

LATHAM & WATKINS LLP

January 31, 2023

VIA CM/ECF

Mark Langer, Clerk of Court
Office of the Clerk
United States Court of Appeals for the D.C. Circuit
333 Constitution Ave., NW, Room 5205
Washington, DC 20001

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Re: *United Therapeutics Corp. v. Johnson*, No. 21-5304: Notice of Supplemental Authority Pursuant to Rule 28(j)

Dear Mr. Langer,

On January 30, 2023, the United States Court of Appeals for the Third Circuit issued a decision in *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, Nos. 21-3167, 21-3379, slip op. (3d Cir. Jan. 30, 2023). In relevant part, a unanimous panel found that the manufacturers' contract-pharmacy policies did not violate 42 U.S.C. § 256b and that "Congress never said that drug makers must deliver discounted Section 340B drugs to an unlimited number of contract pharmacies." *Id.* at 20-21.¹

The Third Circuit squarely addressed (and rejected) the arguments asserted by the Government in this case. *First*, the Court rejected the assertion that the statutory requirement to "offer" discounted drugs to "covered entities" requires delivery to all contract pharmacies. *Id.* at 13-14 ("Nor does the word 'offer' imply that the offeror must deliver goods wherever and to whomever the buyer demands."). *Second*, the Court rejected the Government's reliance on the "purchased by" provision, observing that the language "says nothing about delivery" and that it "imposes only a price term for drug sales to covered entities, leaving all other terms blank." *Id.* at 14. *Third*, the Court held that unless the statute "prohibits" manufacturers "from adopting their policies, [the Government] cannot show [manufacturers] have violated Section 340B." *Id.* at 15. Finally, the Court held that the structure of the statute, drafting history, and legislative purpose did not support the Government's position. *Id.* at 15-18.

The Third Circuit's unanimous decision is directly on all fours here. The Violation Letters issued in that case are virtually identical to the one issued to UT here, and the Government's arguments in that case and this one are indistinguishable.

¹ Judge Ambro dissented on an unrelated issue.

LATHAM & WATKINS^{LLP}

Respectfully submitted,

/s/ Philip J. Perry

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CERTIFICATE OF COMPLIANCE

I certify that this letter complies with the type-volume limitations of Federal Rule of Appellate Procedure 28(j) because it contains 286 words.

/s/ Philip J. Perry

Philip J. Perry