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

MEMORANDUM OF AUTHORITIES IN SUPPORT OF MOTION TO DISMISS PURSUANT TO RULES 12(b)(1) AND 12(b)(6)

Defendant, Dr. Thomas Dobbs, sued in his official capacity as the Mississippi State Health Officer, respectfully submits this 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:

As an initial matter, Plaintiff has failed to establish that it meets Article III standing requirements to challenge all of the laws it asks the Court to invalidate, therefore the Court should dismiss for lack of subject matter jurisdiction. In the alternative, Plaintiff's claims should be dismissed pursuant to Rule 12(b)(6) for failure to state a claim. Plaintiff's conflict preemption claim fails because there is no evidence that Congress ever intended the FDA to have the power to nullify a state's ability to regulate in the controversial and highly sensitive area of abortion. Plaintiff's Dormant Commerce Clause claim fails because the state laws at issue are non-discriminatory and do not impose an unreasonable burden on interstate commerce. Defendant therefore respectfully requests that the Court grant his motion and dismiss Plaintiff's claims pursuant to Rule 12(b)(1) and/or Rule 12(b)(6).

INTRODUCTION

Plaintiff, a manufacturer that was first approved in 2019 to market a generic version of the drug mifepristone (previously available only under the brand name "Mifeprex"), asserts that Mississippi's laws concerning medication abortions are preempted by FDA's regulations for the distribution of mifepristone, and that the laws impose an unreasonable burden on interstate commerce. But this case is not merely about drug safety, as shown by the extraordinarily broad relief requested by Plaintiffs. Specifically, Plaintiff asks the Court to issue:

> A. A declaration pursuant to 28 U.S.C. § 2201 that the state of Mississippi's laws and regulations restricting provision and use of FDA-approved abortion-inducing drugs violate the United States Constitution;
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> B. Permanent injunctive relief and/or a final order enjoining the Defendant from enforcing *any state law or regulation restricting provision and use of mifepristone beyond those outlined by the FDA's 2016 REMS for mifepristone.* In the alternative, permanent injunctive relief and/or a final order vacating any state law or regulation restricting the provisions and use of mifepristone beyond those outlined by the FDA's 2016 REMS for mifepristone.

[Doc. 1 at 29 (emphasis added)]. Thus, there can be no doubt that this case is not simply a case about the safe distribution and marketing of garden variety medications. This case is about the distribution and marketing of drugs used to perform abortions, and Plaintiff's requested relief would result in the complete nullification of "any state law or regulation" that relates to medication abortions, but which differs in the slightest degree from FDA regulations.

Mifepristone is not a typical drug, and this is not a typical implied

preemption case. Because mifepristone is used to perform abortions, and the State has substantial authority to regulate abortions, Plaintiff's request runs squarely into longstanding Supreme Court abortion jurisprudence.

In *Roe v. Wade* itself, the Supreme Court acknowledged that the states "have an important and legitimate interest . . . in protecting the potentiality of human life." 410 U.S. 113, 162 (1973). In *Planned Parenthood of Se. Pennsylvania v. Casey*, 505 U.S. 833, 883 (1992), the Court stated flatly "the State has legitimate interests from the outset of the pregnancy in protecting the health of the woman and the life of the fetus that may become a child." A few years later, the Court stated: the states have "a legitimate and substantial interest in preserving and promoting fetal life" that exists from the moment of conception. *Gonzalez v. Carhart*, 550 U.S. 124, 145 (2007) ("[T]he State, from the inception of the pregnancy, maintains its own regulatory interest in protecting the life of the fetus that may become a child.").

The Supreme Court has upheld the constitutionality of abortion laws intended to promote a State's interest in protecting unborn life. For example, the Court rejected a constitutional challenge to Pennsylvania's informed consent and 24-hour waiting period requirements, holding that a State may "further its legitimate goal of protecting the life of the unborn by enacting legislation aimed at ensuring a decision that is mature and informed, even when in so doing the State expresses a preference for childbirth over abortion." *Casey*, 505 U.S. at 883. Thus,

"a State is permitted to enact persuasive measures which favor childbirth over abortion, even if those measures do not further a health interest." *Id.* at 886. Similarly, in *Gonzalez*, 550 U.S. at 160, the Court upheld the federal Partial-Birth Abortion Ban Act of 2003 because it advanced the state's interest in unborn life.

