

October 1, 2026

VIA ECF

Lyle W. Cayce
Clerk of the Court
U.S. Court of Appeals for the Fifth Circuit
600 S. Maestri Place
New Orleans, LA 70130

Re: *Louisiana v. FDA et al.*, No. 26-30203 (5th Cir.) – Response to
Louisiana’s September 30, 2026 Letter

Dear Mr. Cayce:

On behalf of GenBioPro, Inc., Intervenor-Appellee in the above-captioned appeal, I write to respond to the letter filed by Appellant State of Louisiana on September 30, 2026 to “notify the panel of two legal developments,” namely, Louisiana’s filing of two new lawsuits against individuals, entities, and states that are not parties to this case. Doc. 407 at 1.

To the extent Louisiana’s letter is intended as a Rule 28(j) letter, Louisiana’s allegations against other defendants in other litigation are not “pertinent and significant authorities.” Fed. R. App. P. 28(j). When GenBioPro previously sought to file a Rule 28(j) letter advising the Court of a significant relevant development in related litigation, the Court declined to file it on the ground that “no supporting authority is included.” Doc. 111 (Apr. 27, 2026). By that standard, Louisiana’s letter should not be filed or considered by the panel either.

In any event, to the extent relevant at all, these new actions further support our argument that Louisiana lacks Article III standing to bring its claims against FDA challenging the 2023 REMS in this case. *See* GenBioPro Br. (Doc. 247) at 24, 37, 39; GenBioPro Reply (Doc. 389) at 18-19; Danco Laboratories, LLC Br. (Doc. 391) at 37-38.

Respectfully Submitted,

/s/ John P. Elwood

John P. Elwood

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