (cleaned up). But "in all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied," courts "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." *Wyeth*, 555 U.S. at 565 (cleaned up); *see Ass'n of Taxicab Operators*, 720 F.3d at 537–38 (same, adding: "Principles of federalism inform our search for congressional intent.") (cleaned up).

That presumption against preemption applies here. In *Dobbs*, the Supreme Court "return[ed] t[he] authority" to "regulat[e] or prohibit[ ] abortion" "to the people and their elected representatives." 142 S. Ct. at 2284. The Court thus recognized that the States' historic police powers include the authority to prohibit, restrict, and criminalize abortion. *See id.* at 2252 ("In this country during the 19th century, the vast majority of the States enacted statutes criminalizing abortion at all stages of pregnancy."); *id.* at 2285-2300 (listing state statutes criminalizing abortion); *cf. Brecht v. Abrahamson*, 507 U.S. 619, 635 (1993) ("States possess primary authority for defining and enforcing the criminal law.") (cleaned up). Because the trigger law uses the States' historic, traditional power to restrict abortion, there is a strong presumption that the law is not preempted by the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*

GBP cannot overcome that presumption. The trigger law does not conflict with or frustrate any federal law or policy. On the regulation of drugs, the FDCA declares that the FDA's purpose is to "protect the public health by ensuring that . . . human . . . drugs are safe and effective." 21 U.S.C. § 393(b)(2)(B). The trigger law does not conflict with or

obstruct that purpose. The trigger does not question FDA's determination that mifepristone is safe or effective. The trigger law does not second-guess, dispute, or regulate mifepristone to protect the health and safety of pregnant women.

Rather than obstruct any federal law or policy, the trigger law prohibits the primary conduct of performing abortions—the act of purposefully destroying an unborn human life. Miss. Code Ann. § 41-41-45; *see Harris v. McRae*, 448 U.S. 297, 325 (1980) ("Abortion is inherently different from other medical procedures, because no other procedure involves the purposeful termination of a potential life."). A State is entitled to prohibit that primary conduct. *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2284 (2022) ("The Constitution does not prohibit the citizens of each State from . . . prohibiting abortion."). In doing so, the State has done nothing that conflicts with federal law or policy. Indeed, GBP's proposed amended complaint fails even without a presumption against preemption.

GBP attempts to gain mileage out of the State's prior arguments distinguishing *Zogenix, Inc. v. Patrick*, 2014 WL 1454696 (D. Mass. Apr. 15, 2014), on the basis that it involved a State's complete ban of an FDA-approved drug. Doc. 42 at 6. But the ban in *Zogenix* is materially different from the prohibition imposed by the trigger law. In *Zogenix*, Massachusetts barred the use of Zohydro ER, an opioid designed to provide pain relief, by healthcare providers. 2014 WL 1454696, at *1. Massachusetts thus squarely prohibited the use of an FDA-approved drug. Massachusetts did not prohibit—or claim the authority to prohibit—the primary conduct at issue: pain management. So the case did not involve what the trigger law involves. The trigger law prohibits the primary

conduct of providing abortions—a prohibition that, after *Dobbs*, the State is entitled to adopt. And notably—and again in contrast to *Zogenix*—here the State has not prohibited the use of mifepristone. Mifepristone can still be used under state law for the treatment of incomplete miscarriages. *See* Courtney A. Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 New Eng. J. Med. 2161 (2018).

Here is another way to see why the order in *Zogenix* was preempted but the trigger law is not: In *Zogenix*, Massachusetts banned prescribing and dispensing Zohydro based on its view that the use of the drug would "lead to opioid addiction and overdose fatalities." 2014 WL 1454696, at *1. The State thus "interposed its own conclusion about [the drug]'s safety and effectiveness" and "countermand[ed] FDA's determinations" in approving the sale of the drug. *Id.* at *2. The trigger law does nothing of the kind. The trigger law does not second-guess the FDA's judgment on mifepristone's safety or efficacy. Rather, it exercises the State's traditional authority to prohibit abortions. *Zogenix* provides no support for GBP's preemption claim.