Further, since *Roe*, the Supreme Court has consistently acknowledged the States' broad authority and discretion to regulate abortion to protect patient health and safety: "[a] State has a legitimate interest in seeing to it that abortion, like any other medical procedure, is performed under circumstances that maximize safety for the patient." *Simopoulos v. Virginia*, 462 U.S. 506, 519 (1983) (quoting *Roe*, 410 U.S. at 163. *See also City of Akron v. Akron Center for Reprod. Health*, 462 U.S. 416, 428-29 (1983) ("Because a State has a legitimate concern with the health of women who undergo abortions, 'a State may properly assert important interests in safeguarding health [and] in maintaining medical standards.'") (quoting *Roe*, 410 U.S. at 164); *Planned Parenthood v. Danforth*, 428 U.S. 52, 61 (1976) ("The State may, if it chooses, reasonably regulate the abortion procedure to preserve and protect maternal health").

For example, in furtherance of these interests, a State may require that abortions are "performed by medically competent personnel under conditions insuring maximum safety for the woman." *Connecticut v. Menillo*, 423 U.S. 9, 11 (1975) (per curiam) (citing *Roe*, 410 U.S. at149-50. Indeed, the Court has held that "that the performance of abortions may be restricted to physicians." *Mazurek v. Armstrong*, 520 U.S. 968, 974 (1997) (per curiam) (rejecting challenge to Montana

law that only allowed licensed physicians to perform abortions). *See also Akron*, 462 U.S. at 447 (noting that prior cases "left no doubt that, to ensure the safety of the abortion procedure, the States may mandate that only physicians perform abortions"); *Roe*, 410 U.S. at 165 ("The State may define the term 'physician,' . . . to mean only a physician currently licensed by the State, and may proscribe any abortion by a person who is not a physician as so defined."). As explained in *Casey*, "the Constitution gives the States broad latitude to decide that particular functions may be performed only by licensed professionals, even if an objective assessment might suggest that those same tasks could be performed by others." 505 U.S. at 885 (upholding statutory requirement that licensed physicians, rather than their assistants, provide informed consent information to women seeking abortions).

FACTUAL BACKGROUND

Unquestionably, Congress intends for the Food and Drug Administration ("FDA") to play a significant role in ensuring the safety of medications distributed to the public. However, it is also unquestionable that Congress has never displaced the authority of the states to continue to play a significant role regarding distribution of medications, a task performed exclusively by the states prior to the creation of the FDA. The police power to protect the health and safety of its citizens has been traditionally recognized as one of the most fundamental aspects of State sovereignty under our federal system of government.

A. The Federal Food, Drug, and Cosmetic Act.

In 1906, Congress enacted the Federal Food and Drugs Act "which prohibited

the manufacture or interstate shipment of adulterated or misbranded drugs, supplemented the protection for consumers already provided by state regulation and common-law liability." *Wyeth v. Levine*, 555 U.S. 555, 566 (2009). In the 1930s, Congress enacted the Federal Food, Drug, and Cosmetic Act ("FDCA") which required pre-marketing approval of drugs from the FDA. *Id.* "In 1962, Congress amended the FDCA and shifted the burden of proof from the FDA to the manufacturer." *Id.* at 567. This "required the manufacturer to demonstrate that its drug was safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling before it could distribute the drug." *Id. See also* U.S.C. § 355(b)(1). Drug manufacturers wishing to have their product approved must submit a new drug application ("NDA") that satisfies these requirements. Despite enlargement of the "FDA's powers to protect the public health and assure the safety, effectiveness, and reliability of drugs, Congress took care to preserve state law." *Id.*

In 2007, Congress amended the FDCA "to clarify how the FDA . . . determin[ed] whether a risk evaluation and mitigation strategy (REMS) was necessary to ensure that the benefits of a drug outweigh its risks."[1] The FDA implements these strategies when the drug cannot be safely used without additional safeguards. The Secretary of Health and Human Services ("HHS"), in

[1]U.S. DEP'T OF HEALTH & HUMAN SERVS. & U.S. FOOD & DRUG ADMIN., REMS: FDA's Application of Statutory Factors in Determining When a REMS is Necessary, Guidance for Industry 1 (April. 2019), https://www.fda.gov/media/100307/download (footnote omitted).

consultation with the FDA's Office of New Drugs and others, when reviewing an NDA, must consider six factors to determine whether a REMS strategy is necessary.[2] 21 U.S.C. § 335-1. But for "drugs with known serious risks" the REMS strategy may also include elements to assure safe usage ("ETASU"). *Id.* at § 355-1(e)-(f). ETASU's are required if the Secretary and FDA determine that-

> (A) the drug, which has been shown to be effective, but is associated with a serious adverse drug experience, can be approved only if, or would be withdrawn unless, such elements are required as part of such strategy to mitigate a specific serious risk listed in the labeling of the drug; and
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> (B) for a drug initially approved without elements to assure safe use, other elements under subsections (c), (d), and (e) are not sufficient to mitigate such serious risk.

