UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF MISSISSIPPI
NORTHERN DIVISION

GENBIOPRO, INC **PLAINTIFF**

vs. **CIVIL ACTION NO. 3:20-CV-652-HTW-LRA**

DR. THOMAS DOBBS, State Health Officer of the Mississippi Department of Health, in his official capacity **DEFENDANT**

REPLY IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS

Defendant, Dr. Thomas Dobbs, sued in his official capacity as the Mississippi State Health Officer, respectfully submits this reply memorandum in support of his motion to dismiss pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure:

I. GBP HAS FAILED TO PROVE FIRST OR THIRD-PARTY STANDING.

Unless GBP meets the Article III standing requirements, this Court has no power to hear the case. "When the defendant raises a facial challenge to subject matter jurisdiction, a court must accept [only] the complaint's well-pleaded factual allegations as true . . . ." *American Fed'n of Gov't Employees, Local 1617 v. Fed. Labor Relations Auth.*, 2003 WL 21919486, at *3 (W.D. Tex. Aug. 4, 2003) (citing *Home Builders Ass'n of Miss., Inc. v. City of Madison, Miss.*, 143 F.3d 1006, 1010 (5th Cir. 1998) (ruling that a motion to dismiss pursuant to Rule 12(b)(1) is analyzed under the same standard as a motion to dismiss under Rule 12(b)(6)). Because GBP only offered conclusory allegations of a hypothetical injury, it failed to establish standing.

Mississippi's market for medicated abortion is open.[1] And despite FDA approval for

[1] In fact, the brand name version of mifepristone, Mifeprex, is actively marketed and sold in Mississippi. Jackson Women's Health Organization, https://jacksonwomenshealth.com/abortion-information/ (last accessed Dec. 3, 2020)).

marketing in February 2019, Pl. Compl. at 5 [Doc. 1], GBP failed to provide this Court with a single *factual* allegation to establish that it suffered an actual or imminent injury. Instead, GBP couched conclusory allegations and trigger words such as "substantial revenue loss" and "ongoing economic injury" as factual allegations in an apparent attempt to circumvent its pleading burden. But without any factual allegations regarding GBP's *actual* losses, it is impossible for this Court to know what financial harm, if any, GBP could have possibly suffered. Yet, GBP seems to believe, and asks this Court to believe, that its conclusory allegations of financial injury suffice. They do not. Even though "[i]t is well established that a financial loss generally constitutes an injury," *Texas v. United States*, 787 F.3d 733, 748 (5th Cir. 2015), a party must "offer[] evidence to show financial injury." *Lion Health Services, Inc. v. Sebelius*, 635 F.3d 693, 699 (5th Cir. 2011). GBP fails to offer such facts. Instead, GBP focuses on the risk of injury; but, that is not enough. *See Legacy Cmty. Health Sevs., Inc. v. Smith*, 881 F.3d 358, 370 (5th Cir. 2018), *as revised* (Feb. 1, 2018), *cert denied*, 139 S. Ct. 211 (2018) (explaining that "abstract injury, such as risk alone, is insufficient to confer standing").

Assuming, *arguendo*, that GBP did sufficiently plead a cognizable Article III injury, it is not fairly traceable to any action of the Defendant. As GBP admits, Mississippi's regulations apply to "healthcare providers who may prescribe the medication," not to GBP or any other drug manufacturer. [Doc. 13 at 7]. In fact, Mississippi's regulations neither require GBP to take additional steps to market and sell mifepristone nor restrict GBP from marketing and selling mifepristone. Ultimately, any "regulation" of mifepristone results from its use by *providers* to carry out abortion *procedures*. Thus, any regulatory effect on GBP is incidental and does not satisfy the traceability requirement.

Last, as for GBP's third-party standing argument, it failed to cite to any abortion cases that have allowed a drug manufacturer to bring an FDA preemption claim on behalf of women or providers. Instead, GBP assumes, and asks this Court to *assume*, on the basis of *Singleton v. Wulff*, 428 U.S. 106, 117 (1976), that it has standing. [Doc. 13 at 10]. But *Singleton* allowed physicians to bring a third-party claim on behalf of "an impecunious woman" who could not "easily secure an abortion without the physician's being paid by the State." *Id*. Here, GBP has failed to plead facts that show that either women or providers are hindered from bringing suit on their own behalf.[2] Thus, GBP's assumption of third-party standing fails.

