UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED THERAPEUTICS CORPORATION, Plaintiff, v. DIANA ESPINOSA, *et al.*, Defendants.	No. 21-cv-1686 (DLF)

PLAINTIFF'S RESPONSE TO DEFENDANTS' NOTICE OF SUPPLEMENTAL AUTHORITY

Plaintiff United Therapeutics Corporation ("UT") respectfully submits this response to Defendants' Notice of Supplemental Authority concerning the decision in *Eli Lilly v. Becerra*, No. 1:12-cv-00081-SEB (S.D. Ind.). *See* ECF No. 29. In that case, the court set aside Defendant Health Resources and Services Administration's ("HRSA") May 17 Violation Letter to Lilly as arbitrary and capricious because the agency "fail[ed] to acknowledge or explain the agency's changed position," but also opined that "the statute, correctly construed, does not permit drug manufacturers, such as Lilly, to impose unilateral extra-statutory restrictions on its offer to sell 340B drugs to covered entities utilizing multiple contract pharmacy arrangements." ECF No. 29-1 at 59-60. This Court should similarly set aside HRSA's May 17 Violation Letter to UT, but should reject the statutory analysis employed in *Lilly*.

1. Respectfully, the *Lilly* court erred in its statutory analysis. As Novartis explained at length in its response to Defendants' similar Notice in the related case *Novartis Pharmaceuticals Corp. v. Espinosa*, No. 1:21-cv-01479 (D.D.C.), the *Lilly* court applied the wrong analytical framework for evaluating the statutory questions at issue. *See* ECF No. 30, *Novartis*. UT agrees

with Novartis. As in *Lilly* and *Novartis*, Defendants have argued here that the obligation to provide 340B drugs to contract pharmacies is unambiguously mandated by the statute. ECF No. 27, Hr'g Tr. at 37:7-12. But even the *Lilly* court did not agree with Defendants on that score. *See* ECF No. 29-1 ("[T]he 340B statute does not unambiguously require drug manufacturers to deliver drugs to an unlimited number of contract pharmacies."). And HRSA, which lacks rulemaking authority, has no power to impose that requirement on its own. *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 42 (D.D.C. 2014).[1]

Just as significantly, however, the *Lilly* court reached it conclusion by sidestepping one of the fundamental flaws in Defendants' interpretation as applied in *this* case. Here, Defendants assert that the statute unambiguously requires UT to honor contract pharmacy arrangements that use the replenishment model.[2] As UT has explained at length, the replenishment model directly conflicts with the statutory prohibition on drug transfers by a covered entity to any entity or individual that is not its patient—therefore, it is impossible for the statute to unambiguously require that UT honor such contract pharmacy arrangements. 42 U.S.C. § 256b(a)(5)(B) (prohibiting the "resell[ing]" or "transfer[r]ing" of a 340B drug "to a person who is not a patient of the [covered] entity"); *see also* ECF No. 14 at 28-31; ECF No. 20 at 10-15.

The *Lilly* court expressly declined to analyze the impact of the transfer prohibition during its statutory analysis, noting that "there is no evidence establishing that *every* covered entity

[1] HRSA is not seeking to enforce against UT based on any interpretive rule embedded in its 1994, 1996, or 2010 guidance documents. Indeed, at oral argument, in response to this Court's question on that point, Defendants' counsel explained: "HRSA does not seek to enforce any rule that was . . . contained in the interpretive guidance here." Hr'g Tr. at 42:8-11.

[2] Under the "replenishment model," a contract pharmacy or its consultants can earn fees or other compensation by data-mining at some point after drugs are dispensed to try to find drug purchases on which to seek a retroactive 340B discount. *See* ECF No. 17-1 at 3-4.

working with multiple contract pharmacies uses the 'replenishment model' to order 340B drugs, which is the sole method of purchase that Plaintiffs have claimed constitutes diversion." ECF No. 29-1 at 47 (emphasis added). While that might be true for Lilly, UT *only* sells its relevant 340B drugs through a limited distribution network and the *only* contract pharmacy filling prescriptions in that network uses a "replenishment model." *See* ECF No. 14-8 at 4-5.[3] Defendants have nonetheless argued that UT has violated the statute's purportedly unambiguous terms. Accordingly, the implications of the replenishment model and the statutory prohibition on transfer are unavoidable issues in this case that must be resolved by the Court.[4]

