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)

NOTICE OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Defendants respectfully move for summary judgment pursuant to Federal Rule of Civil Procedure 56 on all claims contained in Plaintiff's Complaint for Declaratory and Injunctive Relief. The grounds for this Motion are set forth in the accompanying Memorandum. A proposed order is attached.

Dated: August 10, 2021

Respectfully submitted,

BRIAN D. NETTER
Deputy Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Jody D. Lowenstein
JODY D. LOWENSTEIN
Mont. Bar No. 55816869
KATE TALMOR
RACHAEL L. WESTMORELAND
Trial Attorneys
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street NW
Washington, D.C. 20005
Phone: (202) 598-9280
Email: jody.d.lowenstein@usdoj.gov

Attorneys for Defendants

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' COMBINED MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Legislative Materials

Regulations

This case is the culmination of a collective strategy by a group of large, highly profitable pharmaceutical companies to unilaterally upend the long-settled operation of a statutory program that provides discounted medications to safety-net healthcare providers and their uninsured and underinsured patients. Nearly thirty years ago, Congress struck a bargain with drug companies by creating the "340B Program," under which participating manufacturers gain valuable access to coverage for their products under Medicaid and Medicare Part B in exchange for providing discounted drugs (at or below a statutory ceiling price) to certain safety-net healthcare providers. The providers, in turn, can either generate much-needed revenue through sale of those medications (particularly to patients who are insured) or pass along the discounts directly to patients. The 340B Program has thus served a crucial role in facilitating healthcare for vulnerable patients.

But late in 2020, Plaintiff United Therapeutics Corporation ("UT") and several of its peers began to unilaterally impose onerous and non-statutory restrictions on safety-net providers' access to 340B-discounted drugs, subverting the 340B Program's decades-old operation and spawning a raft of litigation against the Department of Health and Human Services ("HHS"), the agency to which Congress delegated oversight and implementation of the 340B Program. Specifically, the manufacturers announced that they would no longer honor (or honor without significant restrictions) 340B-discounted drug orders placed by eligible healthcare providers but shipped to, and dispensed by, outside, neighborhood pharmacies. These dispensing arrangements with neighborhood pharmacies (called "contract pharmacies") have been an integral part of the 340B Program's operation from its inception, since the vast majority of 340B-eligible providers do not operate in-house pharmacies and thus rely on contract pharmacies to serve patients (who may live thousands of miles from the provider). The drug manufacturers' novel restrictions have choked off access to discounted medications for healthcare providers serving the country's most vulnerable patients in the midst of a global pandemic, and have resulted in providers losing *hundreds of thousands* (and sometimes *millions*) of dollars in savings by having to purchase 340B drugs well above the statutory ceiling price. UT has maintained that its actions—which stand to boost its profits at the expense of safety-net providers and patients—are permissible under the 340B statute. It now asks this Court to sanction that view by

declaring unlawful HHS's longstanding interpretation of the statute—an interpretation with which UT and its peers had complied, without objection, for decades.

There is no cause for this Court to grant that request because UT's claims fail. After a thorough, months-long review of UT's newly devised contract-pharmacy restrictions—including assessment of thousands of pages of complaints from safety-net providers describing the deleterious effects of these types of restrictions, review of correspondence from UT and other manufacturers setting forth the purported basis for their abrupt changes, and meetings with numerous stakeholders—the Health Resources and Service Administration ("HRSA") has determined that UT is flouting its obligations under the 340B statute by forcing certain covered entities to pay excessive prices for its drugs and conditioning access to 340B discounts on demands which have no basis in the statute. As shown herein, that conclusion is based on sound statutory interpretation and sufficient evidence. The Court should reject UT's challenge to HRSA's 340B-violation determination and allow HRSA's enforcement of the statute to proceed by denying UT's motion for summary judgment and granting summary judgment to HHS on UT's claims.

BACKGROUND

I. STATUTORY AND REGULATORY BACKGROUND

In 1992, Congress created a program, administered by the Secretary of HHS, through which certain safety-net healthcare providers, including hospitals, community health centers, and other federally funded entities (collectively known as "covered entities") serving low-income patients could receive drug discounts. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967–71 (1992), *codified at* § 340B, Public Health Service Act, 42 U.S.C. § 256b (1992). The program has dual benefits: Drug discounts "enable these entities 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 (1992) (conf. report), and also may directly benefit uninsured and underinsured patients when covered entities opt to pass along the discounts by helping patients afford costly medications. To achieve these benefits, Congress directed the Secretary to "enter into an

agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid … to the manufacturer for [such] drugs … purchased by a covered entity … does not exceed [the ceiling price]." 42 U.S.C. § 256b(a)(1). And "[e]ach such agreement … shall require that the manufacturer 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.* Congress expressly conditioned drug makers' access to an incredibly valuable federal benefit—coverage of their products under Medicaid and Medicare Part B—on manufacturers' choice to participate in this drug-discount scheme, known as the "340B Program." *Id.* § 1396r-8(a)(1); *id.* § 256b(a). Pharmaceutical companies thus may opt out of providing 340B-discounted drugs to eligible safety-net providers for their low-income patients, but then lose access to drug coverage under these federal health-insurance programs.

In the beginning of the 340B Program, fewer than five percent of covered entities statutorily eligible to participate in the 340B Program operated in-house pharmacies; instead, the vast majority of safety-net providers relied on arrangements with outside, neighborhood pharmacies, called "contract pharmacies," to dispense prescriptions to patients. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549-01, 43,550 (Aug. 23, 1996) ("1996 Guidance"). And because "covered entities provide medical care for many individuals and families with incomes well below 200% of the Federal poverty level and subsidize prescription drugs for many of their patients, [these arrangements were] essential for them to access 340B pricing." *Id.* at 43,549. Covered entities participating in the 340B Program thus began relying on these contract pharmacies to take delivery from manufacturers of drugs purchased by the covered entity and then to dispense those drugs to the covered entities' low-income patients. *Id.*

In 1996, HHS issued interpretive guidance to aid covered entities in best practices for the use of contract pharmacies. 61 Fed. Reg. at 43,549. HHS explained that "[i]t would defeat the purpose of the 340B program if these covered entities could not use their affiliated pharmacies in order to participate," because "[o]therwise, they would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be

impossible) or forego participation in the program altogether." *Id.* at 43,550. Rather than imposing any new requirements on manufacturers not found in the 340B statute, the 1996 Guidance confirmed: "If 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," and, "[i]f the entity directs the drug shipment to its contract pharmacy," that in no way "exempts the manufacturer from *statutory* compliance." *Id.* at 43,549–50 (emphasis added). Thus twenty-five years ago HHS interpreted the 340B statute to preclude manufacturers from denying purchases by covered entities using contract pharmacies, and nothing in the guidance suggested that the agency viewed this statutory obligation as voluntary on the part of drug makers. On the contrary, the choice presented under the guidance was for covered entities to determine whether to establish such arrangements because they remain liable and responsible, "under any distribution mechanism, [for] the statutory prohibition on drug diversion." *Id.* at 43,550. HHS explained that restricting covered entities' access to 340B discounts to those operating an *in-house* pharmacy would not be "within the interest of the covered entities, the patients they serve, [or] consistent with the intent of the law." *Id.* And the agency explicitly rejected the argument, suggested in comments to the proposed guidance, that the use of contract pharmacies constitutes an unauthorized expansion of the 340B Program: "The statute is silent as to permissible drug distribution systems," and contains "no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself." *Id.* at 43,549. On the contrary, "[i]t is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities." *Id.*

Consistent with HHS's interpretation of the 340B statute and its 1996 Guidance implementing its terms, covered entities have for decades relied on contracts with outside pharmacies to serve their patients and access the discounts Congress provided. Indeed, these arrangements proved so pivotal to covered entities' and their patients' access to drug discounts that, in 2010, HHS issued additional guidance specifying that covered entities need not be limited to a single contract pharmacy. *See* Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272-01 (Mar. 5, 2010) ("2010 Guidance"). After issuing notice and soliciting comments, the agency agreed with

commenters that "[i]t would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements by covered entities" and that, because "some patients currently face transportation barriers or other obstacles that limit their ability to fill their prescriptions," more-flexible use of contract pharmacies "would permit covered entities to more effectively utilize the 340B program and create wider patient access." *Id.* The 2010 Guidance includes "essential elements" to prevent unlawful duplicate discounts or diversion of 340B drugs: a "covered entity will purchase the drug, maintain title to the drug and assume responsibility for establishing its price"; "[a] 'ship to, bill to' procedure [will be] used in which the covered entity purchases the drug; the manufacturer/wholesaler must bill the covered entity … but ships the drug directly to the contract pharmacy"; "[b]oth the covered entity and the contract pharmacy are aware of the potential for civil or criminal penalties" for violations; and both the covered entity and contract pharmacy must maintain auditable records, track prescriptions to prevent diversion, and verify patient eligibility. *Id.* at 10,277-78. The guidance makes plain that a covered entity bears full responsibility to ensure adherence to 340B Program requirements and can lose eligibility if violations occur. *Id.*

Most importantly for the present case, the 2010 Guidance again confirmed HHS's earlier interpretation that, "if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, *the statute directs* the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price," regardless whether the covered entity "directs the drug shipment to its contract pharmacy." *Id.* at 10,278 (emphasis added). As before, that interpretation was framed in mandatory terms—the guidance made no suggestion, and in no way supports, the position that manufacturers can choose whether or not to honor 340B purchases by a covered entity that relies on contract-pharmacy arrangements. HHS also explained that the guidance neither created new obligations on manufacturers nor new rights for covered entities because it merely interpreted the 340B statute itself "to create a working framework for its administration," rather than promulgating "a substantive rulemaking under the APA." *Id.* at 10,273. Not only were there *no* legal challenges from drug manufacturers or trade associations to the substance of the 2010 Guidance but, for more than a decade, participating pharmaceutical manufacturers have complied with the guidance

by honoring orders placed by covered entities regardless of the dispensing mechanism chosen. And thus for years many covered entities have relied on the ability to contract with multiple pharmacies to best serve their patients and maintain flexibility in accessing 340B discounts.