For GBP's preemption argument to have merit, it would have to be true that the FDA's mere approval of a drug forces States to allow the sale and use of the drug despite States' authority to prohibit primary conduct associated with the drug. But that is not true. If it were true, it would mean that, if the FDA approved a drug for euthanasia, state laws banning euthanasia would be preempted and States would have to permit euthanasia—even though the law is settled that States may prohibit euthanasia. *Washington v. Glucksberg*, 521 U.S. 702, 719–26 (1997) (upholding constitutionality of law banning assisted suicide). Or if the FDA approved a drug protocol for executions,

that would mean (on GBP's view) that every State must use the death penalty and must also use that protocol in its executions. The Supremacy Clause requires no such thing. The Court should reject GBP's view that the trigger law is preempted, particularly given the absurd results that follow from that view.

These points establish that GBP's preemption claim against the trigger law fails as a matter of law. Two further points each independently establish the same thing.

First: GBP's preemption claim relies on the proposition that the FDA's "statutorily-authorized REMS for mifepristone" creates a uniform national policy that preempts state laws banning medication abortion. Doc. 41-1 at 20 ¶ 61. But there is no such federal policy. If anything, federal law adopts the opposite policy from what GBP claims. Federal law criminalizes the use of the mails to do what GBP demands this Court to allow it to do: distribute abortion-inducing drugs. *See* 18 U.S.C. § 1461 (declaring "nonmailable" "[e]very article or thing designed, adapted, or intended for producing abortion"). Another federal criminal law, last amended in 1996, prohibits the use of "any express company or other common carrier . . . for carriage in interstate or foreign commerce" of "any drug, medicine, article, or thing designed, adapted, or intended for producing abortion." *Id.* § 1462(c). Conviction under either statute can lead to five years' imprisonment and RICO penalties. *Id.* §§ 1461, 1462, 1961(1)(B). Notably, in claiming a preemptive federal policy requiring States to allow medication abortion, GBP fails to cite either of these statutes—even though they criminalize GBP's business model for mifepristone. *See* Doc. 41-1 at 26 ¶ 77 ("GBP has sold and shipped its mifepristone tablets to providers in 47 states"). Because it is illegal under federal law to distribute

mifepristone by mail or common carrier traveling in interstate commerce, GBP is wrong to claim that the trigger law poses an obstacle to federal objectives. The trigger law is consistent with the announced policy of these federal laws. It is impossible to rule that it was the "clear and manifest purpose of Congress" in enacting the FDCA to "supersede[ ]" the States' "historic police power" to prohibit abortion when federal law criminalizes distributing drugs used to perform abortions. *Wyeth*, 555 U.S. at 565.

Second: The major-questions doctrine independently dooms GBP's argument that FDA approval of a REMS for mifepristone requires States to allow access to the drug. The major-questions doctrine applies when a federal agency is claimed to possess broad statutory authority to effect fundamental changes in areas of "political and economic significance." *West Virginia v. EPA*, 142 S. Ct. 2587, 2608 (2022). Courts "presume that Congress intends to make major policy decisions itself, not leave those decisions to agencies." *Id.* at 2609. So when such sweeping authority is asserted, "something more than a merely plausible textual basis" is required. *Id.* Instead, the claimed power must have "clear congressional authorization." *Id.* (cleaned up); *see Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014) (Congress must "speak clearly if it wishes to assign to an agency decisions of vast economic and political significance.") (cleaned up).

Abortion is an issue of profound political and social importance. *See, e.g.*, *Casey*, 505 U.S. at 866–67 (abortion cases are in a class of "rare" cases involving "intensely divisive controversy"). The major-questions doctrine applies.

GBP cannot surmount the high hurdle that doctrine erects. GBP's preemption claim boils down to the proposition that Congress granted FDA statutory authority to

decide that medication abortion should be legal in all 50 States and that FDA has exercised that authority by approving the sale and use of mifepristone. The assertion is preposterous on its face. And further analysis drives the point home. The only statute in the FDCA that GBP has identified as a source for this sweeping authority is the statute governing REMS, 21 U.S.C. § 355-1. *See* Doc. 41-1 at 1–2 ¶ 2. That statute requires the FDA to ensure that REMS restrictions are "not . . . unduly burdensome on patient access to the drug, considering in particular . . . patients who have difficulty accessing health care (such as patients in rural or medically underserved areas)" and are designed to "minimize the burden on the health care delivery system[.]" 21 U.S.C. § 355-1(f)(2)(C)(ii), (D). Under no stretch of the imagination does that language provide "clear congressional authorization" for the FDA to decide that States must allow access to mifepristone for abortions. *See West Virginia*, 142 S. Ct. at 2609 ("Extraordinary grants of regulatory authority are rarely accomplished through modest words, vague terms, or subtle devices.") (cleaned up). The REMS statute does not address or mention medication abortion or mifepristone.

