

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

DEFENDANT

**DEFENDANT’S RESPONSE TO THE COURT’S INQUIRY REGARDING
THE EFFECT THE U.S. SUPREME COURT DECISION IN *DOBBS v.
JACKSON WOMEN’S HEALTH ORGANIZATION* AND MISSISSIPPI’S
TRIGGER LAW HAVE ON THE MERITS OF THIS CASE**

Introduction

GenBioPro (“GBP”) markets and sells the generic version of the abortion-inducing drug mifepristone. [Doc. 13], p. 1. GBP’s lawsuit challenged the Women’s Health Defense Act of 2013 (“WHDA”), Miss. Code Ann. §§ 41-41-101-117 and accompanying regulations, 15 Miss. Admin Code § 16-1-44.1. This statutory and regulatory framework sets certain standards for the use of abortion-inducing drugs in Mississippi (“State”). MISS. CODE ANN. § 41-41-107. GBP’s suit alleges that the State’s framework conflicts with the Food and Drug Administration’s (“FDA”) regulations approving the sale and use of mifepristone. [Doc. 1], p. 2, ¶ 3.

Specifically, GBP maintains that the WHDA conflicts with the FDA’s Risk Evaluation and Mitigation Strategy (“REMS”) [Doc. 1], p. 18, ¶ 55. GBP also asserts that the WHDA places conditions on the sale and use of mifepristone that impose an undue burden on interstate commerce. *Id.* The State sought dismissal pursuant to Rule 12(b)(1) for lack of Article III standing, and under Rule 12(b)(6) for failure to state a claim as to GBP’s preemption and dormant commerce clause claims. [Doc.8,

9]. Now, in light of the Supreme Court's decision last Friday in *Dobbs*, and Mississippi's trigger law, the case for dismissal is even stronger and GBP's claims should be dismissed forthwith.

Background

On June 8, 2022, this Court conducted a hearing to address the State's motion to dismiss. During that hearing, the Court asked counsel for GBP and the State what impact, if any, a Supreme Court decision in *Dobbs v. Jackson Women's Health Organization*, No. 19-1392, overturning *Roe v. Wade*, 410 U.S. 113 (1973), would have on the merits of this case. Because *Dobbs* had not yet been decided, counsel for the State apprised this Court that the impact would depend on what the Supreme Court actually said in *Dobbs*.

The Court's question has now been addressed by *Dobbs* in favor of the State. *Dobbs v. Jackson Women's Health Organization*. 579 U.S. ___ (2022). It is undeniable that the legal landscape following *Dobbs* has shifted overwhelmingly in favor of the State's authority to regulate or prohibit abortion. Slip Op. at 77-79. The State's grounds for dismissal were compelling before *Dobbs* [Doc 9]. Following *Dobbs*, and the sweeping authority returned to the State to regulate or prohibit abortions, the rationale for dismissing GBP's complaint is overwhelming. To be sure, GBP will no doubt argue that *Dobbs* changes little or nothing, and that the State's authority to regulate a drug that induces abortion is still limited by the FDA and the REMS for mifepristone. That argument is meritless. Accordingly, the State respectfully requests that the Court grant its motion to dismiss.

The Supreme Court's Decision in *Dobbs* Further Requires Dismissal of GBP's Complaint

In overruling *Roe* and *Casey*, the Supreme Court in *Dobbs* held that "[t]he Constitution does not prohibit the citizens of each State from regulating or

prohibiting abortion. *Roe* and *Casey* arrogated that authority. We overrule those decisions and return that authority to the people and their elected representatives.” Slip Op. at 79. The Court explained that “procuring an abortion is not a fundamental constitutional right because such a right has no basis in the Constitution’s text or in our Nation’s history.” Slip Op. at 77.

The Court concluded that rational-basis review will now govern constitutional challenges to state abortion regulations. The Court explained: “A law regulating abortion, like other health and welfare laws, is entitled to a ‘strong presumption of validity.’ It must be sustained if there is a rational basis on which the legislature could have thought that it would serve legitimate state interests.” Slip Op. at 77 (internal citations omitted). “States may regulate abortion for legitimate reasons, and when such regulations are challenged under the Constitution, courts cannot ‘substitute their social and economic beliefs for the judgment of legislative bodies.’” Slip Op. at 77 (quoting *Ferguson v. Skrupa*, 376 U.S. 726, 730 (1963)).