Also in 2010, Congress opted "to strengthen and formalize [HHS's] enforcement authority" over the 340B program. *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 121–22 (2011). Specifically, Congress included provisions in the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), to amend the 340B Program to improve "program integrity" related to manufacturer and covered-entity compliance. For example, the Secretary was granted authority to issue new regulations imposing civil monetary penalties ("CMPs") on manufacturers that knowingly and intentionally overcharge covered entities. 42 U.S.C. § 256b(d)(1). Relying on that authority, the Secretary issued a regulation allowing the imposition of CMPs, including up to $5,000 for each knowing and intentional instance of overcharging by a drug manufacturer. 42 C.F.R. § 10.11(a).

II. PHARMACEUTICAL COMPANIES UNILATERALLY RESTRICT ACCESS TO 340B DISCOUNTS FOR SAFETY-NET HEALTHCARE PROVIDERS

During the latter half of 2020, several drug makers took abrupt, unilateral actions to restrict access to their drugs by covered entities that rely on contract pharmacies to take delivery of, and dispense, medications to low-income patients. These actions began with a July 2020 notice by Eli Lilly (another large pharmaceutical company) that, with certain caveats, it would not offer 340B pricing through contract-pharmacy arrangements for only one of its drugs—Cialis, a drug used to treat erectile dysfunction. *See* Compl. ¶¶ 78-80, *Eli Lilly v. HHS*, No. 1:21-cv-81 (S.D. Ind. Jan. 12, 2021), ECF No. 1. But that relatively modest restriction opened the floodgates to further disruptions of the 340B Program: Only one month later, Eli Lilly extended its new contract-pharmacy restrictions to *all* of its covered drugs (with a self-imposed and administered "exception process" purporting to allow providers without an in-house pharmacy to contact the manufacturer to designate a single contract pharmacy), *see id.* Ex. G, and several other pharmaceutical companies promptly followed suit.

For its part, UT announced in November 2020 a "new 340B contract pharmacy policy" that it intended to implement in "two steps." Administrative Record ("VLTR") at 5768. UT explained that

it would start by "*deny[ing]*" all 340B purchases made by covered entities through their contract pharmacies on or after November 20, 2020, unless (i) the covered entity had previously purchased a UT 340B-eligible drug through the contract pharmacy between January 1 and September 30, 2020, or (ii) the covered entity lacked "its own on-site pharmacy" and had "designate[d] [with UT] a single contract pharmacy" for placing 340B orders. *Id.* (emphasis added). And beginning on May 13, 2021, UT would require covered entities, as a condition of their eligibility to purchase UT's 340B-eligible drugs through *any* contract-pharmacy arrangements, to provide UT with up-to-date "claims data" for all such purchases. *Id.* UT later postponed implementation of its claims-data requirement so as to condition sales of 340B-eligible drugs starting on September 1, 2021. *See* Letter from C. Schott to RADM Pedley (May 26, 2021), ECF No. 1-3.

In addition to Eli Lilly and UT, other large, global pharmaceutical companies imposed their own unilateral restrictions on covered entities' access to discounted drugs. Among others, AstraZeneca imposed the same restrictions as Eli Lilly had mandated, *see id.* 6853–56, and Sanofi-Aventis, Novo Nordisk, and Novartis Pharmaceuticals imposed their own, separate restrictions, *id.* 3160–64, 7618; *id.* 7758—with the combined impact of creating a new cluster of onerous restrictions for providers to navigate in order to receive the discounts to which they are statutorily entitled.

Unsurprisingly, the pharmaceutical manufacturers' abruptly announced, unilateral restrictions on access to 340B prices caused upheaval to the operations of covered entities due to their longstanding reliance on contract-pharmacy arrangements, prompting various safety-net providers to urge HHS to take action by filing emergency motions against the agency seeking to compel HHS to reverse the drug makers' changes. *See* Mot. for TRO & Prelim. Inj., *Ryan White Clinics for 340B Access v. Azar*, No. 1:20-cv-2906-KBJ (D.D.C. Nov. 23, 2020)), ECF No. 24-1; Mot. for Prelim. Inj., *Am. Hosp. Ass'n v. HHS*, No. 4:20-cv-8806-YGR (N.D. Cal. Dec. 11, 2020), ECF No. 7 (dismissed Feb. 17, 2021). HHS moved to dismiss those suits for lack of jurisdiction while confirming that its investigations of the manufacturers' actions were ongoing.

In response to the growing public outcry, HHS's General Counsel issued legal advice on December 30, 2020, confirming his view—in alignment with the agency's longstanding guidance—

"that covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered 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." HHS Gen. Counsel, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program ("Advisory Opinion"), VLTR_6832–39. The Advisory Opinion confirmed that this interpretation was compelled by the 340B statute's text—which requires drug manufacturers to *offer* discounted drugs for *purchase by* covered entities, with no qualifications or restrictions on the mechanism by which a covered entity dispenses those drugs to patients—and further supported by the statute's purpose and history. *Id.* But the General Counsel did not assess the legality of any specific contract-pharmacy policy or restriction, opining on drug manufacturers' statutory obligations only as a general matter. The process of evaluating the legality of individual drug manufacturer's restrictions had been initiated by HRSA—the division of HHS that administers the 340B program—months before the General Counsel published his legal advice. *See infra*.

Following publication of the Advisory Opinion, several pharmaceutical companies filed suit within days of each other to challenge the General Counsel's legal advice. *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, No. 3:21-cv-634-FLW (D.N.J. Jan. 12, 2021), ECF No. 1; *Eli Lilly & Co. v. Becerra*, No. 1:21-cv-81-SEB-MJD (S.D. Ind. Jan. 12, 2021), ECF No. 1; *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 1:21-cv-27 (D. Del. Jan. 12, 2021), ECF No. 1; *Novo Nordisk, Inc. v. Dep't of Health & Hum. Servs.*, No. 3:21-cv-806 (D.N.J. Jan. 15, 2021), ECF No. 1. These lawsuits alleged (incorrectly) that the General Counsel's interpretation of the 340B statute imposed a new, non-statutory obligation on drug manufacturers to honor 340B purchases by covered entities who dispense drugs to patients through contract-pharmacy arrangements. With the drug manufacturers' allegations creating "confusion about the scope and impact of the [Advisory] Opinion," and to avoid any further confusion in this regard, the Acting General Counsel withdrew the legal advice on June 18, 2021. *See* Notice of Withdrawal (June 18, 2021), *available at* https://www.hhs.gov/sites/default/files/notice-of-withdrawal-of-ao-20-06-6-18-21.pdf (last visited June 28, 2021).

III. HRSA DETERMINES THAT UT'S RESTRICTIONS ON PURCHASES BY COVERED ENTITIES DISPENSING 340B DRUGS THROUGH CONTRACT PHARMACIES VIOLATE UT'S STATUTORY OBLIGATION AND HAVE RESULTED IN UNLAWFUL OVERCHARGES

Four months before the Advisory Opinion was issued, and shortly after this cohort of drug manufacturers began announcing their novel restrictions on covered entities' access to 340B-discounted drugs, HRSA explicitly put these drug manufacturers on notice that the agency was "considering whether" their "new [contract-pharmacy] polic[ies] constitute[] a violation of section 340B and whether sanctions apply," including, but "not limited to, [CMPs] pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi)." *See* VLTR_7627; *see also e.g.*, *id.* 7658, 7188. HRSA also expressly disavowed the manufacturers' assertion that their contract-pharmacy restrictions "did not give rise to an enforceable violation of the 340B statute," and warned that the newly imposed restrictions "would undermine the entire 340B Program and the Congressional intent behind enactment of the 340B statute," while "restrict[ing] access" for "underserved and vulnerable populations" during the global pandemic. *Id.* 7627. HRSA transparently explained that it "continues to examine" whether drug manufacturers' "actions amount to attempts to circumvent [the] statutory requirement by inappropriately restricting access to 340B drugs." *Id.* Unfazed by HRSA's warning and concerns, UT and its peers proceeded to implement their new contract-pharmacy restrictions.

HRSA's comprehensive review of UT's policy culminated in a new agency action in the form of a 340B-violation letter issued by HRSA on May 17, 2021. *Id.* 11–12 ("Violation Letter"). That letter informed UT that HRSA "has determined that [UT's] actions have resulted in overcharges and are in direct violation of the 340B statute." *Id.* 11. It relies on statutory text to determine that the requirement that UT honor covered entities' purchases "is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs" to its patients, and that "[n]othing 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." *Id.* HRSA's letter directs UT to "immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether

they purchase through an in-house pharmacy," and confirms that CMPs may be imposed. *Id.* 6. Although the letter instructs UT to "provide an update on its plan to restart selling, without restriction, 340B covered outpatient drugs at the 340B price" by June 1, 2021, that date is *not* tied to the potential imposition of CMPs.[1] *Id.* On the contrary, although "[c]ontinued failure to provide the 340B price to covered entities utilizing contract pharmacies … may result in CMPs," HHS "will determine whether CMPs are warranted based on [UT's] willingness to comply with its obligations under section 340B(a)(1)." *Id.* HHS has therefore made no determination as to whether sanctions are warranted but, should UT continue to flout its 340B obligations, any such sanctions would not necessarily be limited to violations that occur after June 1. Importantly, the Violation Letter does not rest upon—or even reference—the General Counsel's now-withdrawn December 2020 legal advice (although the administrative record demonstrates that the agency considered that advice alongside other statutory interpretations, including the agency's previous guidances, *id.* 8048). Instead, the Violation Letter culminates the evaluative process UT had been aware of months before the Advisory Opinion was issued.

The 8,000+-page administrative record demonstrates the thoroughness of HRSA's review and the voluminous evidence on which its conclusion is based. Alongside the statute and its legislative history, the agency's previous notices and guidances interpreting and administering the program, and several hundred pages of correspondence from manufacturers, covered entities, lawmakers, and other stakeholders, HRSA also gathered proof of the real-world implications of restrictions like UT's and the substantial harm they have caused covered entities.

