IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT

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United Therapeutics Corporation ("UT") has tried and failed to call into question the validity of the Health Resources and Services Administration's ("HRSA") determination that UT has violated its obligations under the 340B statute, 42 U.S.C. § 256b. In support of its cross-motion for summary judgment,[1] UT does not dispute that its contract-pharmacy restrictions impose extra-statutory conditions on covered entities' ability to purchase 340B-discounted drugs to which they are statutorily entitled—a clear-cut violation of § 256b(a)(1). UT instead chiefly disputes HRSA's longstanding interpretation of the 340B statute, arguing that UT has free rein under the 340B Program to impose burdensome restrictions on 340B purchases and that its statutory obligations do not require it to honor any such purchases that will be dispensed through a covered entity's contract-pharmacy arrangements. But UT's arguments misconstrue the statutory text and ignore the congressional purpose and history of the 340B statute—the hallmarks of statutory meaning that collectively demonstrate the correctness of HRSA's interpretation. And UT's erroneous statutory theories further undermine its criticism that HRSA has acted arbitrarily and capriciously in finding UT in violation of its statutory obligations. None of UT's claims are based on a permissible reading of the 340B statute, nor do they reflect an accurate portrayal of the agency's historical guidance or find support in the administrative record.

The Court should therefore enter summary judgment in favor of Defendants on all of UT's claims.

ARGUMENT

I. UT HAS NOT CARRIED ITS BURDEN TO DEMONSTRATE THAT HRSA'S ENFORCEMENT OF THE 340B STATUTE RESTS ON AN INCORRECT INTERPRETATION.

HRSA demonstrated in its opening brief,[2] *see* HRSA Mot. at 16–33, that, read "as a whole," *United States v. Atl. Rsch. Corp.*, 551 U.S. 128, 135 (2007), 42 U.S.C. § 256b(a)(1) plainly requires drug manufacturers to sell discounted drugs to covered entities at no more than the ceiling price—and that

[1] Mem. of Law in Supp. of Pl.'s Mot. for Summ. J., ECF No. 14-1 (hereinafter "UT Mot."); Pl.'s Combined Opp'n to Defs.' Mot. for Summ. J. and Reply Br. in Supp. of Mot. for Summ. J., ECF No. 20 (hereinafter "UT Opp.").

[2] Defs.' Combined Mem. of P. & A. in Opp'n to Pl.'s Mot. for Summ. J. and in Supp. of Defs.' Mot. for Summ. J., ECF No. 16-1 (hereinafter "HRSA Mot.").

UT's self-serving new policies, which it admits are designed to curb the "increase in 340B utilization," UT Mot. at 3, are unlawful. In response UT engages in a revisionist portrayal of the 340B Program's historic operation and HRSA's administration of it, while presenting a view of its own statutory obligation that ignores black-letter interpretive canons. And while UT's current restrictions may be less draconian than some of its peers' (thus far, at least), that in no way undermines HRSA's efforts to prevent the proliferation of contract-pharmacy restrictions that have, over the last sixteen months, wrought havoc on safety-net providers and their patients while threatening the integrity of the 340B program. UT's reading of the statute undermines Congress's purpose and must be rejected.

First, UT continues to misframe HRSA's interpretation as imposing a "requirement for manufacturers to deal with contract pharmacies," UT Opp. at 6. Not so. HRSA hasn't acted to force UT to "deal with" any commercial entity, but instead has found—after an extensive, months-long review and gathering voluminous evidence—that UT and its peers are unlawfully imposing extra-statutory demands on *covered entities*' purchases, with the intent and effect of restricting covered entities' access to discounts to which they are statutorily entitled. UT's similar focus on *delivery* (rather than the price paid for 340B purchases) attempts to obscure its lack of compliance with its actual statutory obligation—to sell its drugs to covered entities at or below the ceiling price, and to treat covered entities' purchases as favorably as commercial purchases. HRSA has initiated enforcement action based on UT's refusal to comply with *those* obligations, not some new shipping obligation invented from whole cloth.[3]

UT next attempts to dissect 42 U.S.C. § 256b(a)(1)'s language into discrete words and phrases, arguing that none of them require UT to *deliver* covered entities' drug purchases to pharmacies legally entitled to dispense them and that, in UT's view, HRSA is "[unable] to anchor its interpretation to the text of the statute" because its litigation position purportedly is not grounded in "the statutory provision HRSA invoked in the Violation Determination." UT Opp. at 5. UT's contention that the

[3] Ironically, it is UT's preferred operation of the statute (where manufacturers are required only to ship 340B drugs directly to covered entities) that would result in new delivery obligations, since many covered entities do not operate a pharmacy and thus do not currently receive any drug shipments.

Violation Letter does not rest, *inter alia*, on the statute's "purchased by" language is inaccurate. UT bases this charge on the fact that the letter *quotes* § 256b(a)(1)'s offer phrase, not the purchase phrase. But as explained in HRSA's opening brief, these commands are found in the same statutory subsection, and the Violation Letter repeatedly discusses "the 340B statute" throughout its text. *See* VLTR_11. There is no obligation for the agency to parse each relevant phrase individually because it plainly states that UT's policies are "in direct violation of the 340B statute"—not only the "offer" phrase. *See id.* Moreover, the letter discusses extensively the PPA that UT is violating, and UT's PPA expressly incorporates its obligation to honor "purchases by" covered entities. *See id.* The Violation Letter plainly shows that UT's policies violate its obligation to honor purchases by covered entities at the ceiling price and not to discriminate against covered entities, and UT's claim that the agency relied on only one piece of the broader statutory subsection is incorrect.

