

**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 Orders dated October 11, 2024, ECF No. 28, and November 22, 2024, ECF No. 31. The October 11, 2024 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 November 22, 2024 Order continued the stay and ordered the parties to file a further joint status report by December 19, 2024.

Upon re-evaluation, on December 19, 2024, FDA issued a declaratory order regarding tirzepatide injection products, determining that the shortage is resolved and providing for periods of enforcement discretion. *See* Exhibit A. Those periods are in addition to the enforcement discretion that Defendants described in their unopposed motion for voluntary remand. Defendants will continue, as described in the motion, to exercise enforcement discretion and not take action against Plaintiffs and their members for conduct arising from conditions that depend on tirzepatide's inclusion on the drug shortage list for two weeks beyond today's decision. ECF No. 27 at 3. If Plaintiffs file a motion for preliminary injunction within two weeks of today's decision, Defendants will continue to exercise such enforcement discretion through the Court's resolution of that motion. *Id.*

The parties believe that this case should continue to be stayed pursuant to the Court's October 11, 2024 Order, ECF No. 28, and intend, absent alternative direction from the Court, to file a further joint status report or motion by January 2, 2025, addressing the next steps in this litigation. The parties will confer regarding a preliminary injunction briefing schedule, including the possibility of extending the enforcement discretion period for Plaintiffs to file their preliminary injunction motion beyond the two weeks described in Defendants' unopposed motion. The parties anticipate apprising the Court that, if Plaintiffs file a preliminary injunction motion within the timeframe proposed in the January 2, 2025 filing, Defendants would continue to exercise the enforcement discretion described in Defendants' unopposed motion for voluntary remand through the Court's resolution of Plaintiffs' motion.

DATED: DEC. 19, 2024

Respectfully submitted,

/s/ Andrew M. Grossman

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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.

December 19, 2024

/s/ Oliver McDonald
OLIVER McDONALD