[1] UT responded to HRSA's Violation Letter on May 26, 2021, to request an extension of the June 1, 2021 deadline. *See* Letter from C. Schott to RADM Pedley (May 26, 2021), ECF No. 1-3. On May 28, 2021, HRSA sent UT a letter granting it an extension until June 10, 2021. *See* Letter from RADM Pedley to L. Robson (May 28, 2021), ECF No. 1-2. In this letter, HRSA also clarified for UT that the Violation Letter pertained to both sets of restrictions under UT's new contract-pharmacy policy. *Id.* On June 10, 2021, UT responded to HRSA, indicating that it would continue restricting 340B purchases by covered entities through contract-pharmacy arrangements under the limitations imposed by its policy in November 2020 and intended to move forward with imposing its claims-data requirement in September 2021. *See* Letter from C. Schott to RADM Pedley (June 10, 2021), ECF No. 1-1.

The record contains *over six thousand pages* of complaints from covered entities. *Id.* 110–6,806. Although the entire volume of evidence of drug manufacturers' overcharges cannot adequately be summarized within the limitations of this brief, a few representative examples demonstrate the firm foundation of HRSA's Violation Letter. To start, UC Davis Medical Center reported in December 2020 that 340B prices had become unavailable for 340B-eligibile drugs manufactured by UT for orders placed through UC Davis's contract pharmacies. *Id.* 5714. UC Davis's "adult and pediatric patients in Northern California" are spread across a 65,000 square mile area, the complaint explained, and thus they "rely on pharmacies closer to their homes." *Id.* Accordingly, UC Davis's ability to work with "many contract pharmacies" to store and dispense the hospital's drugs to patients has helped its "patients to have access to [their] medication[s]." *Id.* Ronald Reagan UCLA Medical Center and Santa Monica UCLA Medical Center submitted similar complaints reporting UT's "refusal to offer 340B pricing" for orders placed through their contract-pharmacy arrangements. *Id.* 5766, 5769.

HRSA also relied on evidence describing the importance of outside, neighborhood pharmacies, even for covered entities that may also operate an in-house pharmacy. For instance, one federally funded health center in Georgia, which represents a sizeable, rural area and a "medically underserved population," submitted sworn testimony confirming that its in-house pharmacy can serve only 40% of its 25,000 patients. *Id.* 7255–56. That health center relies on 340B savings through its contract-pharmacy network to "provide its qualified patients medications such as insulin and epinephrine for as little as $4 to $7 a dose, or even at no cost at all." *Id.* The covered entity also explained that six of its eleven health centers do not operate an in-house pharmacy, and those that do are only open weekdays 8AM to 5PM, so neighborhood pharmacies are crucial because "available time during the traditional workday is a significant barrier for our patient population." *Id.* Aside from the benefit to patients, the covered entity explains that its contract pharmacies enable it to "generate additional revenue" through the spread between the 340B-discount price and the price paid by or on

behalf of some patients, as Congress intended,[2] and that it "reinvest[s] all 340B savings and revenue in services that expand access" for patients and serve "vulnerable populations such as the homeless, migrant workers, people living in public housing, and low-income individuals and families."[3] *Id.*

Copious sworn testimony further documents the harms caused by drug makers' unlawful 340B restrictions. A safety-net provider in Michigan evidenced its reliance on the 340B Program; it serves a "*10,000-mile service area*" and thus relies extensively on retail pharmacies. *Id.* 7260–61. Through its contractual arrangements, it "purchases 340B-priced drugs from the wholesaler and directs those drugs to be shipped to" its pharmacy partners, under contracts specifying that "[t]he health center maintains title to the 340B drugs, but the contract pharmacies store the drugs and provide dispensing services to eligible … patients." *Id.* It passes on 340B discounts "directly to eligible patients who meet federal poverty guidelines," while using savings earned from other dispenses to pay for "essential health care services to its underserved rural community," including those not readily available in the rural Upper Peninsula, such as addiction treatment and OB/GYN care. *Id.* 7261–62. The covered entity detailed the impossibility of serving patients through just one pharmacy, along with the severe impacts on its services and budget that contract-pharmacy restrictions like UT's have caused. *Id.* 7262–63. The administrative record contains numerous similar declarations detailing harms to covered entities. *E.g.*, *id.* 7270–75; 7277–83 (federally funded health center explaining that it does not operate an in-house pharmacy and instead pays for drugs to be shipped to a contract pharmacy where provider "maintains the title to the 340B drugs, and the contract pharmacies, in exchange for a fee, store the

[2] As explained above, Congress designed the program to allow covered entities to generate revenue "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. Much of this revenue is generated through payments by private insurance. Uninsured patients often receive medications for free but also may be charged a small amount on a sliding-income scale, relative to their financial ability. As explained herein, this enables covered entities to reinvest in patient care and services.

[3] This covered entity also thoroughly rebutted manufacturers' portrayal of contract-pharmacy relationships as a boon for for-profit pharmacy chains, explaining that, although it pays a modest, predetermined fee to the pharmacy for its services, "as required by HRSA, [it] does not and will never enter into an agreement with contract pharmacies where it does not retain the majority of the savings from the 340B discount" and that it recently "underwent a 340B HRSA Audit where there were no [non-compliance] findings." VLTR_7257.

drugs and provide dispensing services"; savings generated are "100%" reinvested into patient care, including addiction treatment); 7295–98 (safety-net provider with high-poverty population expects to lose $6 million from its $8 million budget due to 340B restrictions, and is preparing to lay off 35 employees as a result); 7300–06 (federally funded provider in Arizona documenting that patients would have to travel up to 180 miles *each way* to fill prescriptions at in-house pharmacies and that, as a result of lost revenue, entity is weighing services cuts); 7309–14 (confirming that "[u]ninsured patients get 100% of the savings at our partner (contract) pharmacies" and that, for other patients, "[a]ny net revenue we derive from the 340B Program also goes directly to our patients"; further documenting significant harm to patients, *id.* 7312); 7316–20; 7323–25 (explaining that patients are heavily reliant on access to discounted drugs through network of neighborhood and mail-order pharmacies and that covered entity "is responsible for and ensures program compliance in part through daily self-audits of prescription claims and drug purchasing records"); 7331–33; 7347–50.

HRSA also evaluated evidence of the outsized financial impact that restrictions imposed by UT and other drug manufacturers pose for covered entities. For instance, Strong Memorial Hospital, a safety-net healthcare provider, serves an area with "the third highest concentration of poverty in the U.S., with more than 50% of the city's children living in poverty," and "[n]early 40% of [the hospital's] patients … on Medicaid or low-income Medicare." *Id.* 6396. In April 2021, the hospital alerted HRSA that, since October 2020, it "had paid *more than $2 million* over the 340B ceiling price on covered outpatient drugs purchased from" drug manufacturers who were restricting the use of contract pharmacies. *Id.* 6396 (emphasis added). And these overcharges represented only a fraction of "the lost opportunity and financial impact to the hospital"—which it had estimated to "exceed[] $10 million"—because the hospital's inability to purchase 340B drugs at the ceiling price not only resulted in overcharges, but also deterred it from purchasing medications altogether. *Id.* 6396. The hospital explained to HRSA that "[t]he losses incurred due to manufacturer restrictions puts at risk [its] ability to maintain a robust charity care program and community services that [it is] able to provide, often operating at a loss, such as comprehensive mental health and wellness care …, substance abuse treatment programs, and Naloxone training." *Id.*

Many other safety-net providers serving similarly disadvantaged and vulnerable populations echoed Strong's concerns regarding drug manufacturers' restrictions on covered entities' ability to purchase 340B-eligibile drugs. Among those providers adversely affected by such restrictions was Arnot Ogden Medical Center, which "provid[es] care for a region with a poverty rate around 30%." *Id.* 6229. Arnot explained to HRSA that it "has operated for years in the red," attributing its ability to "keep the doors open" to the help it receives from "the 340B program and largely the benefit from contract pharmacy relationships." *Id.* Jones Memorial Hospital, which serves "a rural area" that is "among the poorest in New York," similarly explained that "[t]he 340B program and largely the benefit from contract pharmacy relationships are keeping the hospital's doors open." *Id.* 6331. And St. Charles Health System confirmed that drug manufacturer restrictions on "contract pharmacy relationships" were impacting its "ability to provide expanded care services for [its] underserved and uninsured patients," including "screening programs, diabetes education and other community outreach services" in rural Oregon. *Id.* 5255.

During its evaluation, HRSA gathered relevant evidence through meetings with stakeholders impacted by drug manufacturers' restrictions. For example, HRSA officials met with representatives of Avita Pharmacy, a national chain that almost exclusively contracts with and dispenses for covered entities, including community health centers and AIDS clinics. *Id.* 7891–92. Avita relayed that, of its 270 covered-entity clients—98% of whom do not operate their own pharmacies—all were being denied 340B pricing and stand to lose millions of dollars in lost revenue. *Id.* Avita expressed concern that the changes "will lead to imminent harm to patients and possible site closures," and some health centers were forced to charge $300 for insulin that had been dispensed for as little as $0. *Id.* The very next day, HRSA officials learned in another meeting that one pharmacy in West Virginia that dispenses on behalf of a covered entity "has already had 14 patients denied insulin based on these practices," which had only just gone into effect. *Id.* 7887. In another listening session that same month, HRSA gathered evidence from tribal leaders in multiple states detailing the harms befalling income-disadvantaged tribal members and underfunded rural health clinics as a result of manufacturers' restrictions, including that, for one tribe in California, "[p]atients are having to choose between buying

food and buying medications" and "are ending up in the Emergency Room that costs a lot more money than medications cost." *Id.* 7894–97. Another tribe reported that its pharmacy bill has more than doubled, that it is "not financially feasible for the tribe to operate its own pharmacy" and that it had been forced to pay more than $3,400 for roughly 100 pills, which it described as "[un]sustainable costs." *Id.* 7894, 7898. Yet another tribal leader implored HRSA "to take immediate action," pointing out that drug makers are "experiencing record-breaking profit" so it was "unacceptable for them to g[o]uge small entities." *Id.*

The administrative record also contains the result of an annual survey of 340B hospitals completed by 340B Health, a nonprofit trade organization for certain covered entities. *Id.* 7957–63. In the survey virtually all covered entities reported "feeling the impact of the refusal of some large drug companies to provide discounts on drugs dispensed by community pharmacies" while reporting that "cuts are likely" should these actions continue. *Id.* 7957. Respondents provided detailed information on how they use 340B savings to provide more-comprehensive services for medically underserved and low-income patients, such as addiction treatment, oncology treatment, medication management, and outpatient behavioral health for children. *Id.* 7958. Continued funding cuts caused by lost 340B savings were shown to "threaten a range of services for" hospitals, with the "most impact [to] oncology and diabetes services." *Id.* 7959. Fully one-third of covered-entity hospitals responding said that lost 340B savings could cause a hospital closure. *Id.* Rural hospitals are at even greater risk, since fully three-fourths of such "hospitals rely on 340B savings to keep the doors open" and program cuts are most likely to harm general patient care and diabetes services. *Id.* 7960–61. Notably, respondents expressly tied financial concerns to six manufacturers' contract-pharmacy restrictions, which are impacting the resources of 97% of 340B hospitals—most of which expect to lose *more than fifteen percent* of their annual 340B savings as a result of these restrictions—and "[n]early all 340B hospitals report they will have to cut programs and services if these restrictions become more widespread." *Id.* 7962.