For these reasons, GBP's proposed amended complaint fails to state a preemption claim as to the trigger law.

Preemption and the Other Challenged Laws and Regulations. That leaves GBP's proposed challenge to other laws and regulations. As GBP concedes in its proposed amended complaint, those other challenged laws are relevant only for the very small number of abortions still allowed under the trigger law. Doc. 41-1 at 20 ¶ 63 ("In the limited number of circumstances in which a Mississippi woman may obtain an

abortion—when her life is at stake or she has filed a formal rape charge—Mississippi imposes onerous requirements that further limit access to mifepristone."). And GBP's preemption challenge to these laws fails.

Like the trigger law, these other laws enjoy the presumption 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." *Wyeth*, 555 U.S. at 565 (cleaned up). The State's core police powers include the authority to enact health and safety regulations. *See, e.g.*, *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006) ("[T]he structure and limitations of federalism . . . allow the States great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.") (internal quotation marks omitted).

GBP cannot overcome that presumption. To start, the FDCA lacks any indication that Congress's purpose in enacting the REMS statute was to establish preemptive national standards for medication abortions to the exclusion of all additional state health or safety regulation. The REMS statute aims to promote the safe use of "drug[s] for which there is a serious risk of an adverse drug experience." 21 U.S.C. § 355-1(e)(4). Certain drugs such as mifepristone that are "associated with a serious adverse drug experience" "can be approved [by FDA] only if" their REMS includes additional "elements to assure safe use" (ETASU), such as requiring that healthcare providers be "specially certified" and that the drug be dispensed "only in certain health care settings." *Id.* § 355-1(f)(1)(A), (3)(A), (3)(C); Doc. 41-1 at 14-15 ¶¶ 40–45 (describing ETASU imposed on mifepristone). "ETASU are the most restrictive and burdensome type REMS." *Id.* at 10 ¶ 32.

Further, and in any event, the remaining state laws and regulations challenged by GBP complement rather than obstruct the REMS statute's purposes by providing additional safeguards to protect patients. For example, the MWHDA requires physicians to "physically examine the woman and document in the woman's medical chart the gestational age and intrauterine location of the pregnancy before" dispensing mifepristone. Miss. Code Ann. § 41-41-107(2). These are important safety measures. Performing a physical exam is a basic medical practice. Determining the gestational age of the unborn child is necessary because mifepristone is only "indicated" for abortions up to "70 days gestation." Doc. 41-1 at 155. And ascertaining the intrauterine location of the pregnancy is essential, as mifepristone is "contraindicated" for ectopic pregnancy (when an unborn child grows outside the uterus). Doc. 41-1 at 157. Further, the requirement that mifepristone "be administered [to the patient] in the same room and in the physical presence of the physician" who prescribed the drug mirrors the pre-2016 REMS for mifepristone, which required patients to ingest the drug at their "provider's office or under direct observation by a health care provider." Miss. Code Ann. § 41-41-107(3); Doc. 41-1 at 16 ¶ 48 (cleaned up). There is no conflict between these modest regulations and the REMS statute—and certainly not a conflict "strong enough to overcome the presumption that state and local regulation of health and safety matters can constitutionally coexist with federal regulation." *Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 716 (1985).

Beyond those points, the fact that Congress has criminalized the shipment of abortion drugs by mail and by common carriers traveling in interstate commerce dooms

GBP's claim that these laws are preempted. 18 U.S.C. §§ 1461, 1462. Because federal law prohibits the core conduct that GBP claims it is permitted to undertake, there is no sound basis for concluding that the MWHDA and the other laws challenged by GBP undermine the clear and manifest purposes of federal law.