II. GBP'S IMPLIED PREEMPTION CLAIM FAILS AS A MATTER OF LAW.

A. The 2016 Mifepristone REMS Program Does Not Preempt the Challenged Laws.

GBP's attempt to paint this lawsuit as "a straightforward federal preemption case" rings hollow. [Doc. 13 at 12]. Whether a risk evaluation and mitigation strategy ("REMS") has preemptive effect, and particularly whether the mifepristone REMS program preempts state authority to regulate medication abortions is an issue of first impression. GBP concedes as much in its memorandum. [Doc. 13 at 15].[3]

As this case presents an issue of first impression, the Court must rely on the general

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[2] GBP argues that in *June Medical Services, LLC, v. Russo*, 591 U.S. 140 S. Ct. 2103, 2118 (2020), Louisiana was found to have waived standing. [Doc. 13 at 11, fn 4]. In this case, Defendant raised standing in his initial filing.

[3] GBP initially points to the 2013 telemedicine law, Miss. Code Ann. §§ 41-41-101, *et seq*., as the target of this challenge. [Doc. 1 at 18-20]. However, GBP then complains of the effects of "the full compendium of the state's abortion regulations." [Doc. 1 at 20-21]; *see also infra* pp. 6-8. As discussed in Defendant's memorandum, GBP asks the Court to strike down any law more restrictive than the 2016 mifepristone REMS. Def. Mem. at 2-5 [Doc. 9].

principles of obstacle preemption. The leading case is *Wyeth v. Levine*, 555 U.S. 555 (2009). In *Wyeth*, the Supreme Court held that neither the impossibility nor obstacle prongs of implied preemption doctrine barred a state failure-to-warn claim that required more information than FDA labeling requirements. *Id.* at 581. The Court held that for a state law or regulation to be preempted, it must create an "obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Wyeth*, 555 U.S. at 577 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). The Court specifically rejected the argument that state tort claims:

> are 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. We find no merit in this argument, which relies 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 (internal citation and quotation marks omitted).

The Supreme Court emphasized in *Wyeth* that the implied preemption analysis:

> must be guided by two cornerstones of our pre-emption jurisprudence. First, the purpose of Congress is the ultimate touchstone in every pre-emption case. Second, in all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, 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.

Id. at 565 (internal quotations, alterations, and citations omitted). The Court has also said that: "[t]o infer pre-emption whenever an agency deals with a problem comprehensively is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive. Such a rule, of course, would be inconsistent with the federal-state balance embodied in our Supremacy Clause jurisprudence." *Hillsborough County v. Automated Med. Lab., Inc.*, 471 U.S. 707, 717 (1985).

At issue is the preemptive effect (or lack thereof) of The Food and Drug Administration

Amendments Act of 2007 ("FDAAA"). The FDAAA, which authorized the FDA to adopt REMS for dangerous drugs, does not contain an express preemption provision, so there is no dispute that the Mississippi laws are not expressly preempted. The Mississippi laws are not preempted under the impossibility branch of implied preemption doctrine, because it is not impossible for medical providers to comply with both state and federal requirements.[4] Further, the differences between the state and federal requirements GBP complains of have not impeded, and do not impede, women's access to the drug so as to constitute an obstacle to Congress' intent and objectives in passing the FDAAA.

The FDAAA has nothing specific to do with GBP, mifepristone, or abortion, despite statements by GBP in its memorandum such as "Congress granted the FDA the exclusive authority to regulate GBP's product under a detailed and thorough statutory scheme, which FDA has done, that balances the public health benefits of the medication with its risks"—statements which certainly imply otherwise. The FDAAA grants the FDA general authority to use REMS to balance safety and drug availability for inherently dangerous drugs.[5] However, the FDAAA is devoid of any indication there was congressional intent to preempt or abrogate state regulation of abortion procedures, or to delegate to the FDA the authority to do so. Further, not even the FDA has indicated that it intended the mifepristone REMS to preempt state abortion laws.

The fact that the requirements of Mississippi law and the mifepristone REMS are not

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[4] GBP does not mention impossibility in its complaint, and only makes a pair of passing references to impossibility preemption in its memorandum. [Doc. 13 at 12-13, 15].