As even this truncated overview demonstrates, HRSA spent many months gathering a legion of evidence with which to analyze the legality of UT's contract-pharmacy restrictions and the real-world impact they will have on the 340B Program. After evaluating this evidence, alongside UT's

communications to covered entities, *e.g.*, *id.* 5768, and to the agency explaining its policy, *e.g.*, *id.* 7732, HRSA concluded that UT is violating the 340B statute and issued its May 17, 2021 letter to that effect.

STANDARD OF REVIEW

In a case reviewing final agency action under the APA, summary judgment "serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Landmark Hosp. of Salt Lake City v. Azar*, 442 F. Supp. 3d 327, 331 (D.D.C. 2020) (citation omitted). The agency "resolve[s] factual issues to arrive at a decision that is supported by the administrative record," and the district court "determine[s] whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Buckingham v. Mabus*, 772 F. Supp. 2d 295, 300 (D.D.C. 2011) (citation omitted). "[T]he entire case on review is [thus] a question of law," and "the district court sits as an appellate tribunal." *Athenex Inc v. Azar*, 397 F.Supp.3d 56, 63 (D.D.C. 2019) (citation omitted). The party challenging final agency action bears the burden of demonstrating a violation of the APA. *Lomak Petroleum, Inc. v. FERC*, 206 F.3d 1193, 1198 (D.C. Cir. 2000).

ARGUMENT

HRSA concluded for the first time in its Violation Letter that UT's restrictions on 340B-eligible purchases made through contract-pharmacy arrangements directly violate the 340B statute, 42 U.S.C. § 256b(a)(1), and may warrant sanctions, including expulsion from Medicaid and Medicare Part B. As demonstrated below, that conclusion is based on a correct interpretation of the statute and sufficient evidence. UT fails to grapple with the incontrovertible evidence that its actions require certain covered entities to purchase 340B-eligible drugs well above the statutory ceiling price in violation of the 340B statute, and its contrary reading of the statute conflicts with the statutory text and subverts congressional intent. UT also challenges the reasonableness of HRSA's 340B-violation determination based on factual assertions belied by the administrative record. The dispute between the parties—whether UT is, in fact, in violation of its statutory obligation—is squarely presented in the Violation Letter and must be decided on the basis of HRSA's reasoning contained therein and the

administrative record supporting it. Because that reasoning is sound and supported by the record, the Court should grant summary judgment in favor of HHS on UT's challenge to the Violation Letter and allow HRSA's enforcement efforts to proceed.

I. HRSA CORRECTLY FOUND THAT UT IS VIOLATING ITS STATUTORY OBLIGATION.

The question before the Court is whether HRSA correctly found that UT's contract-pharmacy restrictions violate its obligation under 42 U.S.C. § 256b(a)(1) to ensure that covered entities are not required to purchase UT's 340B drugs above the statutory ceiling price. That question is not answered, as UT suggests, by the fact that the 340B statute does not *explicitly* require UT to "deal with" a covered entity's "distribution partners," or to "ship" medications purchased by a covered entity for its patients to the covered entity's contract pharmacies. *See, e.g.*, UT Mot. 18, 31, 41. The 340B statute does not expressly address the subject of delivery location or dispensing mechanism because Congress's intent was to provide access to discounted medications for safety-net healthcare providers, not to detail the logistics of how such transactions should be effectuated. Congress instead crafted the 340B Program to impose an obligation on drug manufacturers that speaks in "starkly broad terms" to achieve its legislative goals. *See Bostock v. Clayton Cty.*, 140 S. Ct. 1731, 1753 (2020). "As always, this Court's task is to read that language as Congress wrote it—to give [the 340B statute] all the scope and potency Congress drafted it to have." *Brnovich v. Democratic Nat'l Comm.*, 141 S. Ct. 2321, 2356 (2021) (Kagan, J., dissenting).

To give full effect to "the breadth of [this] legislative command," *Bostock*, 140 S. Ct. at 1753, the Court must read the 340B statute "as a whole," *United States v. Atl. Rsch. Corp.*, 551 U.S. 128, 135 (2007), interpreting the meaning of "relevant words not in a vacuum, but with reference to the statutory context, structure, history, and purpose," *Abramski v. United States*, 573 U.S. 169, 179 (2014) (citation omitted). UT's proposed reading of the 340B statute eschews these principles by ignoring key statutory language and by construing the meaning of a few words "in isolation," *see Textron Lycoming Reciprocating Engine Div. Avco Corp. v. United Auto., Aerospace & Agric. Implement Workers of Am.*, 523 U.S. 653, 657 (1998) (citation omitted), divorced from any consideration of congressional purpose or

history. HRSA's interpretation, on the other hand, is supported by all the touchstones of statutory meaning. It thus correctly found that UT's contract-pharmacy policy erects unlawful barriers around covered entities' access to 340B-priced drugs and results in overcharges in violation of the 340B statute.

A. HRSA's interpretation is based on relevant statutory text and context.

HRSA grounded its determination "that [UT's] actions have resulted in overcharges and are in direct violation of the 340B statute" directly in statutory text. *See* VLTR_11 (citing "Section 340B(a)(1) of the Public Health Service (PHS) Act," 42 U.S.C. § 256b(a)(1)). As the letter explains, *see id.*, the 340B statute conditions Medicaid and Medicare Part B access on UT's adherence to the 340B statutory scheme that UT opted into by executing a PPA requiring manufacturers to ensure that "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, 42 U.S.C. § 256b(a)(1). The statute specifies further that "[e]ach such agreement shall require … that the manufacturer 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.* As HRSA explained, that straightforward obligation "is not qualified, restricted, or dependent on how the covered entity chooses to distribute" the drugs it purchases to its patients, and no statutory provision authorizes a drug maker to place conditions on its fulfillment of that mandate. *See* VLTR_11. HRSA thus reminded UT that compliance with its PPA requires UT to "ensure that the 340B ceiling price is available to *all* covered entities." *Id.* (emphasis added).

HRSA explained further that UT's restrictions run afoul of its obligation "to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs" because UT's restrictions prevent covered entities from accessing discounted drugs through the same wholesale channels where drugs are made available for full-price purchase. *Id.* HRSA cited existing regulations confirming that "a manufacturer's failure to provide 340B ceiling prices through" existing wholesale distribution agreements may result in CMPs. *Id.* (citing 340B Drug Pricing Program Ceiling Price & Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1230 (Jan. 5,

2017)). Existing regulations also define an "[i]nstance of overcharging" as "any order for a covered outpatient drug … which results in a covered entity paying more than the ceiling price … for that covered outpatient drug," 42 C.F.R. § 10.11(b), and separate regulations promulgated by HRSA recognize that 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," 42 C.F.R. § 10.21(c)(1) (governing the 340B Program's Administrative Dispute Resolution process); *see also* 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57,233, 57,234 (Sept. 20, 2010) (evidence of overcharge may include "cases where refusal to sell at the 340B price has led to the purchase of the covered outpatient drug outside of the 340B Program"). In short, HRSA's analysis rests on the 340B statute itself, as well as duly promulgated regulations issued through an express grant of rulemaking authority.

HRSA is correct in its statutory interpretation. Since 1992, the 340B statute has conditioned Medicaid coverage on compliance with "an agreement with each manufacturer of covered drugs under which the amount required to be paid … to the manufacturer for covered drugs … purchased by a covered entity … does not exceed" the statutory ceiling price. Veterans Health Care Act of 1992, Pub. L. No. 102-585, tit. VI, § 602(a), 106 Stat. 4943, 4967 (1992). Reading the statute "as a whole," *Atl. Rsch. Corp.*, 551 U.S. at 135, the core requirement of 42 U.S.C. § 256b(a)(1) plainly requires manufacturers to *sell* discounted drugs *to covered entities*, regardless of the manner in which they dispense those drugs to their patients.

And yet, UT's analysis *completely ignores* this key statutory language. *See* UT Mot. 27 (pointing the court to only three statutory provisions, none of which include this core requirement of § 256b(a)(1)). Indeed, UT urges this Court to find that it somehow fulfills its duties under the 340B statute while admitting that it now *denies* 340B-drug "purchases by" covered entities solely based on the delivery location of an order or the dispensing mechanism used by a covered entity—thus forcing covered entities instead to purchase UT's drugs above the ceiling price. *See, e.g.*, VLTR_5768; UT Mot. 44.