GBP's claims are also foreclosed under the teachings of *Wyeth v. Levine*, 555 U.S. 555 (2009). *Wyeth* addressed whether the FDA's approval of a drug label preempted state-law tort claims against the drug manufacturer for failure to warn of risks associated with the drug. The Supreme Court rejected the argument that the tort claims "[we]re pre-empted because they interfere with Congress's purpose to entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives." *Id.* at 573 (cleaned up). That argument, according to the Court, "relie[d] on an untenable interpretation of congressional intent and an overbroad view of an agency's power to pre-empt state law." *Id.* GBP similarly alleges that the challenged laws and regulations "are an obstacle to fulfilling the full purpose and objectives of Congress's grant of authority to a federal agency to *balance the risks and benefits* of and design risk mitigation strategies for the administration of prescription drugs in the United States." Doc. 41-1 at 25 ¶ 73 (emphasis added).

In *Wyeth*, the drug manufacturer did not rely "on any statement by Congress" as evidence for preemption, but rather on the FDA's declaration in a preamble to its drug-labeling regulations "that the FDCA establishes both a floor and a ceiling, so that FDA approval of labeling preempts conflicting or contrary State law." 555 U.S. at 575 (cleaned up). Although "an agency regulation with the force of law can pre-empt conflicting state

requirements," there was "no such regulation in" *Wyeth*, only "an agency's mere assertion that state law is an obstacle to achieving its statutory objectives." *Id.* at 576. The Court concluded that the FDA's views on preemption did not merit deference, in part because the agency "traditionally regarded state law as a complementary form of drug regulation" and had "reverse[d]" its "longstanding position without providing a reasoned explanation." *Id.* at 578–79.

Here, the case against preemption is even stronger. The FDA has never taken the position that the FDCA preempts state regulation of medication abortion procedures. To the contrary, the FDA has acknowledged that healthcare providers who prescribe mifepristone must comply with state laws. For example, the current REMS for mifepristone authorizes healthcare providers who meet certain qualifications to prescribe the drug, but the FDA recognizes that state law governs whether non-physicians may do so: "Some states allow healthcare providers other than physicians to prescribe medications. Healthcare providers should check their individual state laws." FDA, *Questions and Answers on Mifeprex* (https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex); Doc. 41-1 at 13 ¶ 37, 17 ¶ 52. Even if the FDA had declared, as in *Wyeth*, that the mifepristone REMS itself preempts state laws that impose additional requirements on providers of medication abortions, its assertion would be legally unavailing because the REMS is not "an agency regulation with the force of law [that] can pre-empt conflicting state requirements." *Wyeth*, 555 U.S. at 576. It was not adopted in line with the Administrative Procedures Act, 5 U.S.C. § 551 *et seq.*, and does not appear in the Code

of Federal Regulations. *See Anderson v. Eby*, 998 F.2d 858, 863 (10th Cir. 1993) (holding that "to have the force of law, at a minimum "a regulation must be "adopted according to the procedures embodied in the Administrative Procedures Act"); Doc. 41-1 at 145–52 (2016 Mifeprex REMS). And as explained already, the challenged state laws do not conflict with FDA's REMS for mifepristone: those laws do not frustrate Congress's aims.

The proposed amended complaint—like the operative complaint—fails to state any preemption claim as to any of the challenged laws, so amendment would be futile on that claim. This Court should dismiss the preemption claim.

B. GBP's Proposed Amended Complaint Fails to State a Commerce Clause Claim.

GBP's proposed amended Commerce Clause claim also fails as a matter of law, for two independent reasons. First, Congress has affirmatively exercised its Commerce Clause powers to criminalize interstate commerce involving abortion-inducing drugs. Congress has thus removed from the protections of the Commerce Clause the very conduct that GBP claims Mississippi is obstructing. So dormant Commerce Clause principles do not apply or help GBP. Second, even if that were not so, GBP has failed to plausibly allege that any burden on interstate commerce is clearly excessive when compared to the local benefits provided by the challenged laws.

The Commerce Clause provides that "[t]he Congress shall have Power . . . [t]o regulate Commerce . . . among the several States[.]" U.S. Const., art. I, § 8, cl. 3. "The Constitution thus specifically grants Congress power to regulate interstate commerce." *Ford Motor Co. v. Texas Dep't of Transp.*, 264 F.3d 493, 499 (5th Cir. 2001). Congress's affirmative Commerce Clause authority includes power to prohibit distributing products

in interstate commerce. *See Hoke v. United States*, 227 U.S. 308, 322 (1913) ("Congress may prohibit [an article's] transportation between the states."). Supreme Court caselaw also holds that the Clause prohibits more than what Congress has affirmatively barred: The Clause "also prohibits state laws that unduly restrict interstate commerce." *Tennessee Wine & Spirits Retailers Ass'n v. Thomas*, 139 S. Ct. 2449 (2019) (cleaned up). This "interpretation" is generally referred to as "the dormant Commerce Clause." *Id.*