Putting aside UT's inaccurate framing of the statutory bases for HRSA's determination, UT's own portrayal of the "purchases by" language is stunningly revisionist and flatly incorrect. UT contends that the language passed by Congress in 1992 to create the 340B Program "does not even obligate manufacturers to deal with *covered entities*" and that, from the program's inception through 2010, the statute "le[ft] manufacturers free to refuse to deal with covered entities entirely." UT Opp. at 6. This assertion is both unsupported and illogical; UT's theory would mean that, for nearly two decades, the pharmaceutical industry sold deeply discounted drugs to covered entities on a purely voluntary basis. It also would mean that manufacturers could have signed a PPA (thereby gaining the benefit of access to Medicaid/Medicare coverage for their products), refused to sell *any drugs* to safety-net providers whatsoever, at any price, and remained compliant with their PPAs, all while refusing to participate in 340B *at all*. Of course that is not the case (and, judging by their participation, no manufacturer ever has understood that to be the case). In creating the 340B Program Congress struck a deal with manufacturers whereby—from the statute's enactment—drug companies wishing to receive Medicaid reimbursement for their products have been required by both the statute and their PPAs to honor "purchase[s] by a covered entity" at the ceiling price. That obligation did not arise from the 2010 amendments, as UT posits, and has not changed substantively (aside from express

codification of the *additional* non-discrimination requirement) since the statute's enactment. UT's insistence that for nearly two decades manufacturers provided deeply discounted drugs *purely by choice* strains credulity and lacks any evidentiary basis.

UT goes beyond making its ahistorical argument and falsely portrays HRSA's early interpretation of the statute. UT contends that "HRSA recognized this at the beginning of the 340B Program"—that 340B "does *not*, by its plain terms, obligate manufacturers *to* sell anything to covered entities," "which is why it attempted to impose an obligation on manufacturers to deal with covered entities through guidance." *See* UT Opp. at 6 (citing HHS, Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,113 (May 13, 1994) ("1994 Guidance")). UT even contends that, since "HRSA has no authority to impose" a requirement on manufacturers to actually sell drugs to covered entities, "in 2010 Congress was forced to step in and impose a statutory 'Shall Offer' provision." UT Opp. at 7. Not only is there no evidence that Congress's 2010 amendment was designed to newly force manufacturers to sell drugs to covered entities—nor any evidence that manufacturers *did* refuse to sell drugs to covered entities before the amendments—UT's portrayal of HRSA's guidance is inaccurate. In 1994 HRSA interpreted *the statute itself* to require that "manufacturers must offer covered outpatient drugs at or below the section 340B discount prices," and that "[m]anufacturers must not place limitations on the transactions … which would have the effect of discouraging entities from participating in the discount program." 59 Fed. Reg. at 25,113. No manufacturer challenged that interpretation or flouted it by refusing sales to covered entities. Moreover, UT's charge that in issuing that guidance HRSA sought to "impose an obligation on manufacturers" is baseless because HRSA made plain it was only explaining the proper operation of *the statute*.[4]

UT continues to press a statutory interpretation resting on silence: Congress did not expressly write anything "at all about shipping drugs to *anyone*," so no obligation exists to deliver covered entities'

[4] Equally groundless is UT's assertion that "HRSA now appears to concede" that "the Shall Offer provision imposes no such requirement" "to deal with contract pharmacies." UT Mot. at 7. As explained in detail in HRSA's opening brief, UT's policies violate the "must offer" provision's *separate* requirement by discriminating against covered entities' purchases relative to commercial sales.

purchases to a pharmacy legally entitled and capable of dispensing them. *See, e.g.*, UT Opp. at 7. This assertion is nonsensical; as explained in HRSA's opening brief at 22–23, 340B creates a broad rule requiring manufacturers to provide discounted drugs to covered entities, and Congress had no obligation to specify every term of how those transactions should be effectuated. No interpretive doctrine countenances a reading of a statute that would allow a regulated entity to contravene its purpose simply because the challenged action is not expressly prohibited.[5]

Equally inaccurate is UT's assertion that the now-vacated and withdrawn Advisory Opinion from HHS's General Counsel, *see* HRSA Mot. at 7–8, "attempted … to bring *the HRSA contract pharmacy policy into compliance with the statute* by explicitly limiting its application to situations where the pharmacy is an instrumentality of the covered entity itself, *i.e.*, the pharmacy is 'an agent' of a covered entity … and the drug purchases subject to 340B discounts remain at all times within the ownership and control of the covered entity." UT Opp. at 8 (emphasis added). The Advisory Opinion simply says no such thing. And far from being directed to HRSA, as UT asserts without support, the Advisory Opinion made clear that it was issued to address the fact that "certain drug manufacturers participating in the 340B Program are declining to distribute covered outpatient drugs through contract pharmacies at the ceiling price." VLTR_8048. In other words, the Advisory Opinion offered general legal advice to regulated entities, not HRSA, including a caution that "manufacturers are required to offer covered

[5] UT's attempt to brush away the impact of *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020) (discussed UT Opp. at 9–10), as "not remotely the same" as this case is unavailing. As an initial matter, UT flips the Supreme Court's reasoning on its head: Rather than finding that Congress would have intended the "ordinary public meaning" of sex to include sexual orientation "at the time [Title VII] was enacted," as UT states (*id.* at 9), the Court instead found that the term "sex" *unambiguously* encompasses sexual orientation notwithstanding that the drafters "might not have anticipated their work would lead to this particular result." 140 S. Ct. at 1737–38. It is *Bostock*'s mode of statutory interpretation that is highly relevant for this case, because—analogous to the unsuccessful arguments there—UT urges this Court to find that, simply because § 256b(a)(1) does not expressly address delivery location or dispensing mechanism, the statute cannot encompass them. *Bostock* teaches that Congress may write "in starkly broad terms" yet its "failure to speak directly to a specific case that falls within a more general statutory rule" cannot "create[] a tacit exception." *Id.* at 1747. This Court therefore need not stretch "the word 'purchased' … to cover analytically and definitionally distinct concepts like delivery," UT Opp. at 10, because UT is adopting restrictions that violate its obligation to honor covered entities' purchases, full stop.

outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients," while HRSA was conducting its exhaustive review of manufacturers' individual policies. VLTR_8055. And more substantively, the Advisory Opinion was not "premised on the notion that an actual agency relationship between the covered entities and contract pharmacies was necessary under the statute to ensure compliance," *contra* UT Opp. at 9. On the contrary, the Advisory Opinion never suggested that a drug maker's obligation to sell discounted drugs to covered entities distributing those drugs through contract pharmacies depends on whether an agency relationship can be established in a particular instance under the precise laws of any given state. Rather, to rebut the contention (made by UT and its peers) that a covered entity's mere use of a contract pharmacy is *itself* an unlawful transfer, the Advisory Opinion explained that the relationship between these entities generally functions like a principal-agent relationship, "in that [a contract pharmacy] would not resell a … drug but rather distribute [it] on behalf of the covered entity" who purchases and retains title to the drug. VLTR_8053. In other words, both the General Counsel's interpretation in the Advisory Opinion and HRSA's interpretation in its Violation Letters accord in confirming that pharmacies are never entitled to receive 340B discounts or purchase 340B drugs—but that covered entities *are* entitled to make such purchases while relying on real-world, commonplace dispensing mechanisms, including outside dispensers.[6]

Most stunning of all is UT's insistence that the 340B Program has *since its inception* (and to this day) operated in a fundamentally unlawful manner, because covered entities' "customary business practice," 59 Fed. Reg. at 25,113, of relying on outside pharmacies violates the statutory prohibition on "transfer" of discounted drugs. *See* UT Opp. at 10–15 (arguing that 42 U.S.C. § 256b(a)(5)(A) "forecloses" HRSA's "reading" of the statute). As detailed in HRSA's opening brief, the overwhelming majority of covered entities relied on outside pharmacies when Congress enacted the statute, and

[6] HRSA was under no obligation to "d[o] any of the work necessary to determine whether, on a case-by-case basis, the covered entities that UT does business with have *bona fide agency relationships* with any contract pharmacies," *contra* UT Opp. at 12 n.3. Manufacturers have known at least since the issuance of HRSA's 1994 Guidance that covered entities' reliance on "contract pharmacies" "is a customary business practice" and that drug makers may not deny such sales. *See* HRSA Mot. at 28–30.

contract pharmacies have been a critical part of 340B's operation for nearly three decades. Moreover, "[a]pproximately 600 drug manufacturers participate in the 340B Program" now, 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,643-01, 80,643 (Dec. 14, 2020), and all but eight of those manufacturers continue to dutifully comply with their obligation to honor covered entities' purchases regardless of dispensing mechanism or delivery location—indicating that roughly 99% of all participants in the 340B Program do not share UT's newly adopted and self-serving interpretation of the statutory prohibition on transfer. And neither does Congress: Far from reining in covered entities' decades-old reliance on outside dispensers, Congress acted in 2010 to expand the program by designating additional eligible categories of safety-net providers.[7] P.L. 111-148, § 7101.

Nor do covered entities "give[] [their] 340B drugs to a contract pharmacy," thus "'transferring' the drug in violation of the 340B statute," *contra* UT Opp. at 10; the covered entity is the actual (not nominal) legal purchaser of the drug and each 340B-drug-dispense must be "actually tied to a 340B-eligible patient." *See* HRSA Mot. 38–39 (declarant explaining real-world operation of replenishment model). UT's portrayal of the replenishment model is fundamentally inaccurate; neighborhood pharmacies are not engaging in prescription arbitrage whereby they purchase 340B drugs and then "sell those drugs to whoever walks in the door or otherwise presents a prescription." UT Opp. at 13. Discounted-drug sales are individually tied to an eligible dispense to an eligible patient of a covered

[7] UT also ignores more-recent evidence of Congressional intent when asserting that "it takes no great leap of logic to conclude that Congress would not have wanted to expose manufacturers to opportunistic, for-profit pharmacies seeking to pad their bottom line with unearned discounts on the manufacturers' drugs," UT Opp. at 22. That view cannot be squared with the highly public, repeated, bipartisan demands from members of Congress that HHS take enforcement action against UT and its peers for violating the statute. Among other, similar efforts, last fall a bipartisan group of 243 U.S. Representatives wrote the Secretary, explaining that the manufacturers' "actions are in violation of the statutory requirement" because "[t]here are no provisions in that statute that allow manufacturers to set conditions or otherwise impede a provider's ability to access 340B discounts," and "establish a dangerous precedent for other manufacturers to follow if immediate action is not taken." *See* Letter, McKinley et al., to Sec. Azar, Sep. 14, 2020, *available at* https://mckinley.house.gov/uploadedfiles/congressional_member_340b_letter_to_azar_9.14.20.pdf.

entity, and covered entities often rely on the revenue generated from those sales to help fund uncompensated and undercompensated medical services, as Congress intended. Far from having "no meaningful answer to the statutory prohibition on transfers," UT Opp. at 10 (casing and font fixed), HHS documented and explained that the prohibition on transfer always has been understood to mean that covered entities may not provide discounted drugs for use by non-patients or non-covered providers for prescribing to their own patients, HRSA Mot. at 39. There simply is neither statutory nor historical support for UT's novel reading of the transfer prohibition—which would, in practice, require every covered entity to ensure that its own employees physically hand a prescription to a patient, in contrast to the way such safety-net providers have long served their patients' needs.[8]