Rather than consider the entirety of § 256b(a)(1), UT asks the Court to consider only a couple words in isolation, divorced from relevant text and necessary context. Contrary to UT's portrayal, *see, e.g.*, UT Mot. 26, 31, the 340B statute does not only require UT to *offer* drugs for purchase by covered entities, regardless whether the terms of its "offer" pose practical barriers restricting covered entities' access. The "offer" language in § 256b(a)(1), on which UT relies, was added in 2010 to codify an *additional* requirement that manufacturers cannot discriminate by treating commercial purchases more favorably than 340B purchases. *See* VLTR_108–09, Clarification of Non-Discrimination Policy, May 23, 2012. In other words, Congress clarified in 2010 that manufacturers cannot preference full-priced purchases over 340B purchases (a requirement HRSA had already set forth in guidance, as discussed *infra*). That amendment in no way changed the substance of UT's preexisting obligation. Were the requirement to "offer each covered entity" discounted drugs the sum total of manufacturers' obligation, as UT suggests, *see, e.g.*, UT Mot. 27–28, the inescapable conclusion would be that, from 1992 until 2010, the pharmaceutical industry sold deeply discounted drugs to covered entities on a purely voluntary basis (since the "offer" language did not yet exist). But of course that is not the case: From the statute's enactment, drug companies wishing to receive coverage for their products through certain government health-insurance programs have been required by both the statute and their PPAs to ensure that drugs "purchased by a covered entity" do not exceed the ceiling price. That obligation did not arise from the 2010 amendments and has not changed substantively (aside from the *additional* non-discrimination requirement) since the statute's enactment. Moreover, UT fails to grapple with the fact that its restrictions *do* violate the "offer" provision's non-discrimination requirement by treating commercial purchases far more favorably than 340B purchases, as evidenced by the fact that UT places no delivery-location or dispensing-mechanism restrictions on full-priced sales—only covered entities' purchases.

And as already explained, it matters not that Congress, in imposing these obligations on participating drug manufacturers, did not *explicitly* address the subject of delivery location for 340B drug shipments or *expressly* authorize the use of outside-dispensing arrangements (upon which nearly all covered entities relied when Congress enacted the 340B statute, *see infra*). *Contra* UT Mot. 27.

Congress enacted the 340B statute to craft a comprehensive scheme designed to allow safety-net healthcare providers and their patients to actually access discounted medications, which requires drug manufacturers to honor the very purchases UT now denies for certain covered entities. It is axiomatic that a statute may "plainly impose[]" a requirement not expressly delineated in the text, because Congress need not "separately address every conceivable set of circumstances to which [a statute] might apply." *See H. Lee Moffitt Cancer Ctr. & Rsch. Inst. Hosp., Inc. v. Azar* (*H. Lee Moffitt*), 324 F. Supp. 3d 1, 14 (D.D.C. 2018); *accord Milton S. Hershey Med. Ctr. v. Becerra*, No. 19-2680, 2021 WL 1966572, at *7 (D.D.C. May 17, 2021); *see also Engine Mfrs. Ass'n v. EPA*, 88 F.3d 1075, 1088 (D.C. Cir. 1996) ("[Statutory text may] require[] a particular outcome," even though "it does so implicitly rather than expressly."). For example, "'Thou shall not kill' is a mandate neither silent nor ambiguous about whether murder is permissible if committed after 5.00 p.m.—or, for that matter, if committed in the billiard room with the candlestick." *H. Lee Moffitt*, 324 F. Supp. 3d at 14 (citation omitted). By that same logic, a drug manufacturer's statutory obligation to ensure that covered entities not be required to purchase 340B-eligible drugs above the ceiling price is neither silent nor ambiguous about whether a manufacturer violates that obligation by denying a covered entity access to the ceiling price based on the manner in which the covered entity dispenses drugs to its patients.

To adopt UT's cramped reading of its statutory obligation, the Court would need to construe the 340B statute in a manner that would run afoul of recent Supreme Court guidance. In *Bostock*, the Court held "[t]he answer is clear" that Title VII's prohibition on discrimination "because of … sex" encompassed claims of sexual-orientation and transgender-status discrimination—despite the fact that nowhere is sexual orientation referenced in the text and notwithstanding that the drafters "might not have anticipated their work would lead to this particular result." 140 S. Ct. at 1737–38. The Court's approach is highly relevant for this case, as UT's focus on the fact that § 256b(a)(1) does not expressly address delivery location or dispensing mechanism, *see, e.g.*, UT Mot. 41, is directly analogous to the unsuccessful argument that, "[b]ecause homosexuality and transgender status can't be found on th[e] list" of statutorily "protected characteristics," "they are implicitly excluded from Title VII's reach," *Bostock*, 140 S. Ct. at 1746. But that is not so (as the Court made clear), because there is no "such thing

as a 'canon of donut holes,' in which Congress's failure to speak directly to a specific case that falls within a more general statutory rule creates a tacit exception. Instead, when Congress chooses not to include any exceptions to a broad rule, *courts apply the broad rule*." *Id.* at 1747 (emphasis added). The Court further explained that, despite the absence of any language sweeping in sexual orientation or any reason to believe the drafters expressly intended that result, "no ambiguity exists about how Title VII's terms apply to the facts before us," since "the fact that a statute has been applied in situations not expressly anticipated by Congress does not demonstrate ambiguity; instead it simply demonstrates the breadth of a legislative command." *Id.* at 1749 (internal citations and alterations omitted). The Court also noted that Title VII "is written in starkly broad terms" and "has repeatedly produced unexpected applications." *Id.* at 1753.

Bostock demonstrates the flaws in UT's statutory construction. Just as the absence of express statutory text did not prevent sexual-orientation discrimination from falling within Title VII's broad sweep, the absence in § 256b(a)(1) of any express command to deliver to neighborhood pharmacies does not allow UT to sidestep its obligations to honor "purchases by" covered entities at the ceiling price and to treat those sales on par with commercial purchases. True, the 340B statute creates "a broad rule," but that does not allow this Court to "create[] a tacit exception" that Congress omitted by limiting UT's obligation to only purchases shipped to specific locations or dispensed to patients in a specific manner. *See Bostock*, 140 S. Ct. at 1747. No interpretive doctrine requires Congress to spell out the minutiae of every facet of every transaction encompassed within a program created through novel legislation. Stated differently, Congress is permitted to (and often does) legislate through broad commands or prohibitions, and the use of more-general language does not permit a regulated entity to take actions that contravene a statute's purpose simply because those actions were not expressly prohibited by the plain text. This intuitive principle is illustrated by the untenable results that would accrue should UT's interpretation be credited. If Congress's failure to address delivery location or dispensing mechanism indicated that manufacturers have *no* delivery or shipping obligations—as UT's contentions seem to suggest—then it would follow that UT could entirely refuse to deliver 340B-discounted drugs and require each covered entity across the nation to physically pick up their

purchased drugs from UT's warehouses. Similarly, UT's view of the meaning of congressional "silence" would mean that, since the 340B statute is equally "silent" on payment method, UT could require covered entities to pay only in pennies. Congress's failure to address drug quantities could similarly allow UT to require high minimum-order requirements that rendered it infeasible for resource-strapped safety-net providers to purchase UT's drugs. None of these results is permissible under the statute (nor is UT's refusal to honor the ceiling price when covered entities that fail to comply with UT's extra-statutory conditions direct drug shipments to an outside pharmacy) because Congress's intent in mandating maximum prices for covered entities is clear—and Congress was under no obligation to micromanage the details of those transactions in order to achieve its purpose of providing discounted drugs.

UT's additional textual arguments are also unavailing. HRSA fully agrees with UT that contract pharmacies are not among the 15 enumerated categories of safety-net healthcare providers who fall within the definition of "covered entity." *See* UT Mot. 27. HRSA has never included contract pharmacies as a type of covered entity or allowed pharmacies to participate in 340B purchases. *See, e.g.*, VLTR_7589; *see generally* 61 Fed. Reg. at 43,549. But—just as commercial purchasers are able to rely on real-world dispensing models, including outside pharmacies and specialty mail-order pharmacies, and just as the overwhelming majority of covered entities relied on outside pharmacies at the program's inception—covered entities today are permitted to utilize outside pharmacies to dispense medications *the covered entities have purchased* without including those pharmacies as another "type" of covered entity. As HRSA explained decades ago, "the use of contract services is only providing those covered entities (which would otherwise be unable to participate in the program) a process for accessing 340B pricing. The mechanism does not in any way extend this pricing to entities which do not meet program eligibility." 61 Fed. Reg. at 43,550.

Nor do contract-pharmacy arrangements run afoul of Congress's prohibition on unlawful transfers of discounted drugs (as UT contends, *see* UT Mot. 28). *See* 42 U.S.C. § 256b(a)(5)(B) ("[A] covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity."). The proper understanding of that provision has been clear since 1994, when HRSA issued

"guidelines regarding drug diversion." Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,112–13 (May 13, 1994). Those guidelines explained that "[c]overed entities are required not to resell or otherwise transfer outpatient drugs purchased at the statutory discount to an individual who is not a patient of the entity" and that "[t]here are several common situations in which this might occur." *Id.* That guidance went on to explain that covered entities must "develop and institute adequate safeguards" to ensure that discounted drugs are dispensed only to eligible patients, that covered entities must use 340B drugs only in outpatient settings (not for inpatient services), and that a larger provider which contains both a covered entity and non-eligible entity must "maintain separate dispensing records for the eligible entity." *Id.* These situations have in common that they all would involve dispensing and use of 340B-discounted drugs for either ineligible patients, services, or settings—but they certainly would not encompass instances where a licensed pharmacist dispenses outpatient drugs to an eligible patient on behalf of an eligible covered entity.[4] Indeed, the 1994 Guidance specifically acknowledged that the use of "contract pharmacies" is countenanced under the 340B Program, and that manufacturers may not place their own limitations on this form of drug distribution. *See id.* at 25, 111–12. There is no unlawful transfer of discounted drugs when a covered entity purchases drugs for dispensing at outside pharmacies, because pharmacies are only facilitating the exchange of tightly controlled *prescription drugs* on behalf of admittedly eligible patients of admittedly eligible prescribers.

[4] UT "tilts at a windmill of its own invention," *see Lee v. Kemna*, 534 U.S. 362, 385 n.15 (2002), in attacking a so-called "principal-agency rationalization" found nowhere in HRSA's Violation Letter, *see* UT Mot. 29–30. Contrary to UT's insistence, HRSA's determination that UT's contract-pharmacy restrictions violate the 340B statute does not rest on the assumption that a covered entity and its contract pharmacies are "legally one and the same." *See id.* at 29. Rather, the administrative record amply demonstrates that it is *covered entities* purchasing 340B drugs and dispensing them to patients through their contract pharmacies. Such "'distribution' relationship[s]" have been common in the 340B Program since its inception, and UT offers no sound argument to find that these arrangements are "bar[red]" under the 340B statute. *See id.* at 28. UT's contentions relating to the "concepts of agency" are therefore irrelevant to the statutory analysis. *See id.* at 29.