Id. at § 355(f)(1)(A)-(B). ETASU's may include one or any combination of the following:

> (A) health care providers who prescribe the drug have particular training or experience, or are specially certified (the opportunity to obtain such training or certification with respect to the drug shall be available to any willing provider from a frontier area in a widely available training or certification method (including an on-line course or via mail) as approved by the Secretary at reasonable cost to the provider);
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> (B) pharmacies, practitioners, or health care settings that dispense the drug are specially certified (the opportunity to obtain such certification

[2] Those factors are: (a) [t]he estimated size of the population likely to use the drug involved; (b) [t]he seriousness of the disease or condition that is to be treated with the drug; (c) [t]he expected benefit of the drug with respect to such disease or condition; (d) [t]he expected or actual duration of the treatment with the drug; (e) [t]he seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug; (f) [w]hether the drug is a new molecular entity. 21 U.S.C. §§ 355-1(A)-(F).

> shall be available to any willing provider from a frontier area);
>
> (C) the drug be dispensed to patients only in certain health care settings, such as hospitals;
>
> (D) the drug be dispensed to patients with evidence or other documentation of safe-use conditions, such as laboratory test results;
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> (E) each patient using the drug be subject to certain monitoring; or
>
> (F) each patient using the drug be enrolled in a registry.

21 U.S.C. §355(f)(3)(A)-(F). Importantly, the FDA only imposes ETASU's on drugs that pose a serious risk to the health of patients.[3] In fact, "ETASU are the most restrictive and burdensome type of REMS." [Doc. 1 at 10]. Mifepristone, the abortion medication that is the subject matter of this suit, is just such a drug.

Moreover, in none of the amendments to the FDCA did Congress ever authorize, expressly or otherwise, the FDA to nullify a state's right to enact laws to promote respect for all life, and to protect all life, including unborn life. The very same laws the Supreme Court upheld.

B. Mifepristone Poses a Serious Risk to Women's Health.

Mifepristone is one two drugs used in combination for medication abortions.[4]

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[3] U.S. DEP'T OF HEALTH & HUMAN SERVS. & U.S. FOOD & DRUG ADMIN., REMS: FDA's Application of Statutory Factors in Determining When a REMS is Necessary, Guidance for Industry 3 (April. 2019), https://www.fda.gov/media/100307/download (footnote omitted).

[4] U.S. FOOD & DRUG ADMIN., Mifeprex (mifepristone) Information (Feb. 5, 2018), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and providers/mifeprexmifepristone-information.

There are currently two manufacturers selling the drug in the United States. Danco Laboratories, L.L.C. ("Danco"), the manufacturer which makes the branded version, "Mifeprex," and GBP, which now makes a generic version. In 1996, Danco sponsored an NDA for Mifeprex. [Doc. 1 at 5]. In 2000, the FDA approved Danco's application for Mifeprex. *Id.* Before making Mifeprex available, the FDA not only implemented a strenuous REMS plan, but imposed numerous ETASU's articulated in 21 U.S.C. §355-1(3)(A)-(B).[5] In 2008 and 2011, in accordance with the periodic review requirement, the FDA reviewed and required that Mifeprex continue to be distributed under the same 2000 REMS and ETASU's. [Doc. 1 at 14]. This continued implementation of the REMS and ETASU's proves that mifepristone is not a drug that can safely be distributed without supervision and regulation.

In 2013, the Mississippi Legislature passed and implemented The Women's Health Defense Act of 2013 ("the Act"), codified as amended in Mississippi Code Sections §§41-41-101-114. The Act imposed restrictions on the use of abortion drugs and mirrored the regulations imposed by the FDA's 2000 REMS and ETASU's. In 2016, the FDA reapproved Mifeprex for marketing and relaxed some, but not all of, the previous ETASU's. [Ex. C. at 3].

