

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

GENBIOPRO, INC.,

Plaintiff,

v.

Case No. 23-cv-1057-TDC

**U.S. FOOD AND DRUG
ADMINISTRATION, *et al.*,**

Defendants.

JOINT STATUS REPORT

Pursuant to the Court's order of November 1, 2024 (ECF No. 40), the parties respectfully submit this joint status report. The parties state as follows:

1. Last year, the Court granted (ECF No. 31) the parties' joint motion to stay proceedings in this case pending Supreme Court review of the U.S. Court of Appeals for the Fifth Circuit's decision in *Alliance for Hippocratic Medicine v. FDA*, 78 F.4th 210 (5th Cir. 2023), which affirmed in part and reversed in part an order in *Alliance for Hippocratic Medicine v. FDA*, 668 F. Supp. 3d 507 (N.D. Tex. 2023).

2. As described in the parties' prior joint status reports, on June 13, 2024, the Supreme Court held that the plaintiffs in *Alliance* lacked Article III standing to challenge FDA's actions relating to mifepristone. *See FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 372, 397 (2024). The Fifth Circuit subsequently remanded the case to the district court. *All. for Hippocratic Med. v. FDA*, 117 F.4th 336, 340 (5th Cir. 2024).

3. As described in the parties' last status report before this one, on September 30, 2024, the parties in *Alliance* filed a joint status report in the district court stating their respective

positions on further proceedings. *See* ECF No. 191, No. 2:22-cv-223-Z (N.D. Tex. Sept. 30, 2024). The federal defendants and intervenor-defendant Danco Laboratories, LLC argued that the case cannot proceed following the Supreme Court's ruling and proposed filing a motion to dismiss unless the court opted to dismiss immediately. *See id.* at 2-3. The original plaintiffs in *Alliance* argued that the Supreme Court decision applied only to their preliminary injunction motion. *Id.* at 3. The States of Missouri, Kansas, and Idaho—whose motion to intervene the district court had granted on January 12, 2024—argued that they had standing and planned to amend their complaint. *See id.* at 3-4.

4. As previously reported, on October 11, 2024, the intervenor-plaintiff States in *Alliance* filed a motion for leave to file an amended complaint and attached a proposed pleading. *Alliance*, ECF Nos. 195, 195-1. The proposed amended complaint in *Alliance* raises numerous issues relating to various FDA regulatory actions with respect to the product of the Plaintiff in this case, GenBioPro.

5. Since the time of the parties' last status report, the *Alliance* defendants moved to dismiss the original plaintiffs' and intervenor-plaintiffs' complaints, and opposed the intervenor-plaintiffs' motion for leave to amend, *Alliance*, ECF Nos. 196, 199, and the original plaintiffs voluntarily dismissed their claims, ECF No. 203. The motions to dismiss the intervenor-plaintiffs' complaint and the intervenor-plaintiffs' motion for leave to amend are now fully briefed.

6. In this case, Defendants continue to dispute whether Plaintiff's suit is proper and its claims have merit. The parties agree, however, that they would benefit from understanding how the pending motions in *Alliance* will be resolved.

7. Therefore, in the interest of efficiency and to conserve judicial and party resources, the parties respectfully suggest that this case continue to be held in abeyance and that the parties file another joint status report in 120 days.

Dated: December 16, 2024

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