But "[d]ormant Commerce Clause restrictions apply *only* when Congress has not exercised its Commerce Clause power to regulate the matter at issue." *Tennessee Wine*, 139 S. Ct. at 2465 (citations omitted; emphasis added); *see South Dakota v. Wayfair, Inc.*, 138 S. Ct. 2080, 2089 (2018) ("[W]hen Congress exercises its power to regulate commerce by enacting legislation, the legislation controls.") (citation omitted); *Ne. Bancorp, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 472 U.S. 159, 174 (1985) (ruling that dormant Commerce Clause did not apply to state banking regulations because "the commerce power of Congress is not dormant"); *Ford*, 264 F.3d at 499 ("In matters not governed by federal legislation, the Clause has long been understood to have a negative aspect that denies the States the power unjustifiably to discriminate against or burden the interstate flow of articles of commerce.") (cleaned up). So the dormant Commerce Clause is triggered only by Congress's inaction on the specific interstate commerce at issue.

Under these principles, GBP's proposed amended complaint fails to state a Commerce Clause claim. First, the challenged Mississippi laws do not obstruct any lawful interstate commerce because Congress has affirmatively barred the commerce in which GBP seeks to engage. Congress has criminalized mailing abortion drugs, 18

U.S.C. § 1461, and using a common carrier "for carriage in interstate or foreign commerce" of "any drug, medicine, article, or thing designed, adapted, or intended for producing abortion," *id.* § 1462(c). By enacting these criminal statutes, Congress eliminated an interstate market for abortion drugs—removing any potential Commerce Clause protections that GBP's interstate economic activities may have otherwise enjoyed. *See Pic-A-State PA, Inc. v. Com. of Pa.*, 42 F.3d 175, 179 (3d Cir. 1994) ("Where Congress has proscribed certain interstate commerce, . . . it does not offend the purpose of the Commerce Clause for states to discriminate or burden that commerce."); *cf. Predka v. Iowa*, 186 F.3d 1082, 1085 (8th Cir. 1999) ("[M]arijuana is contraband and thus not an object of interstate trade protected by the Commerce Clause."). And even putting aside the fact that those statutes prohibit GBP's core conduct, the fact that Congress has legislated on this subject at all means that dormant Commerce Clause principles do not even enter the picture. GBP fails to state a dormant Commerce Clause claim.

Second, even if dormant Commerce Clause principles applied here, GBP's proposed amended complaint has not pleaded enough facts "to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

In determining whether a state law comports with dormant Commerce Clause principles, "the first step is to determine whether it regulates evenhandedly with only incidental effects on interstate commerce, or discriminates against interstate commerce." *Ford*, 264 F.3d at 499 (cleaned up). Discrimination against interstate commerce means "differential treatment of in-state and out-of-state economic interests that benefits the former and burdens the latter." *Int'l Truck & Engine Corp. v. Bray*, 372

F.3d 717, 725 (5th Cir.), *opinion corrected on denial of reh'g*, 380 F.3d 231 (5th Cir. 2004) (citation omitted). The laws challenged here are non-discriminatory: they do not distinguish between in-state and out-of-state economic interests. GBP does not contend otherwise. *See* Doc. 13 at 17 (arguing that the State's laws impose a burden on commerce that clearly exceeds any local benefits).

Because the challenged laws are non-discriminatory, the Court proceeds to the second step by analyzing the laws "under the balancing test established in *Pike v. Bruce Church, Inc.*, [397 U.S. 137, 142 (1970),] whereby the regulation is valid unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." *Ford*, 264 F.3d at 499–500 (quotation marks omitted). "In assessing a statute's putative local benefits, [courts] cannot second-guess the empirical judgments of lawmakers concerning the utility of legislation." *Bray*, 372 F.3d at 728 (cleaned up). Instead, courts "credit a putative local benefit so long as an examination of the evidence before or available to the lawmaker indicates that the regulation is not wholly irrational in light of its purposes." *Id.* (cleaned up).