2. Although the *Lilly* court sidestepped that key statutory question, it nonetheless concluded, as previously noted, that the Violation Letter issued to Lilly with text very similar to the May 17 UT Violation Letter was arbitrary and capricious. Here, as in *Lilly*, the agency did not acknowledge or explain "HRSA's about-face regarding the agency's authority to compel drug manufacturers to offer 340B pricing to covered entities dispensing drugs through contract pharmacies." *Id*. at 56; *see also id.* at 53-54. But this is *not* the only unexplained (and material) change in HRSA's 340B policy. HRSA, for instance, also failed to explain why it changed from a policy allowing ***only one*** contract pharmacy (in 1996), to allowing an ***unlimited*** number (in 2010). ECF No. 14-1 at 36-37. Likewise, HRSA's endorsement of the "replenishment model" is

[3] *See also* ECF No. 14 at 18-19 n.4.

[4] In a footnote, the *Lilly* court also suggests that "diversion" issues can be resolved by audits and an Alternative Dispute Resolution ("ADR") process. ECF No. 29-1 at 47 n.14. While auditing and ADR may address whether 340B discounts for particular patients are or are not appropriate, the broader question of whether the contract pharmacy "replenishment model" violates the plain text of 42 U.S.C. § 256b(a)(5)(B) is a core issue of statutory interpretation subject to judicial review.

directly at odds with *both* its prior 1996 *and* 2010 guidance.[5] *See* ECF No. 14-1 at 39-40; ECF No. 20 at 29-31; *see also* ECF No. 27, Hr'g Tr. at 31:6-25 (noting conflict with 1996 and 2010 guidance). As briefing and argument in this case make clear, HRSA's May 17 UT Violation Letter has multiple fatal flaws; HRSA's failure to explain its change in position—the ground relied upon by the *Lilly* court to vacate HRSA's Violation Letter in that case—is just one of them. *See e.g. Physicians for Soc. Resp. v. Wheeler*, 956 F.3d 634, 647 (D.C. Cir. 2020) (quoting *Lone Mountain Processing, Inc. v. Sec'y of Labor*., 709 F.3d 1161, 1164 (D.C. Cir. 2013)); *see also Grace v. Barr*, 965 F.3d 883, 900 (D.C. Cir. 2020).

3. Finally, UT has several other fact-specific arguments in this case that were not addressed in the *Lilly* decision. For instance, there is no genuine evidence in the record *in this case* showing that UT deprived any covered entity patient of a 340B priced covered drug. ECF No. 20 at 14 ("Indeed, . . . it appears that UT's contract pharmacy policy *should not affect a single covered entity's ability to procure 340B drugs for its patients*." (emphasis added)); *see also* Hr'g Tr. at 27:1-3 ("UC Davis and UCLA have their own specialty pharmacies that dispense by mail. There's not a single patient that's going to be deprived of any drug by virtue of our policy."). Nothing about the record in the *Lilly* matter bears on those issues. Similarly, nothing in the *Lilly* case addresses UT's claims data portal—which is designed to alert the company, at very little cost to

[5] As HRSA's 1996 and 2010 guidance indicates, HRSA instructed that contract pharmacies employ a *preclearance* process, to determine *at the time of dispensing* if the patient was actually issued his or her prescription by a "covered entity" and thus genuinely subject to the 340B discount. *See* 75 Fed. Reg. 10,272, 10,279 (Mar. 5, 2010) (describing suggested requirements of contract pharmacy agreements); s*ee also id.* at 10,277 (listing "essential elements" of contract pharmacy arrangements and requiring that covered entities retain title to 340B drugs and responsibility for setting the prices patients pay for those drugs.) The retroactive "replenishment model" is directly inconsistent with these "essential" requirements. Indeed, the "replenishment model" has been criticized at length by both the HHS's Office of the Inspector General ("OIG") and the Government Accountability Office ("GAO"). *See* ECF No. 14 at 14 (describing OIG and GAO criticism).

or burden on covered entities, when replenishment data-mined requests for 340B pricing are likely to result in duplicate discounts or constitute diversion. *See* ECF No. 14-8 at 8-9 (detailing the extremely limited time required to enter the requested information); Hr'g Tr. at 31:2-5. The information to be gathered by UT's claims data portal is necessary for UT to identify potential duplicate discounts or unlawful transfers, and to meaningfully exercise its right to seek audits under the 340B statute. *Id*.

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Respectfully submitted,

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