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June 30, 2022

VIA ECF FILING

The Honorable Henry T. Wingate
United States District Court
Southern District of Mississippi
501 East Court Street
Suite 6.750
Jackson, MS 39201

Re: **GenBioPro, Inc. v. Dobbs**
Civil Action No. 3:20-cv-00652-HTW-LGI

Dear Judge Wingate,

We write on behalf of Plaintiff, GenBioPro, Inc., in response to this Court’s inquiry into what effect, if any, the Supreme Court’s June 24, 2022 decision in *Dobbs v. Jackson Women’s Health Org.*, and the Mississippi trigger law, Miss. Code Ann. § 41-41-45, have on the present litigation. GenBioPro maintains that the legal issues decided in *Dobbs* do not affect GenBioPro’s claims.¹ To the extent the trigger law has any impact on the issues presently before the Court—whether GenBioPro has standing and whether GenBioPro has adequately pleaded its preemption and Commerce Clause claims—the trigger law stands only to strengthen GenBioPro’s position.

As explained during the Parties’ oral argument on June 8, 2022, GenBioPro’s claims arise under two provisions in the United States Constitution: the Supremacy Clause and the Commerce Clause, *not* the Fourteenth Amendment. To be clear, GenBioPro’s claims in no way implicate the substantive due process interests at issue in *Dobbs* and *Roe v. Wade*.

Although *Dobbs* concerned separate *legal* issues, as the Court is aware, on June 27, 2022 the Mississippi Attorney General formally certified that the Supreme Court overruled *Roe v. Wade*.

¹ The Court asked that the Parties advise as to whether the Supreme Court’s ruling has any effect, “inasmuch as the authority to regulate abortions (surgical and drug-induced) now lies with each individual state.” GenBioPro wishes to clarify that the majority’s ruling in *Dobbs* did not specifically address medicated abortions.

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As a result, absent judicial intervention,² as of July 7, 2022, nearly all abortions in Mississippi will be banned, including medicated abortions. *See* Miss. Code Ann. § 41-41-45 (defining abortion to include “the use or prescription of any instrument, medicine, drug or any other substance[.]”). Thus, shortly, mifepristone will be unavailable in the state of Mississippi, creating a that-much-more direct and glaring conflict with the Food and Drug Administration’s (FDA) approved regime and Risk Evaluation and Mitigation Strategy for mifepristone. As GenBioPro pleaded, Mississippi’s current restrictions on mifepristone *already* upset the balance the FDA struck between risk mitigation and ensuring access to a safe and effective medication. A ban would further distort that balance and run farther afoul of the Supremacy Clause. *See, e.g., Zogenix, Inc. v. Patrick*, 2014 WL 1454696, at *1-2 (D. Mass. Apr. 15, 2014) (enjoining enforcement of a state order prohibiting the prescribing and dispensing of an FDA-approved medication and explaining that, if a state “were able to countermand the FDA’s determinations and substitute its own requirements, it would undermine the FDA’s ability to make drugs available to promote and protect the public health.”)

But, despite the impending ban in Mississippi, the Supreme Court’s holding in *Dobbs*—that the Fourteenth Amendment does not implicitly protect the right to an abortion—neither abrogates the FDA’s authority under the Supremacy Clause nor allows Mississippi to ban an FDA-approved medication. Indeed, though the merits of GenBioPro’s claims are not currently at issue, this Court need not take GenBioPro’s word that an outright ban would further conflict with the FDA’s approval of mifepristone, but can look to the United States Attorney General’s recent statement to confirm as much. In response to the *Dobbs* decision, Attorney General Merrick Garland issued a press release stating, “the FDA has approved the use of the medication Mifepristone. *States may not ban Mifepristone based on disagreement with the FDA’s expert judgment about its safety and efficacy.*”³ Further, responding to threats from state officials to ban or severely restrict access to mifepristone, President Biden directed the Secretary of Health and Human Services (HHS), who oversees the FDA, “to protect women’s access to critical medications for reproductive health care that are approved by the Food and Drug Administration—including . . . medication abortion.”⁴ In response to President Biden’s direction, HHS Secretary Xavier Becerra stated that HHS “will continue to support the FDA and its rigorous scientific review for these safe and effective drugs,” including mifepristone, and HHS “will also work with the Attorney

² Also on June 27, 2022, Jackson Women’s Health Organization filed a lawsuit in Hinds County Chancery Court seeking to enjoin the state from enforcing the abortion ban.

³ *Attorney General Merrick B. Garland Statement on Supreme Court Ruling in Dobbs v. Jackson Women’s Health Organization*, U.S. DEP’T. OF JUST. (June 24, 2022), <https://www.justice.gov/opa/pr/attorney-general-merrick-b-garland-statement-supreme-court-ruling-dobbs-v-jackson-women-s> (emphasis added).

⁴ *FACT SHEET: President Biden Announces Actions In Light of Today’s Supreme Court Decision on Dobbs v. Jackson Women’s Health Organization*, THE WHITE HOUSE BRIEFING ROOM (June 24, 2022), <https://www.whitehouse.gov/briefing-room/statements-releases/2022/06/24/fact-sheet-president-biden-announces-actions-in-light-of-todays-supreme-court-decision-on-dobbs-v-jackson-womens-health-organization/>.

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General and the Justice Department as they work to ensure that states may not ban medication abortion[.]”⁵

Respectfully submitted,

/s/ U. Gwyn Williams

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/s/ J. Carter Thompson, Jr.

J. Carter Thompson, Jr. (MSB No. 8195)
of BAKER, DONELSON, BEARMAN,
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Counsel for Plaintiff, GenBioPro, Inc.

cc: Counsel of Record

⁵ *Remarks by Secretary Xavier Becerra at the Press Conference in Response to President Biden's Directive following Overturning of Roe v. Wade*, U.S. DEP'T OF HEALTH & HUM. SERVS. (June 28, 2022), <https://www.hhs.gov/about/news/2022/06/28/remarks-by-secretary-xavier-becerra-at-the-press-conference-in-response-to-president-bidens-directive-following-overturning-of-roe-v-wade.html>.