Here, the "local benefits" of the challenged laws plainly justify the modest burdens that they could be said to impose. The challenged laws deliver important benefits. The Supreme Court recognized in *Dobbs* that States may regulate and prohibit abortion "for legitimate reasons." 142 S. Ct. at 2283. The legitimate interests furthered by abortion laws include: "respect for and preservation of prenatal life at all stages of development, the protection of maternal health and safety; the elimination of particularly gruesome or barbaric medical procedures; the preservation of the integrity of the medical

profession; the mitigation of fetal pain; and the prevention of discrimination on the basis of race, sex, or disability." *Id.* at 2284 (cleaned up). The trigger law advances the State's important and legitimate interests in preserving prenatal life, protecting maternal health and safety, preserving the integrity of the medical profession, and preventing discriminatory abortion procedures. Indeed, the trigger law will save the lives of untold numbers of children. The other challenged laws all protect the health and safety of women seeking abortions.

On the other side of the ledger, GBP claims that the trigger law has made it impossible for GBP to sell mifepristone in Mississippi. Doc. 41-1 at 25 ¶ 75. But GBP admits that it was not selling mifepristone in the State before the trigger law took effect because the only abortion clinic in Mississippi had an agreement with Danco, the other manufacturer of mifepristone. *Id.* at 26 ¶ 78. Thus, GBP has not alleged any facts plausibly suggesting that the trigger law has affected its ability to engage in interstate commerce in Mississippi. And preventing a company or two from selling a single product in one State is not a burden on interstate commerce that is clearly excessive as compared to the important local benefits provided by the trigger law.

As for the other laws challenged by GBP, the proposed amended complaint contains no allegations plausibly showing that those laws impose any burden on interstate commerce. "A statute imposes a burden when it inhibits the flow of goods interstate." *Bray*, 372 F.3d at 727. GBP has not adequately alleged that any of those laws have impeded or will impede the flow of mifepristone into Mississippi. Any burden they may impose on interstate commerce is *de minimis*, and not clearly excessive in

relation to the benefits they provide.

GBP argues that "Mississippi's restrictions on mifepristone impose significant burdens on interstate commerce because they interfere with the FDA's national system of regulation." Doc. 41-1 at 31 ¶ 99. This is just GBP's unavailing preemption argument re-packaged as a dormant Commerce Clause claim. Similarly, GBP contends that "Mississippi's conflicting regulations impose significant burdens on interstate commerce because they harm patients living in Mississippi, as well as patients residing outside of Mississippi who seek healthcare providers in the state." *Id.* at 32 ¶ 100. But any harm the challenged laws may cause women seeking access to mifepristone is not a burden on interstate commerce. *See Exxon Corp. v. Gov. of Md.*, 437 U.S. 117, 128 (1978) (an argument that "the consuming public will be injured" "relates to the wisdom of the statute, not to its burden on commerce"). Further, women seeking medication abortion in Mississippi have no right to do so after *Dobbs*. GBP cannot use the Commerce Clause to reinstate constitutional protections for abortion after the Supreme Court has held that "no such right is implicitly protected by any constitutional provision." 142 S. Ct. at 2242.

For these reasons, GBP's proposed amended complaint—like its existing complaint—fail as a matter of law to state a Commerce Clause claim. The Court should deny leave to amend based on futility and it should dismiss this case.

II. Amendment Would Be Futile Because GBP's Proposed Complaint Fails to Establish Its Article III Standing.

GBP also cannot satisfy the standing requirements of Article III. It has not suffered a concrete injury from any of the challenged laws because it never attempted to sell mifepristone in Mississippi. And it offers only speculation that it will be able to do

so if the challenged laws were enjoined. Thus, GBP cannot show that its alleged injury is traceable to the challenged laws or would be redressed by a favorable decision. And because federal law effectively forecloses GBP's ability to sell mifepristone in Mississippi, GBP cannot satisfy the traceability and redressability prongs of the standing inquiry.

To litigate the merits of its claims, GBP must establish its Article III standing. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992). It "must have suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized; and (b) actual or imminent, not conjectural or hypothetical." *Id.* at 560 (cleaned up). It must show "a causal connection between the injury and the conduct complained of—the injury has to be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court." *Id.* (cleaned up). And "it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Id.* at 561 (cleaned up).