B. HRSA's interpretation furthers congressional purpose.

HRSA's reading of the 340B statute is the only plausible interpretation that furthers, rather than frustrates, Congress's clear purpose in enacting the 340B Program. Although "the starting point for [a] court's[] interpretation of a statute is always its language, the court may not stop after reading one textual provision in isolation," but must also "look to the provisions of the whole law, and to its *object and policy*." *H. Lee Moffitt*, 324 F. Supp. 3d at 10 (cleaned up with emphasis added) (quoting *Czyzewski v. Jevic Holding Corp.*, 137 S. Ct. 973, 985 (2017)); *accord Kelly v. Robinson*, 479 U.S. 36, 43 (1986) ("[T]he text is only the starting point [when] expounding a statute …." (citation omitted)). Indeed, a reviewing court's "obligation is to give effect to congressional purpose so long as the congressional language does not itself bar that result." *Johnson v. United States*, 529 U.S. 694, 710 n.10 (2000).

Congress legislated against the backdrop of real-world facts in enacting the 340B statute, and in creating the program, it surely knew both that (1) covered outpatient drugs can only be dispensed by licensed pharmacies, not any healthcare provider entitled to prescribe them, and (2) when the statute was enacted in 1992, only 5% of covered entities had an in-house pharmacy, and reliance on outside pharmacies was commonplace. *See* 61 Fed. Reg. at 43,550. Had Congress intended to *exempt* covered entities from the usual business practice of the day (and require them to undertake the expense and effort to dispense medication in-house) surely it would have said so explicitly. *See id.* On the contrary, Congress's addition in 2010 of the non-discrimination requirement shows it intended covered entities to be treated on par with commercial purchasers, who plainly *are* permitted to serve patients through outside dispensers. The statute provides no reason to believe that Congress enacted a comprehensive legislative scheme to aid safety-net providers and vulnerable patients—but intentionally and implicitly structured it in such a way that only 5% of the providers statutorily eligible to participate would be able to access the program in practice. Such an interpretation would run afoul of "the presumption against ineffectiveness," *United States v. Castleman*, 572 U.S. 157, 178 (2014) (Scalia, J., concurring), a canon of statutory interpretation that requires a court to adopt "a textually permissible interpretation that furthers rather than obstructs [a statute's] purpose," *Tex. Workforce Comm'n v. U.S. Dep't of Educ.*, 973 F.3d 383, 389 (5th Cir. 2020) (citation omitted). One court has

already confirmed that "HHS's current interpretation of the statute is permissible." *AstraZeneca Pharms. LP v. Becerra* (*Astra*), No. 21-27-LPS, 2021 WL 2458063, at *11 (D. Del. June 16, 2021). And this Court should therefore decline UT's request to now interpret it in a manner that would render it toothless in practice. *See United States v. Hayes*, 555 U.S. 415, 426–27 (2009) (rejecting a construction of a statute that "would frustrate Congress' manifest purpose" and would have meant that the statute was "'a dead letter' in" many of its applications "from the very moment of its enactment").

UT fails to confront the fact that its refusal to deliver its drugs to pharmacies capable of dispensing them on behalf of the covered-entity purchaser renders its "offer" to sell drugs meaningless in practice in many instances. These are prescription drugs, some of which are controlled substances—not everyday commodities that can be shipped to any address. Congress did not need to impose any explicit *delivery* obligation on manufacturers; it is self-evident that prescription drugs *cannot* be delivered to just any location. Just because a healthcare facility employs doctors able to prescribe medications does not mean it has the infrastructure, including state licensing, DEA registration, staff pharmacists, appropriate storage space to keep and safeguard medications, software to bill insurers, etc., that would allow it to take delivery of, and dispense, pharmaceuticals. As has been explained, the majority of covered entities do not operate a licensed pharmacy or employ a pharmacist and thus are not entitled to handle their own dispensing or even to *take delivery* of UT's medications. And even for those that do operate an in-house pharmacy, as explained *supra* pp. 11–14, covered entities often serve vulnerable populations over huge geographic areas with transportation and timing difficulties, making it impossible for all patients (tens of thousands per provider, in some cases) to fill their prescriptions each month on-site or in just one location. *See, e.g.*, VLTR_7260–61 (explaining that covered entity "provide[s] primary health care and related services *across a 10,000 square mile service area*" for population that "is significantly underserved, aging, and impoverished" and who rely on "local retail pharmacies" to obtain medications) (emphasis added)). Were it as simple as UT portrays for covered entities to accept its "offer" through direct, in-house dispensing, 340B sales would not have taken the nosedive evidenced in statistical analysis prepared for HRSA once drug manufacturers began imposing their extra-statutory restrictions. *See id.* 7936–47.

These practical realities demonstrate that a manufacturer's purported offer to ship its drugs to each provider's physical location would often be meaningless in practice (and that Congress could not have intentionally created a scheme that, in reality, would be inaccessible to the majority of intended beneficiaries). If UT were correct that it only had to *offer* drugs to covered entities, not also to "ship" 340B drugs to a location where the covered entity can accept and use the drugs for its patients, *see, e.g.*, UT Mot. 8, 18, 31, the statutory scheme would be ineffective in many instances. Clearly, in mandating that manufacturers provide discounted drugs to covered entities, Congress intended manufacturers to honor real-world, preexisting supply chains (including sales made through wholesale channels for delivery to pharmacies, which UT now refuses), not to force safety-net providers to restructure their businesses entirely to allow for in-house drug dispensing *or* to require thousands of patients of the covered entity all to obtain their monthly refills at one designated location. Manufacturers like UT have known for thirty years that they "may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective," nor can they "place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program." 59 Fed. Reg. at 25,113. UT's restrictions thwart the intent of Congress by erecting barriers to covered entities' ability to access the program in practice.

C. Historical evidence supports HRSA's interpretation.

Legislative history supports HRSA's reading of the 340B statute, too. *See U.S. Ass'n of Reptile Keepers, Inc. v. Jewell*, 103 F. Supp. 3d 133, 145 (D.D.C. 2015) ("Whether proceeding under *Chevron* or not, the Court must exhaust the traditional tools of statutory construction to determine the plain language of [a] statute, including examination of the statute's text[and] legislative history …." (internal quotation marks omitted) (quoting *Petit v. U.S. Dep't of Educ.*, 675 F.3d 769, 781 (D.C. Cir. 2012)); *see also Johnson*, 529 U.S. at 710 at n.10 ("[T]o discover the design of the legislature, we have seized every thing from which aid can be derived." (cleaned up)). In 1992, Congress actually considered, but *removed from the statute*, a provision that would have mirrored UT's explanation of the program's proper operation. The draft of what would become § 256b(a)(1) that first was considered by the Senate

proposed to restrict 340B-discounted sales to drugs "purchased *and dispensed by*, or under a contract entered into *for on-site* pharmacy services with" a covered entity. *See* S. Rep. No. 102-259, at 1–2 (1992) (emphasis added). In other words, the bill as originally drafted would have restricted covered entities' purchases of 340B drugs to only those dispensed *directly by* the covered entity or *on-site* at the same location. Rather than codify that plain restriction on covered entities' choice of dispensing mechanism—indeed, a constraint that necessarily flows from UT's reading of the statute, *see, e.g.*, UT Mot. 5 ("UT is not required by the 340B statute to deal with *any* contract pharmacy[,]although it *voluntarily* does so …." (second emphasis added)); *id.* at 31 ("Congress said that manufacturers must offer 340B prices to covered entities …. [It did not] require manufacturers to deal with distribution partners … of covered entities.")—Congress omitted it from the final bill and instead enacted a statute containing no requirement that 340B drugs be dispensed by a covered entity. Congress's *removal* nearly three decades ago of any restriction on delivery site or dispensing mechanism can best be interpreted as evidence that it knew how to—but chose not to—restrict safety-net providers' access to the discount scheme. "[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), and Congress's clear choice to omit from the final bill *any* requirement that 340B-priced drugs be dispensed in-house or on-site precludes an interpretation that would impose those restrictions (or allow manufacturers to impose those restrictions) now—particularly in light of the fact that covered entities have relied on these mechanisms for decades.

HRSA's guidances bolster the interpretation set forth in the Violation Letter, and demonstrate that HRSA has always understood the statute (and, as evidenced by their past conduct, so have manufacturers) to prohibit drug makers from placing restrictive conditions on covered entities' access to 340B discounts. Nearly thirty years ago, HRSA issued "final program guidelines," after notice and comment, confirming that manufacturers *may not* place conditions, even those which purport only to "require [covered] entity compliance" with the statute, before fulfilling 340B orders. 59 Fed. Reg. at 25,112–14. In 1994, HRSA demonstrated the distinction between manufacturer requirements that *facilitate* access versus those that *restrict* access, explaining that manufacturers could "require the covered

entities to sign a contract containing only the manufacturer's normal business policies (e.g., routine information necessary to set up and maintain an account) if this is a usual business practice of the manufacturers." *Id.* at 25,112. But—although the ministerial task of collecting "standard information" such as that needed "to set up … an account" is permissible—HRSA made clear that manufacturers could not deny 340B purchases by covered entities unless non-statutory demands are met. "Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective," nor can they "place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program." *Id.* at 25,113. Indeed, "[a] manufacturer may not [even] condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions," and drug companies are prohibited from conditioning 340B sales on covered entities "submitting information related to drug acquisition, purchase, and inventory systems." *Id.* at 25,113-14. HRSA may not have conceived in 1994 of the *precise* restrictions UT now imposes, whereby it denies sales based on the delivery location and commonplace dispensing mechanism employed by the covered entity, but the agency made plain that manufacturers cannot impose their own conditions generally on whether, and when, they will fulfill 340B orders.