In 2019, GBP appeared and sought to "bypass the burdensome NDA process and obtain FDA approval to market the[ir] generic version" by submitting an

[5] U.S. DEP'T OF HEALTH & HUMAN SERVS. & U.S. FOOD & DRUG ADMIN., *Approval Letter* 2 (Sep. 2000) https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.pdf

Abbreviated New Drug Application ("ANDA"). [Ex. A] (citing 21 U.S.C. § 355(j)(2)(A)). Relying on the record previously presented by Danco, GBP submitted, and the FDA ultimately approved, GBP's application to market and sell its generic version of Mifeprex. [Doc. 1 at 5]. GBP now belatedly complains that Mississippi's abortion laws prevent it from doing what Danco has done since 2013-market its drug in Mississippi. GBP, not Danco, argues that Mississippi's regulations are either preempted by federal law or unconstitutional because they violate the commerce clause. [Doc. 1 at 26, 28]. But the legislative history of the FDCA, discussed *supra*, proves that GBP's speculative claims are false. [Doc. 1 at 7]. Congress never intended to displace the police powers of the states to ensure the health and safety of its citizens in connection with drug regulation and safety. In fact, from 1960 until 2006, the states, not the FDA, were responsible for ensuring the health and safety of their citizens. *Riegel v. Medtronic, Inc.*, 522 U.S. 312, 315 (2008).

ARGUMENT

Fed. R. Civ. P. 12(b)(1)

A motion to dismiss under Rule 12(b)(1) of the Federal Rules of Civil Procedure challenges a federal court's subject matter jurisdiction. Federal courts are courts of limited jurisdiction; without jurisdiction conferred by the Constitution and statute, they lack the power to adjudicate claims. *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). Indeed, because "[j]urisdiction is power to declare the law," if a court lacks jurisdiction, it may only do one thing: "announc[e]

the fact and dismiss[ ] the cause." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998).

The United States Constitution, Article III, section 2, clause 1, requires an actual case or controversy to sustain federal jurisdiction. *Amar v. Whitley*, 100 F.3d 22, 23 (5th Cir. 1996). "The case-or-controversy doctrines state fundamental limits on federal judicial power in our system of government." *Allen v. Wright*, 468 U.S. 737, 750 (1984). The question of Article III justiciability is of critical importance and "not merely a troublesome hurdle to be overcome if possible so as to reach the merits of the lawsuit." *Valley Forge Christian Coll. v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 476 (1982). The burden of establishing federal jurisdiction rests on the party seeking the federal forum. *Howery v. Allstate Ins. Co.*, 243 F.3d 912, 916 (5th Cir. 2001).

A district court may dismiss for lack of subject matter jurisdiction based on (1) the complaint alone; (2) the complaint supplemented by undisputed facts in the record; or (3) the complaint supplemented by undisputed facts plus the court's resolution of disputed facts. *Montez v. Department of the Navy*, 392 F.3d 147, 149 (5th Cir. 2004) (internal citations omitted); *Williamson v. Tucker*, 645 F.2d 404, 413 (5th Cir. 1981)). "In short, no presumptive truthfulness attaches to the plaintiff's allegations, and the court can decide disputed issues of material fact in order to determine whether or not it has jurisdiction to hear the case." *Montez*, 392 F.3d at 149. If a party lacks standing, the case or controversy requirement is not satisfied, and a federal court lacks subject matter jurisdiction.

I. This Court Lacks Subject-Matter Jurisdiction Because GBP Cannot Prove a Concrete Injury and Cannot Establish Third-Party Standing.

GBP bases its claims on conjectural and speculative harm, not concrete and particularized injuries. GBP is also attempting to assert the legal rights of third-party healthcare providers and women, which GBP has no standing to do. GBP lacks standing, requiring dismissal for lack of jurisdiction.

"[T]he irreducible constitutional minimum of standing contains three elements:" an (1) injury in fact (2) that is fairly traceable to the challenged conduct (3) that would be redressed by a favorable decision. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992). Because the elements of standing "are not mere pleading requirements but rather an indispensable part of the plaintiff's case, each element must be supported . . . with the manner and degree of evidence required at the successive stages of the litigation." *Id.* at 561. It is well-settled "that standing cannot be inferred argumentatively from averments in the pleadings;" rather, a plaintiff must allege facts that are "essential to show jurisdiction." *FW/PBS, Inc. v. Dallas*, 493 U.S. 215, 231 (1990).