Moreover, UT's own argument is internally inconsistent in at least two ways. First, it insists that covered entities' reliance on outside pharmacies directly violates the statute, while contending that its own policy, which (for now) grandfathers in certain pre-existing contract-pharmacy arrangements and exempts certain medications entirely, "*should not affect a single covered entity's ability to procure 340B drugs for its patients*," UT Opp. at 14. If UT actually believed that "the plain text of the transfer provision provides that the prevalent contract pharmacy models are unlawful," *id.* at 18, surely it would not continue to acquiesce in unlawful transactions.[9] Second, UT accuses HRSA of adding non-statutory

[8] UT's bold assertion that, in 1992, Congress created a drug-discount scheme that roughly 95% of intended beneficiaries could not access without expending tremendous resources to establish a new, in-house pharmacy, UT Opp. at 20–21, is irreconcilable with what Congress actually said: that it intended the program to permit safety-net providers "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12. UT's baseless assertion that, "in the absence of HRSA's illegal contract pharmacy policy," perhaps covered entities "would [] create their own in-house pharmacies," UT Opp. at 21, strains credulity and defies Congressional intent. UT's own speculation that "covered entities that establish in-house pharmacies would enjoy all of the fruits of the 340B discounts," *id.*, does not permit it to require of covered entities something that Congress chose not to impose.

[9] UT similarly makes much of the fact that, in its view, the administrative record contains "vanishingly few complaints about UT's contract pharmacy policy." UT Opp. at 14. This assertion gets UT nowhere; the fact that few covered entities have yet documented an inability to purchase UT's discounted drugs clearly stems from the fact that it has (for now) grandfathered in certain pharmacy arrangements and that its "claims data policy," which will deny covered entities' sales unless they accede to UT's unlawful restrictions, is not yet in effect. *See* Barton Decl. ¶ 33. More importantly, HRSA spent months gathering evidence of the impact of a web of contract-pharmacy restrictions put

obligations on manufacturers while contending that, in order for a covered entity's reliance on an outside dispenser to *potentially* comply with the statute, "the licensed pharmacist [must] work[] for a third party that is an agent or instrumentality of the covered entity and is handling covered entity inventory being dispensed exclusively to the covered entity patients." UT Opp. at 11. Congress wrote no such precise restrictions into the statute and neither can UT; on the contrary, Congress explicitly chose to remove a provision that would have imposed similar dispensing-mechanism restrictions. HRSA Mot. at 27–28.

UT next urges this Court to find that, contrary to HRSA's nearly three-decade interpretation, the 340B statute does not require manufacturers to treat covered entities' sales on par with commercial purchases. *See* UT Opp. at 15–17. But once again, UT ignores historic practice and Congress's intent in carefully crafting a comprehensive scheme designed to allow safety-net providers and patients to *actually access* discounted medications. UT once again misportrays HRSA's 1994 Guidance as having sought to "impos[e] a regulatory 'shall offer' requirement in a set of agency guidelines," and that, since Congress later codified language that explicitly matched part of HRSA's 1994 interpretation (*i.e.*, the "must offer" language), that Congress "decisive[ly]" rejected the remaining language in that same 1994 guidance document. UT Opp. at 17–18. This tortured logic is unavailing; the 1994 guidance did not seek to impose any new regulatory obligations, but merely alerted regulated entities to the manner in which HRSA interpreted and intended to administer the statute. And that guidance made plain that "[m]anufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective." 59 Fed. Reg. at 25,113. Congress's later express codification of HRSA's guidance into the statute (by mandating that "manufacturers must offer" drugs to covered entities) confirmed HRSA's existing interpretation that covered entities cannot

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into place by (at that point) six manufacturers and, having determined that UT's announced policy is every bit as unlawful as its peers', is under no obligation to wait until serious harms *actually accrue* as a result of UT's impending changes. And finally, UT's not-yet-operative (but planned) claims-data policy mimics that of its peers, most prominently including Sanofi-Aventis, and HRSA was entitled to rely on evidence of the impact of that materially indistinguishable policy to predict the likely impact should UT proceed with its own claims-data demands.

be subject to restrictions that prevent their accessing the program in practice.[10]

Equally unhelpful is UT's observation: "Had Congress wished to create a 'non-discrimination' provision here, it could have written" that "HRSA 'shall require that manufacturers offer each covered entity for purchase at or below the applicable ceiling price covered outpatient drugs, and shall prohibit manufacturers from discriminating against covered entities by imposing different commercial terms regarding delivery, payment and other arrangements that the manufacturer imposes on other commercial purchasers of those drugs.'" UT Opp. at 17. UT is not entitled to rewrite the statute for itself, and "[t]he mere possibility of clearer phrasing cannot defeat the most natural reading of a statute," *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 416 (2012). UT's hypertechnical reading—where anything not expressly prohibited is fair game—does not comport with precedent, and Congress's selection of broad language supports HRSA's reading, which fulfills the program's purpose. UT and its peers have known for decades that HRSA interpreted the statute to prohibit any "restrictive conditions" on covered entities' access to their drugs, and Congress's express codification of that interpretation in 2010 only bolsters HRSA's view.[11]

UT next quibbles over whether HRSA has established record evidence demonstrating that its policy has prevented any covered entity from purchasing covered outpatient drugs. UT Opp. at 19–20. Critically, UT here acknowledges that "conditions imposed by manufacturers may become so onerous that a manufacturer cannot truly be said to be 'offering' a 340B drug to a covered entity." *Id.* at 19. But as exhaustively explained in HRSA's opening brief, HRSA assembled an 8,000+ page

[10] Nor has HRSA "abandoned the premise of its Violation Determination—the Shall Offer provision … in favor of yet another statutory hook." UT Opp. at 23. As explained in HRSA's opening brief, HRSA found that UT is violating *the 340B statute*, not merely one phrase found within it, and HHS has vigorously defended that finding before this Court.