[5] That the FDA is charged with balancing competing objectives does not give a REMS preemptive effect. In the drug labeling context the Supreme Court called such an argument "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.

identical does not mean the state and federal requirements cannot coexist. The FDA uses REMS as a tool to permit the availability of drugs that would otherwise "not be approved or would be withdrawn from the market because of known or potential serious risks."[6] Mississippi does not bar mifepristone from the market or make it unavailable. After all, the branded drug Mifeprex has been distributed and dispensed in Mississippi under the existing laws and regulations for years.

B. The Requested Relief Would Create a Two-Tiered System for Abortion Regulation in Mississippi.

In its memorandum, GBP attempts to disclaim the extraordinary scope of the relief it has requested, arguing that its claims would not affect the state's authority to regulate abortions:

> Defendant, however, raises multiple red herrings by suggesting — inaccurately — that GBP's requested relief would somehow "nullify" the state's ability to regulate abortions and that Mississippi would lose its ability to license healthcare providers, safeguard patient health, maintain medical standards, and provide informed consent. But this parade of speculation has no basis in reality. Mississippi's ability to regulate abortion procedures, in keeping with the police powers of the state, would remain untouched.

[Doc. 13 at 12]. However, in its complaint, GBP expressly references Mississippi laws requiring licensing for abortion facilities, minimum standards applicable to licensed abortion facilities, informed consent laws, fetal ultrasound law, and the 24-hour waiting period as laws that GBP thinks conflict with the 2016 REMS requirements.[7] [Doc. 1, at 18-23]. GBP also specifically

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[6] https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/frequently-asked-questions-faqs-about-rems.

[7] Other Mississippi laws would also be potentially vulnerable to the injunctive relief requested by GBP. For example, Mississippi has a statute requiring written parental consent before an abortion can be performed on an unemancipated minor, Miss. Code Ann. § 41-41-53, and provides a judicial bypass allowing a minor who does not seek or is unable to obtain consent from her parents to seek relief in chancery court. Miss. Code Ann. § 41-41-55. Such laws are expressly authorized by landmark Supreme Court precedent. *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 899 (1992) (holding

complains that "[a]s Mississippi does not carve out unique provisions for medicated abortion, provision of mifepristone is subject not only to the 2013 Act governing abortion-inducing drugs, but to the full compendium of the state's abortion regulations."[8] [Doc. 1 at 20-21].

The fundamental disconnect between what GBP says in its complaint and what it argues in its memorandum is apparently based on the (mistaken) premise that "abortion" means only surgical abortion, so a medication abortion is not an abortion procedure. But the common denominator in the phrases "surgical abortion" and "medication abortion" is the word "abortion." Mississippi law regulates abortions, regardless of the *mechanism* by which the procedure is carried out. Miss. Code Ann. § 41-75-1(e) (defining "abortion" as "the use of any instrument, medicine, drug or any other substances or device to terminate the pregnancy of a woman . . . ."). Therefore, GBP's assertion that "[t]his case is not challenging Mississippi's ability to regulate medical procedures, which has traditionally been within each state's police powers," is inaccurate at best. Mississippi has not attempted to create its own drug regulation system competing with the FDA. Mississippi regulates medical providers, medication

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that "a State may require a minor seeking an abortion to obtain the consent of a parent or guardian, provided that there is an adequate judicial bypass procedure.") (citations omitted). However, if a minor was seeking a medication abortion in Mississippi, the parental consent and judicial bypass laws would be more restrictive than requirements of the 2016 mifepristone REMS program. Carrying GBP's argument to its logical and inevitable conclusion, Mississippi could require a minor to obtain parental consent for a surgical abortion, but could not require a minor to obtain parental consent for a medication abortion.

[8] GBP complains that Mississippi law limits the persons who are authorized to prescribe abortion-inducing drugs. [Doc. 13 at 14 n.7]. That is true. However, that is a matter squarely within traditional State regulatory authority. The FDA recognizes and defers to state authority on this issue: "[h]ealthcare providers who prescribe and who meet certain qualifications are authorized to order and dispense Mifeprex. *Some states allow healthcare providers other than physicians to prescribe medications. Healthcare providers should check their individual state laws.* These requirements also apply to the approved generic version of Mifeprex." https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex (emphasis added).

prescribers, and medical procedures, including abortion procedures.

