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August 18, 2023

Via ECF

Honorable Robert C. Chambers
United States District Court for the
Southern District of West Virginia
Sidney L. Christie Federal Building
845 Fifth Avenue, Room 101
Huntington, WV 25701

Re: *GenBioPro, Inc. v. Sorsaia et al.*, No. 3:23-cv-00058 (S.D. W. Va.)

Dear Judge Chambers:

Plaintiff GenBioPro, Inc. (“GenBioPro”) respectfully submits this notice of supplemental authority informing the Court of the Fifth Circuit’s recent opinion in *Alliance for Hippocratic Medicine v. United States Food & Drug Administration*, No. 23-10362 (5th Cir. Aug. 16, 2023) (“*AHM*”), ECF No. 543. The Fifth Circuit held that the plaintiffs lacked standing to challenge FDA’s 2019 approval of GenBioPro’s generic drug and vacated the portion of the district court’s order staying the effective date of FDA’s approval of GenBioPro’s generic mifepristone. *Id.* at 3, 36-37. The Fifth Circuit also vacated the district court’s order staying branded mifepristone’s approval in 2000, holding that the plaintiffs’ challenge to Mifeprex’s 2000 approval was untimely. *Id.* at 3, 38-43. The court affirmed portions of the district court’s order concerning changes FDA made in 2016 to mifepristone’s REMS and the agency’s 2021 decision to no longer require that mifepristone be dispensed in person.

The Fifth Circuit noted that any effect of the portions of its holdings affirming the district court’s order is “subject to the prior order of the Supreme Court” staying the district court’s order pending the Supreme Court’s resolution of any petition for writ of certiorari. *Id.* at 4; *see also id.* at 62-63.

This Court recognized in its April 21, 2023 Order denying Defendants’ Motion for Stay that any decision by the Fifth Circuit in *AHM* is “not binding upon this Court.” ECF No. 52 at 1. The Fifth Circuit did not consider or address the preemptive effects of the 2007 Food and Drug

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Administration Amendments Act or the dormant Commerce Clause, which form the bases of the instant litigation. *See* ECF No. 50 at 6-7.

A copy of the opinion is enclosed as Exhibit A for the Court's convenience.

Respectfully submitted,

/s/ David C. Frederick
David C. Frederick (admitted *pro hac vice*)

/s/ Anthony J. Majestro
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