The legitimate State interests recounted in *Dobbs* 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 integrity of the medical profession; the mitigation of fetal pain; and the prevention of discrimination on the basis of race, sex, or disability. Slip Op. at 78 (internal citations omitted). *Dobbs* does not impose limitations on the State’s authority to regulate abortion based on the manner in which the abortion is carried out. Indeed, under *Dobbs* States may “prohibit[] abortion” outright. Slip Op. at 79.

Even before the decision in *Dobbs*, there was no evidence that Congress intended the FDA to have the power to restrict a state’s ability to regulate medication-induced abortion. Now that the Supreme Court has held that States, subject to rational-basis review, have the authority to regulate or prohibit abortion, GBP’s

claims of federal preemption and under the dormant commerce clause even more clearly fail. *Dobbs* recognizes that the authority over abortion is part of States' traditional authority, sharply undermining a case for preemption or federal control.

Consistent with *Dobbs*, and as explained further below, the trigger law “prohibit[s]” most abortions—removing the foundation for GBP’s claims that the State has unlawfully regulated a drug. Slip Op. at 79. When a State may prohibit and does prohibit the primary conduct at issue (here, providing an abortion), questions about regulation of a drug used to carry out that primary conduct never enter the picture. Because the State may prohibit abortions and has done so, GBP’s claims about improper regulation fall apart. For the same reason, GBP’s dormant commerce clause claim fails.

**Mississippi’s Trigger Law and the Attorney General’s
Determination Regarding Mississippi Code Annotated Section 41-41-45**

This Court further inquired about the ramifications of Mississippi’s trigger law on this litigation. In short, the trigger law forecloses GBP’s claims in the case *sub judice*. In 2007, Mississippi enacted Mississippi Code Annotated Section 41-41-45, which 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.” MISS. CODE ANN. § 41-41-45(2). This trigger law was set to take effect if the Supreme Court overruled *Roe*. The trigger law provides specifically that Section 2 would “take effect and be in force from and after ten (10) days following” publication in the Secretary of State’s administrative bulletin that “the Attorney General has determined that the U.S. Supreme Court has overruled the decision of *Roe v. Wade*, 410 U.S. 113 (1973), and that it is reasonably probable that Section 2 of this act would be upheld by the court as constitutional.” 2007 Miss. Laws Ch. 441 § 6.

On June 27, 2022, Attorney General Lynn Fitch published her determination, in accordance with the governing provisions of Section 41-41-45, that the United States Supreme Court overruled *Roe*. Attorney General’s Determination Regarding Section 41-41-45, Miss. Code Ann., No. 26438 (June 27, 2022) (available at <https://www.sos.ms.gov/adminsearch/ACProposed/00026438b.pdf> and also attached hereto as Exhibit A). Consistent with her statutory authority, the Attorney General determined that in *Dobbs*, the Supreme Court held that “rational-basis review is the appropriate standard” for constitutional challenges to state abortion regulations. *Id.* The Attorney General also determined that it is reasonably probable under rational-basis review that Section 41-41-45 would be upheld by the Supreme Court as constitutional were it challenged. *See* 2007 Laws Ch. 441 § 6.

Mississippi Code Annotated Section 41-41-45(1) defines abortion as “the use or prescription of any instrument, medicine, drug or any other substance or device to terminate the pregnancy of a woman. . . .” *Id.* Section 41-41-45(2) provides that “[n]o abortion shall be performed or induced in the State of Mississippi, except in the case where necessary for the preservation of the mother’s life or where the pregnancy was caused by rape.” *Id.* Indeed, that provision makes no distinction regarding the manner in which an abortion is induced, whether by drug or other means specified in the statute, “except in the case where necessary for the preservation of the mother’s life or where the pregnancy was caused by rape.” MISS. CODE ANN. § 41-41-45(2).