[11] Equally unpersuasive is UT's reading of the legislative history. UT posits that the fact that Congress explicitly considered, *but removed from the final bill*, language that would have restricted 340B sales to drugs "purchased and dispensed by, or under a contract entered into for on-site pharmacy services," "cannot be taken as a reasonable guide to what Congress intended." UT Opp. at 20 (citing S. Rep. No. 102-259 at 1-2 (1992)). The fact that Congress originally drafted the bill to include, as UT admits, "a bar on what *covered entities* could do," UT Opp. at 20, but removed that "bar" before passage, forecloses UT's attempt to read that very restriction back into the statutory text. "[T]his Court may not narrow a provision's reach by inserting words Congress chose to omit." *Lomax v. Ortiz-Marquez*, 140 S. Ct. 1721, 1725 (2020).

administrative record evidencing serious harms to covered entities from the various contract-pharmacy policies instituted by six drug manufacturers, including hundreds of thousands of dollars in overcharges, and the denial of access to 340B discounts altogether. That most of those complaints addressed other manufacturers' policies is unsurprising, since those policies went into effect before UT's and because UT has (for now) allowed covered entities to "grandfather" in certain preexisting pharmacy relationships and has (for now) delayed implementation of its claims-data demands. But that does not undercut the foundation of HRSA's finding; as an enforcement agency, HRSA is not required to wait until covered entities are harmed in large numbers in practice before determining, based on voluminous evidence of the impacts of similar contract-pharmacy restrictions imposed earlier or more abruptly by other manufacturers, that UT's analogous policies are equally unlawful. For instance, while most covered entities may now continue to rely on pre-existing dispensing relationships, UT has disavowed any obligation to allow dispensing through new contract-pharmacy relationships. More importantly, UT will soon implement its claims-data demands, and HRSA has gathered specific evidence that an identical policy put in place by Sanofi-Aventis has resulted in significant denials of covered entities' access to 340B drugs. HRSA need not wait until UT's unlawful data demands cause equal harms before finding the policy writ large to be unlawful.

UT's interpretation of the 340B statute is inconsistent with its text, undermines Congress's purpose, and should be rejected.

II. THE VIOLATION LETTER COMPLIES WITH THE APA.

As explained in HRSA's opening brief, *see* HRSA Mot. at 33–42, the Violation Letter satisfies the APA's highly deferential arbitrary-and-capricious standard because it rests on a correct interpretation of the 340B statute and reflects HRSA's reasonable analysis of the record evidence. *See FCC v. Prometheus Radio Proj.*, 141 S. Ct. 1150, 1158 (2021) ("The APA's arbitrary-and-capricious standard requires [only] that agency action be reasonable and reasonably explained."). In contending otherwise, UT largely rehashes its erroneous statutory theories; resorts to flyspecking the record for materials that are irrelevant to HRSA's determination; and glosses over evidence demonstrating that

its extra-statutory contract-pharmacy restrictions violate its statutory obligations. UT's arguments thus identify no sound basis on which to set aside the Violation Letter under the APA.

A. The Violation Letter is legally sound and supported by the administrative record.

As explained above, *see supra* § I, HRSA correctly determined that the 340B statute precludes UT from imposing extra-statutory restrictions on covered entities' access to 340B-priced drugs and that UT's contract-pharmacy restrictions violate its obligations under § 256b(a)(1)—namely, that UT not require a covered entity to purchase UT's 340B-eligble drugs above the statutory ceiling price or disadvantage 340B purchases relative to commercial sales.

In response, UT chiefly contends that the Violation Letter sets forth a legal rationale different from that advanced by HRSA in this litigation. *See* UT Opp. at 24. Specifically, UT claims that the Violation Letter "cite[s] only the Shall Offer provision," and does not cite "the statutory Purchased By provision." *See id.* But that is incorrect. In explaining UT's statutory obligations, the Violation Letter contains virtually a direct quotation of § 256b(a)(1)'s "purchased by" language: "Nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on *covered outpatient drugs purchased by covered entities*." *See* VLTR_11 (emphasis added); *compare with* 42 U.S.C. § 256b(a)(1) (requiring a participating manufacturer to have an agreement with the Secretary "under which the amount required to be paid … to the manufacturer for *covered outpatient drugs* … *purchased by a covered entity* … does not exceed" the statutory ceiling price (emphasis added)). Underscoring the Violation Letter's reliance on the "purchased by" provision is the letter's discussion of the "1996 contract pharmacy guidance,"[12] in which HRSA explained "that the 340B statute requires manufacturers to honor [340B] purchases regardless of the dispensing mechanism" used by a covered entity. VLTR_11. For reasons already explained, *see* HRSA Mot. at 20, the 1996 Guidance necessarily grounded its statutory analysis in § 256b(a)(1)'s "purchased by"

[12] Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549-01 (Aug. 23, 1996) ("1996 Guidance").

language rather than the "shall … offer" language, because the latter was not codified until 2010. The Violation Letter thus enforces the same statutory obligations analyzed above, *supra* § I.

UT also maintains that it is "almost certain[]" that the Violation Letter "rest[s]" on the since-withdrawn Advisory Opinion. *See* UT Opp. at 24. But UT offers no cogent explanation for this claim. As already explained, *see* HRSA Mot. at 34, HRSA (the component of HHS that administers the 340B Program) issued the Violation Letter to announce *its* determination—based on *its* interpretation of the 340B statute and *its* months-long investigatory process—that UT has violated the 340B statute and may face CMPs. *See* VLTR_11–12. And nowhere does the Violation Letter reference or purport to adopt the General Counsel's legal advice contained in the Advisory Opinion. UT argues nonetheless that HRSA could not have possibly interpreted the 340B statute in its own right, because the General Counsel is vested with the regulatory authority to advise most components of HHS, citing Statement of Organization, Functions, and Delegations of Authority, 86 Fed. Reg. 6,349-01 (Jan. 21, 2021). *See* UT Opp. at 24. But this uncodified Statement of Organization, Functions, and Delegations of Authority for HHS's Office of General Counsel merely explains the structure and function of the Office of General Counsel, and does not suggest that the General Counsel's advice would *bind* HRSA in making its own regulatory or enforcement decisions (as UT suggests, *see id.*). Similarly, UT offers no support for the assertion that the General Counsel's Advisory Opinion was "plainly the upshot" of HRSA's then-ongoing investigation into individual drug manufacturer's contract-pharmacy restrictions. *See id.* at 25. The Advisory Opinion did nothing more than opine on the 340B statute as a general matter, *see* VLTR_8055 ("The Advisory Opinion is limited to interpretation of the 340B statutory requirements in general …."); it issued no determinations regarding the actions of any individual manufacturer and made no factual findings and cited no evidence in this regard.