"To be an injury in fact, a threatened future injury must be (1) potentially suffered by the plaintiff, not someone else; (2) concrete and particularized, not abstract; and (3) actual or imminent, not conjectural or hypothetical." *Stringer v. Whitley*, 942 F.3d 715, 721 (5th Cir. 2019) (citations omitted). "Federal courts consistently deny standing when [the] claimed anticipated injury has not been shown to be more than uncertain potentiality." *Prestage Farms v. Bd. of Sup's of*

Noxubee Cty., 205 F.3d 265, 268 (5th Cir. 2000). And the second and third elements of standing are self-explanatory. For example, an injury is not "fairly traceable" to a defendant's conduct if its existence depends on people or forces outside of the court's control. *See Little v. KPMG LLP*, 575 F.3d 533, 540 (5th Cir. 2009). Similarly, to establish redressability, a plaintiff must demonstrate that an order against the defendants sued would remedy the harm about which they complain. *See Fusilier v. Landry*, 936 F.3d 447, 467 (5th Cir. 2020) (Duncan, J., dissenting in part and concurring in the judgment in part).

Here, GBP alleges that it "stands to suffer substantial lost sales in Mississippi as a result of the state's conflicting regulation of abortion inducing drugs." [Doc. 1 at 25]. That GBP "stands to suffer substantial lost sales" illustrates two things. First, GBP has not suffered an *actual* injury. Next, it reveals that GBP is speculating as to what harm it might suffer in the future. Thus, GBP has failed to establish it is suffering a concrete and particularized injury that is actual or imminent. There is no evidence, only conjecture, that Mississippi's laws might have any effect whatsoever on GBP's sales of mifepristone.

Moreover, GBP fails to provide a traceable connection between its speculative damages and Mississippi's laws. The challenged laws regulate the relationship between an abortion provider and its patient. Those laws do not directly regulate GBP. Therefore, GBP lacks first-party standing. Perhaps tacitly admitting this fact, GBP attempts to bolster its claims by asserting purported injuries to healthcare providers and women seeking abortions, who are third parties as to whom Plaintiff

has no right to raise a claim or request relief.

A litigant "generally must assert his own legal rights and interests, and cannot rest his [or her] claim to relief on the legal rights or interests of third parties." *Kowalski v. Tesmer*, 543 U.S. 125, 129 (2004) (citation omitted). But an exception to the general rule permits litigants to assert the rights of third parties only when: (1) the litigant has a close relationship to the third party; and (2) a some hindrance affects the third party's ability to protect his or her own interests. *Id.* at 130 (citations and internal quotation marks omitted).

Despite this exception, the Supreme Court has precluded litigants from asserting constitutional rights of third parties. *See McGowan v. Maryland*, 366 U.S. 420, 429 (1961) ("[T]he general rule is that a 'litigant may only assert his [or her] own constitutional rights or immunities'" (quoting *United States v. Raines*, 362 U.S. 17, 22 (1960)). But in *Singleton v. Wulff*, 428 U.S. 106, 108 (1976), the Supreme Court allowed abortion providers to assert hypothetical patients' rights in challenging a prohibition against using Medicaid to pay for nontherapeutic abortions. The Court, finding a closeness in the relationship, explained that "[a] woman cannot safely secure an abortion without the aid of a physician, and an impecunious woman cannot easily secure an abortion without the physician's being paid by the State." *Id.* at 117. But this ruling has been, and still is, controversial.

In fact, the State of Mississippi has an active petition for certiorari pending before the Supreme Court seeking review of this exact issue, *i.e.*, when abortion providers should not have third party standing to challenge health-and-safety

regulations on behalf of pregnant women, and whether this is merely a prudential doctrine or an issue of Article III significance. *See* Petition for Writ of Certiorari, *Dobbs v. JWHO*, No. 19-1392 (U.S. Jun. 18, 2020). And though historically, in the abortion context, the Supreme Court has allowed providers to bring claims on behalf of women, the Court *has not* extended that authority to drug manufacturers.

Here, then, it is not even an issue that GBP–a generic drug manufacturer–has absolutely no standing to challenge Mississippi's health and safety regulations on behalf of abortion providers or women or to seek relief on their behalf. First, GBP is a corporate entity that readily admits that its only interest is "to promote and sell mifepristone in Mississippi." [Doc. 1 at 23]. In other words, GBP is only interested in profit, not providers or people. Furthermore, GBP does not have a confidential relationship analogous to that of a physician and patient. *See Griswold v. Connecticut*, 381 U.S. 479, 481 (1965) (holding that defendant physician could assert privacy rights of married person whom they advised.)). Yet, in its Complaint, GBP has made abundantly clear this its ultimate aim is for medication abortions to be performed in Mississippi free of all restraints.