GBP's proposed amended complaint fails to satisfy these requirements. GBP claims that it is injured because "Mississippi has made it essentially impossible for GBP to sell mifepristone in" the State. Doc. 41-1 at 25 ¶ 75. But GBP admits that, before the trigger law took effect, GBP did not sell mifepristone in Mississippi because the only abortion clinic in the State had a "Prescriber Agreement in place with Danco," the manufacturer of the branded version of mifepristone. *Id.* at 26 ¶ 78. GBP alleges that it has a "Prescriber Agreement" with Planned Parenthood Southeast, Inc., which operates a clinic in Hattiesburg. *Id.* at 26 ¶ 79. But GBP acknowledges that the Hattiesburg clinic did not provide abortions even before the trigger law took effect, allegedly "due to

Mississippi's restrictions on medicated abortion." *Id.* at 26–27 ¶ 79. According to GBP, "[t]hough the Hattiesburg clinic remains open, like before, it does not provide any abortion services because of the Mississippi restrictions and now ban." *Id.* at 27 ¶ 80.

These allegations do not establish injury in fact or traceability. Given that GBP could have tried to market and sell mifepristone before the trigger law took effect but failed to do so, its claim that it is now losing business as a result of any of the challenged laws is pure speculation. GBP alleges that, "[o]n information and belief," the Hattiesburg clinic "would have provided medicated abortions and would have purchased GBP's mifepristone tablets" if not for "Mississippi's regulations restricting who could prescribe mifepristone and under what conditions." Doc. 41-1 at 27 ¶ 79. But it is undisputed that those regulations did not prevent medication abortions from being performed in Mississippi. The proposed complaint alleges that the abortion clinic in Jackson performed medication abortions with mifepristone supplied by Danco. *Id.* at 26 ¶ 78.

Because GBP has not alleged facts explaining how the State's laws prohibited the Hattiesburg clinic from performing medication abortions with its drug, it cannot show that it has suffered an injury in fact. For the same reasons, GBP cannot show that its alleged injury is fairly traceable to the challenged laws, rather than the result of the Hattiesburg clinic's independent actions. And even if GBP could show injury in fact or traceability, it has not shown that a decision in its favor would redress that injury. "[T]he nature and extent of facts that must be averred . . . in order to establish standing depends considerably upon whether the plaintiff is himself an object of the action (or forgone action) at issue." *Lujan*, 504 U.S. at 561. When "a plaintiff's asserted injury

arises from the government's allegedly unlawful regulation . . . of someone else," it is "ordinarily substantially more difficult to establish" standing. *Id.* at 562. This is so because when the "asserted injury arises from the government's allegedly unlawful regulation . . . of someone else," redressability will "ordinarily hinge on the response of the regulated (or regulable) third party." *Id.* In such a circumstance, "it becomes the burden of the plaintiff to adduce facts showing that those choices have been or will be made in such manner as to . . . permit redressability of injury." *Id.* GBP has not alleged sufficient facts to plausibly show that it is likely, as opposed to merely speculative, that the Planned Parenthood clinic would begin performing abortions with GBP's mifepristone if this Court enjoined the challenged laws.

GBP also cannot establish Article III standing for a separate, independent reasons: Federal laws—unchallenged by GBP—now effectively foreclose GBP's business model. As noted above, Congress has criminalized the use of the mail and common carriers to transport abortion drugs across state lines. 18 U.S.C. §§ 1461, 1462. GBP does not challenge these statutes. Because federal law independently prohibits GBP from shipping any mifepristone it might sell to Mississippi, GBP cannot show that any alleged injury is fairly traceable to the State's abortion laws. GBP also cannot show that its alleged injury would likely be redressed by a favorable decision. Even if this Court were to enjoin the state laws at issue, federal criminal law would still block what GBP seeks to do. Allowing GBP to amend its complaint would therefore be futile.

CONCLUSION

For the reasons set forth above, and the reasons set out in its motion to dismiss and accompanying briefing, Docs. 8, 9, 15, the State respectfully requests that the Court

deny GBP's motion for leave to amend, grant the State's motion to dismiss, and dismiss this case with prejudice.

This the 4th day of August, 2022.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Wilson D. Minor, Special Assistant Attorney General for the State of Mississippi, do hereby certify that on this date I electronically filed the foregoing document with the Clerk of this Court using the ECF system which transmitted a copy to all counsel of record.

This the 4th day of August, 2022.

s/Wilson D. Minor
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