Aside from manufacturer-imposed conditions, that early guidance also confirms that pharmaceutical companies may not restrict the *methods* by which covered entities obtain and dispense drugs. UT's argument that the "offer" language in § 256b(a)(1) represents the full extent of its statutory obligation, *see, e.g.*, UT Mot. 27, 31, suggests that the requirement to offer discounted drugs was first imposed through language added in the 2010 amendments. But *in 1994*, HRSA interpreted the statute as it then stood to require that "manufacturers must offer covered outpatient drugs at or below the section 340B discount prices," and that, "[i]f the manufacturer's drugs are available to covered entities through wholesalers, the discount must be made available through that avenue." *Id.* at 25,113. Furthermore, that guidance—in response to a comment urging the agency *not* to require manufacturers to honor contract-pharmacy sales—confirmed that use of contract pharmacies "is a customary business practice," that "[e]ntities often use purchasing agents or contract pharmacies," and that "[b]y

placing such limitations on sales transactions," drug makers would "be discouraging entities from participating in the program." *Id.* at 25,111. In other words, since other commercial customers are freely able to purchase drugs through intermediaries and dispense to their patients through outside pharmacies, so too are 340B purchasers. *Id.* It also stated plainly that "[a] covered entity is permitted to use a purchasing agent without forfeiting its right to the section 340B drug discounts." *Id.* at 25,113. In this early guidance HRSA made plain that manufacturers *may not* place limitations on sales to covered entities based on the dispensing mechanism or purchasing arrangement selected by the covered entity, particularly for a "customary business practice" such as the use of "purchasing agents or contract pharmacies." *Id.* at 25,111.

In addition to the 1994 Guidance, both the 1996 and 2010 Guidances interpreted the statute to require manufacturers to honor purchases by covered entities regardless how they dispense those drugs (importantly, both guidances were issued *before* Congress amended the statute to include the "offer" language). *See* 61 Fed. Reg. at 43,549 ("the statute directs the manufacturer to sell the drug at the discounted price" regardless whether "a covered entity us[es] contract pharmacy services [when it] requests to purchase a covered drug"); *accord* 75 Fed. Reg. at 10,278 ("[I]f a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price," regardless whether the covered entity "directs the drug shipment to its contract pharmacy."). The 1996 Guidance explained that, if a covered entity "directs [a] drug shipment to its contract pharmacy," there is simply "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.

D. The decision in *Astra* does not compel a different interpretation.

The district court's recent decision in *Astra* does not answer the statutory question before this Court—whether HRSA correctly found that UT is violating its statutory obligation. Indeed, the Violation Letter was not even before the district court when it issued its decision. On the contrary,

the *Astra* court made plain that its "role" in that opinion was "to decide only the narrow question[]" whether "the position outlined in the [Advisory Opinion] [is] compelled by the unambiguous text of the 340B statute." *See Astra*, 2021 WL 2458063, at *1. Answering that question, the court found the Advisory Opinion to be "legally flawed," *id.* at *8, because its "analysis is not the sole reasonable interpretation of the statute," *id.* at *1. Far from setting forth a position *contrary* to law, however, the court confirmed that "HHS's current interpretation of the statute is permissible." *Id.* at *11. Thus not only did the *Astra* court have neither any claims regarding HRSA's Violation Letter nor the administrative record before it, the Court expressly found that the General Counsel's view regarding manufacturers' obligations represents a permissible reading, albeit not an unambiguous one.

HRSA respectfully disagrees that there is ambiguity regarding whether manufacturers can comply with their statutory obligations while denying 340B-priced drugs to covered entities based on the dispensing mechanism or delivery location chosen by the purchaser. In determining whether a statute is ambiguous, "a reviewing court [must] first exhaust[] [all of] the traditional tools of statutory construction to determine whether a congressional act admits of plain meaning." *See Ariz. Pub. Serv. Co. v. EPA*, 211 F. 3d 1280, 1287 (D.C. Cir. 2000); *accord Loving v. IRS*, 742 F.3d 1013, 1016 (D.C. Cir. 2014 ("In determining whether a statute is ambiguous …, [a court] must employ all the tools of statutory interpretation, including 'text, structure, purpose, and legislative history.'" (citation omitted)). As explained above, the text, structure, purpose, and history of the 340B statute collectively demonstrate that Congress carefully crafted a comprehensive scheme designed to allow safety-net healthcare providers and their patients to actually access discounted medications, which requires drug manufacturers to honor 340B purchases made by covered entities regardless of whether an in-house or outside pharmacy is used to dispense those drugs to patients.

But even if this Court agrees with the district court in *Astra* that the statute is ambiguous, HRSA's interpretation is based on the best reading of the statute and the agency's decades of expertise administering the statute, and thus HRSA's interpretation is entitled to deference. Moreover, the Violation Letter does not purport to rest on unambiguous statutory text (nor do the arguments presented herein depend on any lack of ambiguity), so HRSA's rationale would not suffer from the

same "flaw" identified by the *Astra* court. As demonstrated above, even if the Court finds ambiguity in the statute, HRSA's conclusion that UT is violating its statutory obligations by refusing discounted-drug orders made by covered entities and imposing unlawful, extra-statutory conditions is well-grounded in statutory text, congressional purpose, historic evidence of the agency's interpretation, and material in the administrative record.

And to the extent the Court finds ambiguity in the 340B statute, it should afford deference to HRSA's statutory interpretation under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), under which informal interpretations such as this one "are 'entitled to respect' … to the extent that [they] have the 'power to persuade.'" *Orton Motor, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 884 F.3d 1205, 1211 (D.C. Cir. 2018) (citation omitted). Because HRSA's interpretation is based on its "specialized experience" and the "broader … information available to [it]," *see Ctr. for Bio. Diversity v. Jackson*, 815 F.Supp.2d 85, 90–91 (D.D.C. 2011) (citation omitted), evidenced HRSA's "thorough[]" consideration and "valid[]" reasoning, and was "consisten[t] with earlier … pronouncements," the interpretation has the "power to persuade" and should be accorded deference, *Orton Motor*, 884 F.3d at 1211 (citation omitted).

The *Astra* court's other observations do not undermine HRSA's conclusions in the Violation Letter. True, as the court found, 340B "is silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs." *Astra*, 2021 WL 2458063, at *9. But as explained above, that observation overlooks the fact that Congress considered *and explicitly removed* a provision from the statute that would have limited 340B purchases to drugs dispensed in-house or on-site at a covered entity;[5] this, coupled with the fact that 95% of covered entities at the time of enactment did not have an in-house pharmacy, makes it unlikely that Congress created the 340B

[5] The *Astra* court wrote incorrectly that Congress considered including this restriction when it "added the 'must offer' requirement to the statute in 2010." *See Astra*, *See* 2021 WL 2458063, at *10. As explained above, Congress considered restricting covered entities to in-house or on-site dispensing *when the statute was enacted in 1992*. Rather than "suggest[ing] that Congress did not clearly intend to require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies," *id.*, Congress's *removal* nearly three decades ago of any restriction on delivery site or dispensing mechanism is best interpreted as evidence that it knew how to—but chose not to—restrict safety-net providers' access to the discount scheme.

Program in such a way that the majority of intended beneficiaries had no means to access the program's benefits in practice.[6] Similarly, the fact that § 256b(a)(1) is directed to the Secretary of HHS, requiring him to enter agreements obligating manufacturers to honor covered-entity purchases, *see id.* at *9, does not displace HRSA's finding because HRSA is acting (through delegation from the Secretary) to enforce against UT the requirement in the statute and its PPA to provide discounts to safety-net providers. In other words, the Violation Letter is HRSA's effort to effectuate § 256b(a)(1)'s command to the Secretary, and there is no question that the statute instructs the Secretary to ensure that covered entities are not charged more than the 340B ceiling price.

Because the decision in *Astra* was limited to the narrow ground of finding the Advisory Opinion erred in concluding its interpretation was compelled by unambiguous statutory text, and the court explicitly found that "HHS's current interpretation of the statute is permissible," *id.* at 22, *Astra* does not undermine HRSA's determination that UT is violating the statute.

II. HRSA'S VIOLATION LETTER IS NEITHER ARBITARY NOR CAPRICIOUS.

HRSA reasonably explained its conclusion that UT is violating its statutory obligation in the Violation Letter, and properly grounded its determination in the 340B statute's text. "The APA's arbitrary-and-capricious standard requires that agency action be [only] reasonable and reasonably explained." *FCC v. Prometheus Radio Proj.* (*Prometheus*), 141 S. Ct. 1150, 1158 (2021). Judicial review is

[6] HRSA respectfully disagrees with the *Astra* court's statement that "[t]he statute's total omission of contract pharmacies renders it ambiguous *with respect to the central issue in this case*." *Astra*, 2021 WL 2458063, at *9 (emphasis added). The central issue in that case (and this one) is not the role of contract pharmacies under 340B, but the obligation of drug makers to honor purchases by covered entities. Similarly, that court's statement that "[i]t is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication," *id.* at *10, is inapposite to HRSA's conclusion. HRSA is not including contract pharmacies as a "type of covered entity" nor allowing pharmacies to participate in 340B. Congress's "silence" strongly supports HRSA's conclusion: At time of the statute's enactment, the overwhelming majority of healthcare providers relied on outside pharmacies to serve their patients. Had Congress intended to *exempt* covered entities from the usual business practice of the day (and require them to undertake the expense and effort to dispense medications in-house) surely it would have said so explicitly. Finally, Congress's addition in 2010 of the non-discrimination requirement shows it intended covered entities to be treated on par with commercial purchasers—who plainly *are* permitted to serve patients through outside dispensers.

"deferential, and a court may not substitute its own policy judgment for that of the agency." *Id.* (citation omitted). A court "should 'uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned.'" *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 513–14 (2009) (citation omitted). UT's attempts to pick apart HRSA's reasoning are unpersuasive.

A. HRSA's determination has a reasonable basis in the administrative record.

Notwithstanding UT's arguments that the Violation Letter "contains no legal or factual justification," the Violation Letter is both grounded in HRSA's correct interpretation of the 340B statute—which HRSA alone is charged with administering—and supported by the administrative record. *See* UT Mot. 31. To survive a claim that HRSA's action was arbitrary and capricious, its conclusions need only be "reasonable and reasonably explained," based on consideration of "the relevant issues." *Prometheus*, 141 S. Ct. at 1158. Here, HRSA's conclusion that UT was overcharging covered entities in violation of the 340B statute was reasonably based on the statute itself, along with regulations HRSA promulgated regarding the imposition of CMPs. VLTR_11. And, as explained *supra* § I, the Violation Letter is consistent with the 340B statute.