At its core, GBP's complaint fails to allege an actual or imminent concrete and particularized injury that is sufficiently traceable to the Mississippi laws it challenges. Therefore, GBP has failed to establish first-party standing. Additionally, GBP has absolutely no standing to bring claims on behalf of abortion providers or women. Most importantly, GBP does not have a right to seek relief for the types of injuries that it purports are occurring to these third-parties. Accordingly, this

Court lacks subject-matter jurisdiction over this matter and must dismiss. In addition, GBP has also failed to state any claims upon which relief can be granted.

Fed. R. Civ. P. 12(b)(6)

If a party fails to state a claim on which relief can be granted, dismissal is required. "Under [Rule 12(b)(6)], a complaint fails to state a claim upon which relief may be granted when it does not contain 'sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.'" *Rogers v. Boatright*, 709 F.3d 403, 407 (5th Cir. 2013) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

"Rule 12(b)(6) affords a defendant the opportunity to test the legal sufficiency of the complaint, *i.e.*, whether the plaintiff pleads a legal claim for which relief can be sought." *Knoth v. Apollo Endosurgery US, Inc.*, 425 F. Supp. 3d 678, 683 (S.D. Miss. 2019) (citing *Electrostim Medical Services, Inc. v. Health Care Service Corp*, 614 Fed. Appx. 731, 736 (5th Cir. 2015)). "The plausibility standard requires that the complaint's factual allegations 'be enough to raise a right to relief above the speculative level.'" *Id.* (quoting *Twombly*, 550 U.S. 544, 570 (2007)). And "[a]lthough a district court ruling on a motion to dismiss is required to accept all well-pleaded facts as true, 'courts are not bound to accept as true a legal conclusion couched as a factual allegation.'" *Bass v. Stryker Corp.*, 669 F.3d 501, 507 (5th Cir. 2012) (quoting *Twombly*, 550 U.S. at 555)). Even "'when the allegations in a complaint, however true, could not raise a claim of entitlement to relief, 'this basic deficiency should . . . be exposed at the point of minimum expenditure of time and money by the parties and the court.'" *Cuvillier v. Taylor*, 503 F.3d 397, 401 (5th Cir. 2007)

(quoting *Twombly*, 550 U.S. at 558)).

II. Mississippi's Abortion Laws Are Not Preempted by Federal Law or Regulations.

The FDCA does not expressly preempt state law. Thus, Plaintiff has to travel under an implied preemption theory: (a) impossibility preemption (it is impossible to comply with both sets of law) and (b) obstacle preemption (the state law places an obstacle in the way of the full purposes and objectives of the federal law). Plaintiff does not even attempt to make an impossibility argument, tacitly acknowledging the futility of such a claim. With both express preemption and impossibility off the board, all Plaintiff has left is an implied obstacle preemption claim.

"[T]he purpose of Congress is the ultimate touchstone in every pre-emption case." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). Further "[i]n 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." *Wyeth*, 555 U.S. at 565. This applies to the area of drug regulation, creating a presumption "that state and local regulation of health and safety matters can constitutionally coexist with federal regulation." *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 716 (1985).

Chief Justice Roberts has warned that "[i]mplied preemption analysis does not justify a 'freewheeling judicial inquiry into whether a state statute is in tension with federal objectives'; such an endeavor 'would undercut the principle that it is Congress rather than the courts that pre-empts state law.'" *Chamber of Commerce of U.S. v. Whiting*, 563 U.S. 582, 607 (2011) (quoting *Gade v. National Solid Wastes Management Assn.*, 505 U.S. 88, 111, 112 S. Ct. 2374, 120 L.Ed.2d 73 (1992) (Kennedy, J., concurring in part and concurring in judgment). To support a finding of obstacle preemption, this Court would have to conclude that the FDA requirements for the administration of mifepristone was intended to be both the "floor" and the "ceiling" for administration of the drug, and state regulations to impose further safety requirements for the administration of the drug are preempted to the extent they vary in the slightest degree—and moreover, that this is a result intended by Congress.

In *Wyeth*, the Court pointed out that Congress had expressly preempted state law regulation of medical devices, but had chosen not to do so with regard to drugs, despite clear knowledge that states were regulating drugs through common law tort and products liability claims:

> If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70–year history. But despite its 1976 enactment of an express pre-emption provision for medical devices, see § 2, 90 Stat.574 (codified at 21 U.S.C. § 360k(a)), Congress has not enacted such a provision for prescription drugs. *See Riegel*, 552 U.S., at 327, 128 S. Ct., at 1009 ("Congress could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices"). Its

> silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.

Wyeth, 555 U.S. at 574.