Therefore, the Court should not accept GBP's invitation to ignore the elephant in the room: this case *is* about abortion, and GBP *is* attacking any Mississippi law that would impose a restriction more stringent than the 2016 REMS requirements on a medication abortion. GBP is asking this Court to create a two-tiered system of abortion regulation in Mississippi. The first tier, consisting of surgical abortions, could be regulated by the State in accordance with existing Supreme Court precedent. The second tier would include only medication abortions, which would be beyond the State's regulatory power, subject only to Danco's FDA-approved REMS.

III. GBP'S DORMANT COMMERCE CLAIM ALSO FAILS AS A MATTER OF LAW.

"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). Here, GBP's prayer for relief makes clear what local benefits are at stake. [Doc. 1 at 29]. Specifically, the preservation of the State's ability to regulate abortion procedures, the 24-hour waiting period, the informed consent laws, fetal ultrasound law, and more. [Doc. 1, at 18-23]. Importantly, the United States Supreme Court has repeatedly validated these local benefits. Def. Mem. at 3-5 [Doc. 9]. Because of this, GBP's dormant Commerce Clause claim fails for two reasons.

First, GBP's conclusory allegations concerning a clearly excessive burden are insufficient to sustain its claim.[9] Stripped of its conclusions, GBP's complaint fails to establish a

[9] *See Zogenix, Inc. v. Baker*, 2015 WL 1206354, at *7 (D. Mass. Mar. 17, 2015) (ruling that "conclusory allegations are an insufficient basis upon which to sustain a claim of discrimination against

"clearly excessive" burden in relation to the important local benefits. [Doc. 1 at 29]. Even if GBP had articulated a cognizable burden, "[i]t does not contravene the dormant [C]ommerce [C]lause for a state merely to regulate the distribution within its borders of a product that travels in interstate commerce."[10] *Zogenix, Inc. v. Baker*, 2015 WL 1206354, at *7 (D. Mass. Mar. 17, 2015) (citation omitted). Mississippi's regulations clearly effectuate a legitimate local public interest; thus, its incidental effect on mifepristone imposes, at best, a minimal burden that is not excessive in relation to the important local benefits.

Last, GBP's complaint recites *almost verbatim*, the dormant Commerce Clause argument of the manufacturer in *Zogenix*.[11] Notably, *Zogenix* directly contradicts GBP's position. GBP argues that the challenge to the burden on interstate commerce is not "to be resolved at the motion to dismiss stage." [Doc. 13 at 17]. But the *Zogenix* court did just that when it ruled that the manufacturer's dormant Commerce Clause claim failed as a matter of law. *Zogenix*, 2015 WL 1206354 at * 7-8. GBP sabotages its own argument by relying on the exact allegations as the manufacturer in *Zogenix*. Therefore, this Court should reach the same result and hold that GBP's dormant Commerce Clause claim fails as a matter of law.

CONCLUSION

For the foregoing reasons, Dr. Dobbs respectfully requests that the Court grant his Motion and dismiss all claims for lack of subject matter jurisdiction and/or failure to state a

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interstate commerce.")

[10] However, GBP has not alleged that it has even entered Mississippi's market. *See supra.* But even if it had, Mississippi's incidental regulation of mifepristone would not contravene the dormant Commerce Clause.

[11] *Compare* [Doc. 1 at 28] *with* Verified Third Amended Complaint [Doc. 75-1], *Zogenix, Inc. v. Baker*, No. CIV. A. 14-11689-RWZ, (D. Mass. Mar. 17, 2015).

claim.

RESPECTFULLY SUBMITTED, this the 4th day of December, 2020.

THOMAS E. DOBBS, M.D., M.P.H., in his official capacity as STATE HEALTH OFFICER OF THE MISSISSIPPI DEPARTMENT OF HEALTH

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CERTIFICATE OF SERVICE

This is to certify that on this day I, Paul Barnes, Special Assistant Attorney General for the State of Mississippi, electronically filed the foregoing document with the Clerk of the Court using the ECF system which sent notice of such filing to the following:

THIS, the 4th day of December, 2020.

s/Paul Barnes
PAUL E. BARNES