IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA HUNTINGTON DIVISION

GENBIOPRO, INC.,

Plaintiff,

v.

Civil Action No. 3:23-cv-00058

MARK A. SORSAIA, in his official capacity, AND PATRICK MORRISEY, in his official capacity,

Hon. Robert C. Chambers

Defendants.

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR STAY

Defendants, Mark A. Sorsaia, in his official capacity as Prosecuting Attorney for Putnam County, and Patrick Morrisey, in his official capacity as Attorney General of the State of West Virginia, herby file this memorandum in support of their motion to stay.

This case concerns Plaintiff GenBioPro's claim that the FDA's approval of mifepristone preempts certain West Virginia laws, including new statutes regulating abortion. Compl. ¶¶ 94–101. On April 7, 2023, the Northern District of Texas stayed the FDA's September 28, 2000, approval of mifepristone and the FDA's 2019 approval of Plaintiff's generic mifepristone. *Alliance for Hippocratic Medicine v. U.S. Food & Drug Admin.*, No. 2:22-cv-00223, 2023 WL 2825871, at *32 (N.D. Tex. Apr. 7, 2023). The district court also held that "the Comstock Act plainly forecloses mail-order abortion." *Id.* at 18.

The FDA appealed that decision, and on April 12, 2023, the Fifth Circuit modified the effect of the district court's order by staying the lower court's action against the FDA's approval

Case 3:23-cv-00058 Document 49 Filed 04/18/23 Page 2 of 5 PageID #: 636

of mifepristone in 2000 but leaving in place the district court's action against the FDA's 2019 approval of the generic form of mifepristone produced by Plaintiff. *Alliance for Hippocratic Medicine v. Food & Drug Admin.*, No. 23-10362, 2023 WL 2913725, at *1 (5th Cir. Apr. 12, 2023) (attached as Exhibit A). On April 14, 2023, the Supreme Court entered an administrative stay temporarily halting the Fifth Circuit and district court rulings until Thursday, April 20, 2023. Meanwhile, the Fifth Circuit has set a briefing schedule to hear the merits of the FDA's appeal. Oral argument is set for May 17, 2023.

As long as either the FDA's 2000 approval of mifepristone or its 2019 approval of generic mifepristone remains stayed or is permanently enjoined, Plaintiff cannot sell mifepristone anywhere in the United States regardless of the outcome of this case affecting only West Virginia. And if the district court's interpretation of the Comstock Act stands, Plaintiff may not mail or ship via common carrier mifepristone in the United States, which also would preclude such mailing or shipping into West Virginia. Thus, the *Alliance for Hippocratic Medicine v. Food & Drug Administration* litigation directly impacts this case, as has been demonstrated to this point in the form of the district court's ruling and the Fifth Circuit's action to date.

In the interest of judicial economy, Defendants respectfully request that the Court stay this case until a final decision is reached in *Alliance for Hippocratic Medicine v. Food & Drug Administration*.

2

Respectfully submitted,

PATRICK MORRISEY West Virginia Attorney General

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**visiting attorney*

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/s/ Jennifer Scragg Karr (by permission) Jennifer Scragg Karr (WV Bar # 8051) Assistant Prosecuting Attorney OFFICE OF THE PROSECUTING ATTORNEY Putnam County Judicial Building 12093 Winfield Rd. Winfield, WV 25213 Tel.: (304) 586-0205 Fax: (304) 586-0269 jkarr@putnamwv.org

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CERTIFICATE OF SERVICE

I hereby certify that, on this 18th day of April, 2023, I electronically filed the foregoing

"Memorandum in Support of Defendants' Motion for Stay" with the Clerk of Court and all parties

using the CM/ECF System.

/s/ Curtis R. A. Capehart Curtis R. A. Capehart Deputy Attorney General