In short, obstacle preemption is a narrow doctrine, and it would require an expansion of the law for it to apply in this case. Further, because the challenged state regulations promote health and safety, there is a strong presumption that they can coexist with the federal regulations. Even in a case involving mundane drugs, implied preemption is disfavored. Here, there is the added factor that this case involves a drug used to perform abortions, and the federal courts should not use the blunt tool of implied obstacle preemption to undercut the holdings of numerous Supreme Court abortion decisions.

The most analogous case to the instant circumstances that Defendant has identified to date is *Zogenix v. Baker*, 2015 WL 1206354 (D. Mass. Mar. 17, 2015), and that case did not involve abortion drugs. That case is instructive because the Massachusetts district court concluded that while a state could not ban the sale of an FDA-approved medication, even one with a high propensity for abuse, the state was not prohibited from regulating certain aspects of drug distribution. *Zogenix*, 2015 WL 1206354, at *2-4. In that case, the Massachusetts governor issued an emergency ban of the use of a hydrocodone- based opioid named Zohydro. *Id.* at *1. The manufacturer sued, raising claims, *inter alia*, that the state ban was preempted by FDA regulations and also violated the Dormant Commerce Clause. *Id.* The

district court agreed with the manufacturer that the state could not ban the sale of the drug, but held that not all state regulations pertaining thereto were barred under obstacle preemption doctrine. *Id.* Massachusetts modified its regulations several times to remove language the court found unacceptable and the case was dismissed.

Here, Mississippi law does not ban the sale of mifepristone. At most, Mississippi law supplies some additional safeguards still deemed prudent by the State, but which the FDA saw fit to relax to a limited degree in 2016. Even with regard solely to the drug safety issue, Mississippi law does not impose an obstacle to the FDA aim of uniformity sufficient to justify striking down the law. Mississippi's laws concerning mifepristone were not expressly preempted by Congress in the FDCA. It is not impossible for GBP to comply with both state and federal requirements, just as Danco, the branded manufacturer, has done since 2013. Last, the Mississippi laws do not impose an obstacle sufficient to overcome the presumption that state and federal laws and regulations of the drug may co-exist. Therefore, Plaintiff's implied preemption claim fails as a matter of law.

III. Mississippi Laws Applicable to Mifepristone Do Not Violate the Dormant Commerce Clause.

GBP also asserts that the challenged Mississippi laws violate the Dormant Commerce Clause. The *Zogenix* case is again instructive. There, the manufacturer asserted that Massachusetts' regulation of Zohydro violated the Dormant Commerce Clause. However, the district court rejected that claim, concluding that

the plaintiff had not alleged sufficient facts or shown evidence that the Massachusetts laws imposed an unreasonable burden on interstate commerce. The district court in that case summarized the law applicable to such a Dormant Commerce Clause claim:

> Commerce Clause doctrine, which is implicit in Article I, § 8 of the United States Constitution, holds that state and local laws are unconstitutional if they place an undue burden on interstate commerce. The Dormant Commerce Clause, like the Commerce Clause itself, applies to "[a]ll objects of interstate trade," including pharmaceutical products. *City of Philadelphia v. New Jersey*, 437 U.S. 617, 622, 98 S. Ct. 2531, 57 L.Ed.2d 475 (1978); *cf. Pharm. Research & Mfrs. of Am. v. Cnty. of Alameda*, 768 F.3d 1037, 1045–46 (9th Cir.2014). The Supreme Court "has adopted what amounts to a two-tiered approach to analyzing state economic regulation under the Commerce Clause." *Brown–Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 57879, 106 S. Ct. 2080, 90 L.Ed.2d 552 (1986). First, "[w]hen a state statute directly regulates or discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out-of-state interests, [the Court has] generally struck down the statute without further inquiry." *Id.* at 578 (citations omitted). But, if "a statute has only indirect effects on interstate commerce and regulates evenhandedly," it is reviewed under a less stringent standard. "Under that test[,] ... courts employ a balancing approach whereby they examine whether the state's interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits." *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 312 (1st Cir.2005) (citing *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142, 90 S. Ct. 844, 25 L.Ed.2d 174 (1970)).

Zogenix, 2015 WL 1206354, at *7.

Defendant does not dispute that GBP's product is, at least theoretically, an object of trade moving in interstate commerce. However, Mississippi's safety requirements in question are non-discriminatory—they do not distinguish between intrastate and interstate commerce. Therefore, those requirements must be upheld

unless Plaintiff demonstrates to the Court that the laws are so unreasonable and clearly excessive in light of the putative local benefits. Thus, the Court must balance the burden imposed on interstate commerce by Mississippi's safety requirements for the administration of the drug (*de minimus* at most) against the benefits of the safety requirements, which are substantial. There is a strong presumption that the exercise of state police powers should be sustained unless the exercise of such powers is clearly excessive. This is a very high hill for Plaintiff to climb, and it has failed to do so.