To be clear, Mississippi’s trigger law does not regulate the safety or efficacy of mifepristone addressed by the FDA in the REMS. [Doc. 1], p. 2, ¶2. The trigger law prohibits the primary conduct (providing abortions), regardless of the means used to induce an abortion, except to preserve the mother’s life or in where the pregnancy was caused by rape. MISS. CODE ANN. § 41-41-45(2). Intuitively, the trigger law does not implicate the issues addressed through the REMS for mifepristone. As explained

already, in its trigger law, the State has prohibited most abortions and in doing so has overwhelmingly eliminated the basis for GBP's claims in this case.¹

GBP's Claims Fail as a Matter of Law Under Mississippi's Trigger Law

GBP seeks to permanently enjoin the State from enforcing any state law or regulation restricting the provision and use of mifepristone beyond the FDA's 2016 REMS. [Doc. 1] p. 29. Pre-*Dobbs*, GBP argued that Mississippi would maintain its ability to regulate abortion *procedures* under its police powers, but that the State is prohibited from placing restrictions on the sale and use of mifepristone beyond the FDA's framework. [Doc. 13], p. 12. Throughout, GBP has tried to avoid any overt discussion about abortion, going so far as to argue that this is a "a garden variety preemption case about the safe distribution and marketing of an FDA-approved medication. . . ." *Id.*

This is anything but a garden variety preemption case. This case is not about the safety of an FDA-approved drug, or considerations under the REMS for mifepristone. This case is about the State's primary authority over abortion, regardless of the means by which the abortion is induced. Under the trigger law, the State is not regulating as to whether mifepristone is safe. Instead, the trigger law imposes the conditions upon which an abortion may be performed at all. From the beginning, GBP has attacked any Mississippi law that would impose a restriction more stringent than the 2016 REMS requirements on a drug-induced abortion. Under GBP's view, a drug used to induce an abortion is beyond the reach of the State's

¹ On June 27, 2022 the Jackson Women's Health Organization filed a complaint for declaratory and injunctive relief in Hinds County Chancery Court challenging the enforcement of Mississippi's trigger law, Miss. Code Ann. § 41-41-45(2), and Miss. Code Ann. § 41-41-34.1 which prohibits a person from "knowingly perform[ing] an abortion" when a "fetal heartbeat has been detected." MISS. CODE ANN. § 41-41-34.1(2)(a). On June 28, 2022, plaintiffs filed a motion for temporary restraining order. *Jackson Women's Health Organization, et al. v. Thomas E. Dobbs, in his official capacity as State Health Officer of the Mississippi Department of Health, et al.*, Case No. G-2022-739. This case is currently pending.

regulatory authority and subject only to FDA approval. While this view was incorrect before *Dobbs*, any doubt regarding the State's authority over abortion has been removed by *Dobbs* in the State's favor.

GBP seeks to avoid Mississippi law by creating an artificial distinction between surgical abortions and those abortions induced by a drug such as mifepristone. [Doc. 13], p. 13. *Dobbs* creates no such distinction and ruled that states may regulate or prohibit abortions through laws subject to rational-basis review. And Mississippi law makes no distinction between surgical abortions or abortions induced by a medication or drug. MISS. CODE ANN. § 41-41-45(1). Finally, that law prohibits abortion except in a case where necessary to preserve the mother's life or where the pregnancy was caused by rape. MISS. CODE ANN. § 41-41-45(2). Following *Dobbs*, the State has primary authority over abortions subject to rational-basis review. Slip Op. at 79. GBP's preemption and dormant commerce clause claims fail.

CONCLUSION

For the reasons set forth in its motion to dismiss and accompanying memorandum, [Doc. 8, 9], and for the reasons set forth herein, the State respectfully requests that the Court grant its motion and dismiss this case with prejudice.

This the 30th day of June, 2022.

Respectfully submitted,

LYNN FITCH
Attorney General

By: /s/ Douglas T. Miracle
Douglas T. Miracle (Bar. No. 9648)
ASSISTANT ATTORNEY GENERAL
OFFICE OF THE ATTORNEY GENERAL
CIVIL LITIGATION DIVISION
Post Office Box 220
Jackson, Mississippi 39205-0220
doug.miracle@ago.ms.gov

*Counsel for Defendant, Thomas E. Dobbs, M.D.,
MPH, in his official capacity as State Health
Officer of the Mississippi Department of Health*

CERTIFICATE OF SERVICE

I, Douglas T. Miracle, 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 30th day of June, 2022.

/s/ Douglas T. Miracle
Douglas T. Miracle