Because the Violation Letter sets forth the correct view of the 340B statute, UT cannot seriously dispute that record evidence supports HRSA's determination that UT's contract-pharmacy restrictions violate its statutory obligations and have also resulted in overcharges. *See* VLTR_11. As the record reflects, UT informed covered entities that it will deny them access to 340B-priced covered outpatient drugs dispensed through their contract-pharmacy arrangements unless they satisfy UT's

extra-statutory conditions. *See* VLTR_5713. And UT admits, for example, that "if a covered entity refuses to provide" UT with claims data relating to its contract-pharmacy arrangements, "then its access [to 340B prices] may be restricted" when UT puts this condition into effect. *See* UT Opp. at 39; *see also* VLTR_5713. In other words, if a covered entity does not comply with UT's extra-statutory conditions on 340B purchases, the covered entity will only be able to purchase and dispense UT's 340B-eligible drugs through its contract-pharmacy arrangements if it pays for those drugs at the commercial price (*i.e.*, above the statutory ceiling price). Such restrictions on covered entities' access to 340B-priced drugs are a straightforward violation of UT's statutory obligations. *See* 42 U.S.C. § 256b(a)(1) (requiring a participating manufacturer to enter an agreement with the Secretary, under which the manufacturer is obligated not to "require[] … covered outpatient drugs" to be "purchased by a covered entity" above the statutory ceiling price).

Also, contrary to what UT suggests, the record does contain "*bona fide*" complaints by covered entities reporting that 340B prices for UT's drugs had become unavailable (or would soon become unavailable) because of UT's contract-pharmacy restrictions. *See* VLTR_5714, 5766, 5769. And HRSA reasonably analyzed this evidence to determine that UT's restrictions have resulted in overcharges. *See* 42 C.F.R. § 10.21(c)(1) (recognizing that, in the 340B Program's Administrative Dispute Resolution process, a covered entity can establish "that it has been overcharged by a manufacturer for a covered outpatient drug" when "a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price").

Furthermore, it makes no legal difference whether UT distributes its covered outpatient drugs only through in-house pharmacies and a limited number of "specialty" contract pharmacies.[13] Even setting aside UT's claims-data requirement, UT's policy denies a covered entity access to 340B-priced drugs for all orders placed through existing or new contract-pharmacy arrangements if the covered

[13] *See* 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210-01, 1225 (Jan. 5, 2017) ("All requirements as set forth in this final rule for offering the 340B ceiling price to covered entities apply regardless of the distribution system. If a manufacturer is using a specialty pharmacy to distribute covered outpatient drugs, it must ensure the covered entity is not overcharged if drugs are accessed through that pharmacy.").

entity (i) has an in-house pharmacy and (ii) did not dispense UT's outpatient drugs through an outside pharmacy between January 1, 2020, and September 30, 2020. *See* VLTR_5713. And it is not uncommon for a covered entity to "maintain[] a contract with a specialty pharmacy" even though it may "not dispense[] 340B drugs through that pharmacy [for] several years," because such an arrangement may prove "financially beneficial" for a resource-strapped covered entity "should it have a patient [who needs to] fill a 340B-eligible specialty drug [through a specialty] pharmacy in the future."[14] In instances like these, a covered entity would be able to purchase and dispense UT's covered outpatient drugs through an outside "specialty" pharmacy only if it were to purchase the drug at the commercial rate—a direct violation of UT's obligations under § 256b(a)(1).

B. The Violation Letter reflects HRSA's longstanding, consistent position regarding manufacturers' obligations under the 340B statute.

For nearly three decades, HRSA has made clear that a manufacturer participating in the 340B Program cannot unilaterally impose extra-statutory, restrictive conditions on 340B-eligible drug purchases by covered entities, as UT has done here. *See* HRSA Mot. at 28–30, 36–37 (surveying HRSA's relevant guidance documents). UT's cursory and selective review of HRSA's prior guidance documents identifies no inconsistencies on this point.

Start with the 1994 Guidance. There, HRSA stated in no uncertain terms that "[m]anufacturers must not place limitations on [340B] transactions … which would have the effect of discouraging entities from participating in the discount program," and "may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective." 59 Fed. Reg. at 25,113. And HRSA made plain that manufacturer-imposed "limitations" on the use of "contract pharmacies" in 340B transactions are among those prohibited restrictions that discourage covered-entity participation, 59 Fed. Reg. at 25,111. Therefore, UT cannot escape the conclusion that its contract-pharmacy policy—including its claims-data requirement—imposes unlawful restrictions on 340B-eligible purchases by simply suggesting that these restrictions are "normal business policies"

[14] GAO, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* (June 2018), at 18 (cited in UT Opp. at 3, 33, 36).

that it can address permissibly in an agreement with a covered entity. *See* UT Opp. at 39 (citation omitted). The 1994 Guidance permitted manufacturers to enter into contracts containing "provisions relating to normal business policies" and "other appropriate contract provisions," but understood those provisions to address matters akin to the gathering of "routine information necessary" for participants "to set up and maintain [a 340B] account." 59 Fed. Reg. at 25,112. HRSA thus drew a sharp contrast between permissible contract provisions that *facilitate* purchases of 340B drugs and manufacturer-imposed, extra-statutory conditions that unlawfully *restrict* purchases and discourage covered-entity participation. UT's arguments based on the 1994 Guidance efface this distinction. *See* UT Opp. at 39.