In its Complaint, Plaintiff makes the following bare bones, conclusory allegations about the burden they assert the challenged laws impose on interstate commerce:

> 1. Mississippi's restrictions on mifepristone impose significant burdens on interstate commerce because they interfere with the FDA's national and uniform system of regulation. If Mississippi (and other states) is allowed to make its own determinations as to how the risks and benefits of prescription drugs should be weighed and whether and how they should be approved, regulated, and administered, the result will be an unworkable patchwork of state-specific regulation governing how prescription drugs are administered that would effectively eviscerate the mission of the FDA and create different (and potentially conflicting) sets of rules for deciding what constitutes safe and effective pharmaceuticals[;]
>
> 2. Mississippi's conflicting regulations also impose significant burdens on interstate commerce because they harm patients living in Mississippi, as well as patients residing outside of Mississippi who see health care providers in the state. Because health care providers are restricted in their ability to prescribe mifepristone to patients (regardless of their state of residence), patients across several states will experience restricted access to mifepristone thus impacting commerce beyond the borders of the state[;]

> 3. The burden imposed on interstate commerce by Mississippi's conflicting regulations is clearly excessive in relation to the purported protections touted by the state legislature. The additional restrictions on provision and use of mifepristone in Mississippi above and beyond those imposed by the FDA are excessive, especially in light of the FDA's careful and comprehensive balancing of the risks and benefits of such medication for the public health as evidenced, generally, by its approval of the drug and by the REMS process, in particular.

[Doc. 1 at 28-29]. Addressing each paragraph in turn reveals the fatal flaws in Plaintiff's Dormant Commerce Clause claim.

As for the first paragraph, not only is it completely conclusory, but it also appears to describe a species of field preemption. As discussed in *Wyeth v. Levine*, 555 U.S. 555, 575 (2009), had Congress wanted to preempt all state regulation of medication distribution and safety, it could have done so, but did not.

Turning to the first sentence in the next paragraph raises a significant question: Based on what evidence? GBP provides nothing more than its conclusory allegations to support its premise. GBP does not explain what, exactly, is harming the patients. GBP also does not allege a causal link between the challenged laws and the purported injuries to providers and women. And the last sentence in this paragraph provides more of the same-barebone, conclusory allegations.

As for the last paragraph, GBP supports its "clearly excessive" allegation with nothing more than conclusory allegations, the implication of which is that mifepristone is inherently safe to use. But if mifepristone was "safe", the FDA would not have continuously imposed a REMS program with applicable ETASU's. Even GBP admits that the FDA's "ETASU['s] are the most restrictive and

burdensome type of REMS." [Doc. 1 at 10]. GBP's allegation that the burden is clearly excessive is supported by no *evidence* of any burden at all, much less a clearly excessive burden. The only burdens GBP ostensibly describes are the burdens in the two preceding paragraphs. These paragraphs, if anything, address only a burden purportedly imposed upon healthcare providers and women. But as discussed in the standing portion of this memorandum, GBP lacks third-party standing to bring any claim on behalf of abortion providers or women.

Ultimately, it is GBP, not the Defendant, that bears the burden of proving the jurisdiction of the Court and the plausible viability of its claims. And in considering this motion, the Court should reject the speculative and conclusory allegations GBP asserts in its Complaint. Without these conclusory allegations, GBP's Dormant Commerce Clause claim simply evaporates.[6]

CONCLUSION

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

RESPECTFULLY SUBMITTED, this the 6th day of November, 2020.

[6]Notably, GBP, in its complaint, recites almost verbatim the claim alleged by Zogenix, Inc., in the Zenhydro case. *Compare* [Doc. 1 at 28] *with* Verified Third Amended Complaint, *Zogenix, Inc. v. Baker*, No. CIV. A. 14-11689-RWZ, 2015 WL 1206354 (D. Mass. Mar. 17, 2015) (ECF No. 75-1). There, the Massachusetts district court dismissed the Dormant Commerce Clause claim because it "fail[ed] as a matter of law." *Zogenix, Inc. v. Baker*, No. CIV. A. 14-11689-RWZ, 2015 WL 1206354, at *4 (D. Mass. Mar. 17, 2015).

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 6th day of November, 2020.

s/Paul Barnes
PAUL E. BARNES