UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division

Outsourcing Facilities Association, *et al.*, Plaintiffs, v. U.S. Food and Drug Administration, *et al.*, Defendants.	Case No. 4:24-cv-00953-P

JOINT STATUS REPORT

The parties submit this joint status report pursuant to this Court's October 11, 2024 Order, ECF No. 28. That Order granted Defendants' unopposed motion to voluntarily remand the challenged decision to the United States Food and Drug Administration (FDA) and stayed litigation pending further court order. The Court also ordered the parties to file a joint status report by November 21, 2024. Subsequently, the Court administratively closed this case, ECF No. 29.

Defendants' Report: Consistent with the Court's October 11, 2024 Order, FDA has made substantial progress reevaluating the challenged decision. FDA is carefully assessing the challenged decision and continues to prioritize issuing a new decision on remand.

Plaintiffs' Report: To assist FDA in its reevaluation of the challenged decision, Plaintiffs have continued to monitor market conditions for Tirzepatide and that they, their members, and other interested persons have provided the agency with evidence that the drug remains in shortage. Survey data from this month shows increasing numbers of patients unable to obtain branded GLP-1 agonist products, including

specifically branded Tirzepatide products.[1] Pharmacy distributors continue to list branded Tirzepatide products as out-of-stock or available in only limited quantities.[2] Meanwhile, production of compounded Tirzepatide products by members of Plaintiff Outsourcing Facilities Association has remained steady or grown, reflecting still more market demand and medical need that is unable to be met by branded Tirzepatide products.

Joint Report: The parties believe that this case should continue to be stayed pursuant to the October 11, 2024 Order, and they intend, absent alternative direction from the Court, to file a further joint status report by the earlier of December 19, 2024, or within seven days of FDA's decision on remand.

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[1] *See, e.g.*, Hims & Hers Health, Inc., Public Comment on Compounding of Human Drug Products Under the Federal Food, Drug, and Cosmetic Act, Dkt. No. FDA-2015-N-0030 (filed Nov. 15, 2024).

[2] *See, e.g.*, *id.*; Alliance for Pharmacy Compounding, Proof: Tirzepatide Is Still in Shortage, https://a4pc.org/stillinshortage (last visited Nov. 20, 2024).

DATED: NOV. 21, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the CM/ECF system, will be sent via electronic mail to the registered participants as identified on the Notice of Electronic Filing.

November 21, 2024

/s/ Oliver McDonald
OLIVER MCDONALD