UT also selectively reads HRSA's 1996 and 2010 Guidances,[15] obscuring the agency's position regarding manufacturers' *statutory obligations* that was also reflected in HRSA's Violation Letter. UT first points out that these guidance documents did not create new obligations for manufacturers participating in the 340B Program. UT Opp. at 28; *see also* 61 Fed. Reg. at 43,550 ("[T]hese guidelines create no new law and create no new rights or duties."); 75 Fed. Reg. at 10,273 ("This guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law."). But this observation only bolsters the consistency of HRSA's position. Contrary to what UT suggests, the Violation Letter does not purport to enforce an obligation created by non-binding agency guidance documents. Rather, as the 1996 and 2010 Guidances both confirm, HRSA has for decades interpreted *the 340B statute itself* to impose the obligations that HRSA is now enforcing through the Violation Letter. *See* VLTR_11 ("*Section 340B(a)(1)* … requires that manufacturers 'shall … offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.'"); *id.* ("Nothing in the 340B statute

[15] Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272-01 (Mar. 5, 2010) ("2010 Guidance").

grants a manufacturer the right to place conditions on its fulfillment of its *statutory obligation* to offer 340B pricing on covered outpatient drugs purchased by covered entities.").[16]

In this respect, the 1996 and 2010 Guidances speak plainly: "[I]f a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, *the statute directs* the manufacturer to sell the drug at the discounted price." 61 Fed. Reg. at 43,549; *accord* 75 Fed. Reg. at 10,278. "If the entity directs the drug shipment to its contract pharmacy," the 1996 Guidance explained, there is "no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance," as a contrary reading "would defeat the purpose of the 340B program" and would be "[in]consistent with the intent of the law." 61 Fed. Reg. at 43,549–50. Rather than grapple with these points, UT focuses on peripheral matters that are irrelevant to a *manufacturer's* obligations under the 340B statute. Namely, UT attempts to compare its own extra-statutory restrictions with the limitations imposed by HRSA in the 1996 Guidance on the number of contract pharmacies a covered entity can utilize (a limitation that has not been in effect since 2010, *see* 75 Fed. Reg. at 10,273). But as the 1996 Guidance makes clear, the fact that *HRSA* (the agency authorized to administer the 340B Program) designed these guidelines for covered entities to facilitate their participation and compliance, *see* 61 Fed. Reg. at 43,555, in no way suggests that *manufacturers* are authorized under the 340B statute to take matters into their own hands by unilaterally imposing restrictions on contract-pharmacy arrangements as they see fit. Such a conclusion cannot be squared with the 340B statute or the agency's historical guidance.

[16] Similarly, UT cites to a July 2020 news report in which HRSA was purported to have acknowledged that agency guidance is not itself legally enforceable. UT Opp. at 30. But this straightforward proposition in no way conflicts with HRSA's decades-old interpretation of manufacturers' *statutory* obligation to honor purchases. As already explained, the 1996 and 2010 Guidances contained guidelines for covered entities to facilitate their participation and oversight; but these guidelines in no way suggested that manufacturers' *statutory* obligations were voluntary or unenforceable. Indeed, UT's argument is belied by HRSA's letters to another drug manufacturer in mid-2020 stating that its contract-pharmacy restrictions may circumvent its statutory obligations and may result in penalties. *See, e.g.*, VLTR_7627.

C. HRSA considered all relevant factors relating to its violation determination.

Finally, UT alleges that HRSA acted arbitrarily and capriciously by "ignor[ing]" that instances of diversion and duplicate discounting may occur at contract pharmacies. *See* UT Opp. at 31–32. But this claim is both factually and legally incorrect.

As a factual matter, the Violation Letter explicitly addresses diversion and duplicate discounting (something UT simply ignores). The letter explains:

> United Therapeutics purports that the rationale for its restrictive action is to prevent diversion and duplicate discounts. The 340B statute provides a mechanism by which a manufacturer can address these concerns. Specifically, the manufacturer must (1) conduct an audit and (2) submit a claim through the Administrative Dispute Resolution process as described in section 340B(d)(3)(A) of the PHS Act. The 340B statute does not permit a manufacturer to impose industry-wide, universal restrictions.

VLTR_12. The Violation Letter thus addresses a critical point: Congress, in designing the 340B Program, provided manufacturers with a dispute-resolution process for resolving concerns regarding whether a covered entity has violated the statutory prohibitions on diversion or duplicate discounting. But nowhere does the 340B statute allow a manufacturer (or a covered entity) to devise its own alternative self-help mechanism for resolving these disputes. And UT admits that creating its own self-help remedy was a principal goal of its contract-pharmacy restrictions. *See, e.g.*, UT Opp. at 41.

For this reason and others previously explained, *see* HRSA Mot. 14–16, UT has failed to show that issues of diversion or duplicate discounting were relevant factors HRSA needed to consider in making its violation determination. *See Prometheus*, 141 S. Ct. at 1158 ("A court simply ensures that the agency … has reasonably considered the relevant issues ….''). Whether a manufacturer believes that a specific dispensing method heightens the risk of non-compliance, it has no authority to superintend the 340B Program by unilaterally imposing extra-statutory, restrictive conditions on 340B-eligible drug purchases by covered entities. And a manufacturer cannot evade its obligations under § 256b(a)(1) simply because it has generalized concerns with "the potential for illegal transfers and duplicate discounting." *See* UT Opp. at 31. It was thus unnecessary for HRSA to consider these peripheral issues before determining that UT's contract-pharmacy restrictions plainly violate its statutory obligations by denying access to 340B-priced drugs for covered entities who fail to meet UT's extra-statutory

conditions. *See Confederated Tribes of Coos, Lower Umpqua & Siuslaw Indians v. Babbitt*, 116 F. Supp. 2d 155, 165 (D.D.C. 2000) ("[I]t was not arbitrary and capricious to not consider materials which, under the interpretation being employed, were irrelevant.").

In arguing to the contrary, UT spills considerable amounts of ink describing how it believes the "replenishment model" generally operates. *See* UT Opp. at 32–36. But for the reasons just explained, the precise workings of the replenishment model are irrelevant to the question addressed by the Violation Letter—*i.e.*, whether UT's contract-pharmacy restrictions violate the 340B statute. At any rate, UT's various criticisms of the replenishment model (and contract-pharmacy arrangements in general) are meritless, as already explained in HRSA's opening brief. *See* HRSA Mot. 37–39.

Take, for example, UT's assertion that "contract pharmacies frequently make [the 340B] purchases" as opposed to the covered entity, for which it cites a single complaint of a covered entity explaining that a drug manufacturer had "stopped extending the 340B ceiling priced on its drugs purchased through 340B contract pharmacies." UT Opp. at 34 (citing VLTR_5834). UT fails to mention that two sentences after that vague statement, the complaint explains that *the covered entity*—*not* the contract pharmacy—had been charged an amount in excess of the ceiling price when it made a drug purchase through its contract-pharmacy arrangement (which utilizes the replenishment model). *See* VLTR_5834. This is consistent with a host of other complaints or sworn declarations in the record showing that it is the covered entities making the purchases of 340B drugs through their contract-pharmacy arrangements, including those using the replenishment model. *See, e.g.*, VLTR_7260–61, 7279, 7296.

Or consider another example: UT asserts that "contract pharmacies using the replenishment model have no idea whether any individual patient is 340B eligible," citing what it portrays as an "OIG finding that under [the] replenishment model 'contract pharmacies do not know at the time they dispense the drugs whether patients' prescriptions are 340B-eligible.'" UT Opp. at 34 (quoting VLTR_7977). But that is *not* what the OIG report says. The report states that, of the thirty covered entities OIG interviewed (which are "not representative of or generalizable to other covered entities," VLTR_7971), seven covered entities who do not pass on 340B discounts to uninsured patients

"determine 340B eligibility after drugs are dispensed, which means that ***their*** contract pharmacies do not know at the time they dispense the drugs whether patients' prescriptions are 340B-eligible," but may still "later identify uninsured patients' prescriptions are 340B-eligible." VLTR_7977 (emphasis removed and added). And in contrast to these seven unrepresentative covered entities, OIG found that eighteen covered entities who offer 340B discounts to uninsured patients use various methods to identify 340B eligibility *at the time the prescription is written*, including "340B discount cards[that] the patients present at contract pharmacies so that pharmacies know to charge the discounted 340B price." *See id.* This finding also belies UT's unsupported claim "that every covered entity patient … pays whatever price the *pharmacy* decides to charge—without any benefit from the 340B discount at all."[17] *See* UT Opp. at 36. And further, OIG's report explains that "[s]ome covered entities … identify 340B-eligible prescriptions when the prescriptions are written, whereas others … do so after the prescriptions are written," VLTR_7972—directly contradicting UT's unsupported assertion that "at no step in the process … does a contract pharmacy ensure that the specific patient it is dispensing drugs to is a 340B-elibigle patient," *see* UT Opp. at 35; *see also* VLTR_7279 (covered entity describing the "careful 340B eligibility assessment" used to ensure that all 340B "dispense[s] meet[] all eligibility criteria" under the replenishment model). In sum, UT's assertions are contradicted by its own sources selected from the record.

D. UT cannot pre-litigate whether the imposition of CMPs would be proper.

As already explained in HRSA's opening brief, UT's arguments regarding whether its overcharges constitute "knowing and intentional" violations of the 340B statute sufficient to support the imposition of CMPs are premature and meritless. *See* HRSA Mot. at 42–43. Without retreading the same ground, it is at least worth noting that UT clearly misunderstands the process by which CMPs are imposed. In UT's view, the only thing stopping "HRSA" from immediately imposing these

[17] Aside from being unsupported, UT's implicit suggestion that 340B discounts were designed to directly benefit patients is belied by the fact that Congress wrote the statute to limit the prices charged *to covered entities*, with no requirement that discounts be passed on to patients. Covered entities thus are free to provide free or discounted medications to their patients (especially the uninsured) or to charge higher retail prices to those patients able to pay (including those with commercial insurance) and use that revenue to help fund additional medical services.

penalties is "executive grace." UT Opp. at 42. But that is wrong. CMPs for a manufacturer's "knowing and intentional" overcharges are "imposed pursuant to the applicable procedures at 42 CFR part 1003." 42 C.F.R. § 10.11(a). And under those procedures, it is OIG—not HRSA—that has been delegated the authority from the Secretary to impose CMPs. *Id.* § 1003.150; *see also* 82 Fed. Reg. at 1220–21 ("[P]ursuant to a delegation of authority, OIG will have authority to impose a CMP…. HHS will [thus] defer to OIG to determine whether a given situation constitutes a 'knowing and intentional' 340B drug overcharge based on the specific case being investigated."). Because no decision has been made by OIG whether to impose CMPs on UT, the matter is far from ripe (*see* 42 C.F.R. § 1003.1540(b) (requiring exhaustion of administrative procedures before seeking judicial review)), and the Court should thus reject UT's attempt to pre-litigate it.

CONCLUSION

Because each of UT's claims is meritless, the Court should grant summary judgment in favor of Defendants.

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