UT's primary argument to the contrary is that the Violation Letter was improperly based on the since-withdrawn Advisory Opinion, the conclusions of which UT contends are not supported by the administrative record. UT Mot. 31–34. But the conclusions of the Advisory Opinion are wholly irrelevant here, as the Advisory Opinion—which was subsequently withdrawn and vacated—operated independently from the Violation Letter, and HRSA does not purport to base the Violation Letter on the Advisory Opinion. HRSA's Violation Letter is the culmination of a separate process begun *months* before the General Counsel issued the Advisory Opinion, and it is based on the statute itself along with evidence gathered through HRSA's investigative process. It also embodies a determination by a different entity—HRSA, the HHS operating division charged with administering Congress's mandate—that UT is overcharging covered entities and may face civil monetary penalties. More importantly, whereas the Advisory Opinion opined generally on what the 340B statute requires, without purporting to analyze the legality of UT's policy, the Violation Letter concludes directly and for the first time that UT's specific policy violates the statute. The actual dispute between the parties—

whether HRSA's violation finding is correct—must be decided on the basis of HRSA's reasoning in the Violation Letter and the administrative record supporting it, not by comparing the conclusions of the Advisory Opinion to the record supporting the Violation Letter. Moreover, HRSA's position about manufacturers' obligations should come as no surprise given its unequivocal view that manufacturers are obligated to honor covered entities' arrangements with contract pharmacies and may not impose extra-statutory restrictions or conditions on fulfillment of their drug purchases.

UT also argues that the Violation Letter cannot stand because it was based "on an erroneous view of the law." UT Mot. 33 (quoting *Prill v. NLRB*, 755 F.2d 941, 947 (D.C. Cir. 1985)). But, contrary to the line of cases holding that agency action is unlawful when the agency provides no basis for its decision other than an incorrect interpretation of the law, *see, e.g., Prill*, 755 F.2d at 947, HRSA's Violation Letter does not purport to rely on unambiguous statutory text or the withdrawn Advisory Opinion. True, HRSA found that UT's policy is directly violating its statutory obligation, consistent with conclusions made in the Advisory Opinion. But that is because HRSA found that UT is overcharging covered entities by wrongly denying 340B-drug "purchases by" covered entities. Were UT correct, there would be no need for HRSA officials to have spent months considering the impact of manufacturers' restrictions and compiling an 8,000+ page administrative record. Clearly, HRSA's careful analysis and evidence-gathering would have been unnecessary had its conclusions been based on nothing more than unambiguous statutory text or the Advisory Opinion, which was issued months after HRSA began its investigation.

Finally, the administrative record does contain evidence that UT overcharged covered entities. UC Davis Medical Center, for example, a disproportionate share hospital serving an area of more than 6 million residents, submitted a notice of "340B price unavailability" for drugs manufactured by UT. VLTR_5714. Santa Monica UCLAMC and Orthopedic Hospital and Ronald Reagan UCLA Medical Center did the same. *Id.* 5766, 5799. Regardless of the number of complaints, it is clear that HRSA considered evidence from these covered entities in determining that UT violated its statutory obligations.

B. Manufacturers' obligations have been consistent since at least 1994.

Despite UT's attempt to invent a change in HRSA's position over time, HRSA's guidance makes clear that its view of manufacturers' obligations has not changed in more than twenty-five years—manufacturers are obligated to honor covered entities' arrangements with contract pharmacies and may not impose extra-statutory obligations or conditions on fulfillment of covered entities' 340B-drug purchases. Because there has been no "change in position over time" for HRSA to explain, the Violation Letter is not rendered arbitrary and capricious by failure to do so. *See* UT Mot. 36–37.

In 1994, HRSA issued "final program guidelines," after notice and comment, confirming that manufacturers *may not* place conditions, even those which purport only to "require [covered] entity compliance" with the statute, before fulfilling 340B orders. 59 Fed. Reg. at 25,112–14. Aside from manufacturer-imposed conditions, that early guidance also confirms that drug makers may not restrict the *methods* by which covered entities obtain and dispense drugs. Furthermore, that guidance—in response to a comment urging the agency *not* to require manufacturers to honor contract-pharmacy sales—confirmed that use of contract pharmacies "is a customary business practice," that "[e]ntities often use purchasing agents or contract pharmacies," and that "[b]y placing such limitations on sales transactions," drug makers would "be discouraging entities from participating in the program." *Id.* at 25,111. It also stated plainly that "[a] covered entity is permitted to use a purchasing agent without forfeiting its right to the section 340B drug discounts." *Id.* at 25,113.

In 1996, HHS issued further guidance, concluding that the 340B statute does not allow drug makers to refuse 340B-discounted drug purchases by covered entities that rely on contract pharmacies. 61 Fed. Reg. at 43,549 (confirming that, if a covered "entity directs the drug shipment to its contract pharmacy," that in no way "exempts the manufacturer from statutory compliance"). There is nothing voluntary in that interpretation of the statute; on the contrary, the only voluntary aspect of the 1996 Guidance was the choice of covered entities whether to use contract-pharmacy arrangements, given that covered entities remain liable to prevent duplicate discounting and diversion regardless of the dispensing mechanism chosen for covered drugs. *See id.* at 43,549–50.

In 2010, HHS once again definitively set forth its statutory interpretation: "Under section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, *the statute directs the manufacturer to sell the drug* at a price not to exceed the statutory discount price." 75 Fed. Reg. at 10,278 (emphasis added). That mandatory language reiterated the agency's considered decision on what the *340B statute* requires—not, a new position or obligation created by the agency.

Consistent with these prior interpretations, the Violation Letter concluded that: "HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor [covered entities'] purchases regardless of the dispensing mechanism." VLTR_11. UT argues that the Violation Letter represents a shift in prior policy because it is the first time that HRSA explicitly took the position that manufacturers must recognize all of covered entities' contract-pharmacy arrangements. UT Mot. 36–37. But this is not the relevant inquiry. HRSA had no reason to be so explicit regarding manufacturers' obligations vis-à-vis *multiple* neighborhood pharmacies because HRSA repeatedly was clear that manufacturers cannot refuse covered entities' purchases based on dispensing mechanism or other manufacturer-imposed restrictions (and until mid-2020, manufacturers universally complied). Whether HRSA's allowance for the number of contract pharmacies *a covered entity may engage* has changed over time, each of these guidances consistently explained that "the statute directs the manufacturer to sell the drug at the discounted price" regardless whether "a covered entity us[es] contract pharmacy services [when it] requests to purchase a covered drug." 61 Fed. Reg. at 43,549. The broader obligation to honor 340B purchases without manufacturer-imposed restrictions encompasses the more-explicit discussion of the number of contract-pharmacy arrangements. Properly viewed as the obligation to provide discounts to covered entities without non-statutory restrictions, HRSA's interpretation of drug makers' obligations has not shifted over time.

C. The Violation Letter adequately addresses all relevant issues.

UT's argument that the Violation Letter fails to consider all relevant issues is rooted in a misunderstanding of the predominant replenishment model utilized by covered entities in their

contract-pharmacy arrangements and prior HRSA guidance, which, in any event, is not at issue in the Violation Letter. Generally speaking, under the replenishment model, a covered-entity patient who is 340B-eligible fills a prescription at a neighborhood pharmacy and, after the pharmacy dispenses the prescription out of its general inventory, its inventory is "replenished" with a drug that the covered entity has purchased at the 340B price. Decl. of Krista M. Pedley ("Pedley Decl.") ¶ 3, attached here as Exhibit 1;[7] *see also, e.g.*, VLTR_7323 (declaration of covered entity CEO explaining that "contract pharmacy partners use their own inventory for 340B eligible fills, and third-party administrators tally 340B accumulations and automatically trigger drug orders from the appropriate wholesaler to replenish their inventory whenever a full package size of a particular drug has been used"); VLTR_7257 (same).

The model works in three main steps. First, a contract pharmacy dispenses a drug to a patient, and 340B-tailored software programs determine whether the patient was eligible for 340B product. Pedley Decl. ¶¶ 5–6. The software is operated under the oversight of the covered entity, and HRSA audits the process by taking a sample of drugs dispensed and requiring the covered entity to show "each dispense that was deemed 340B-eligible is actually tied to a 340B-eligible patient." *Id.* ¶ 6. Second, the software will notify the covered entity that it may place a replenishment order for drugs when enough dispenses have accumulated to reach a pre-set package size. *Id.* ¶¶ 7–8; *see also, e.g.*, VLTR_7317 (covered entity CEO explaining "virtual inventory" system where "each contract pharmacy dispenses covered prescriptions to our patients, and when enough medication is dispensed … [the covered entity] places an order via our 340B wholesaler to replenish the contract pharmacies' stock"). Importantly, the replenishment order is placed on a covered entity's 340B account and the covered entity is billed for that order. Pedley Decl. ¶ 9. If any dispute (including instances of non-payment) about the invoice arises, it is the covered entity that is responsible—not the contract pharmacy—which merely serves as the "ship to" address on the invoice. *Id.* During this process, "the

[7] While UT's arbitrary-and-capricious claim should be decided on the basis of the administrative record, RADM Pedley submits her declaration in response to UT's reliance on statements therein as docketed in other, related cases.

covered entity is the legal purchaser and authorized the order." *Id.* ¶ 10; *see also, e.g.* VLTR_7296 (declaration of covered entity CEO explaining that it purchases "drugs at 340B pricing … and direct[s] those drugs to be shipped to our contract pharmacies on a replenishment basis," during which time the covered entity "maintains title to the drugs, but storage, distribution, and patient-related information is done by the contract pharmacies"); VLTR_7279 (same). Indeed, the covered entity should be aware of all replenishment orders, and "the order is often approved by the covered entity prior to submission to the wholesale/distributor to ensure accuracy." Pedley Decl. ¶ 10. Finally, the "replenished" drug is shipped to the contract pharmacy, where it becomes neutral inventory "and may be dispensed to any subsequent patient." *Id.* ¶ 11.

UT argues that this replenishment model enables diversion, but this claim is meritless. *See* UT Mot. 37–38. The 340B statute states that "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity," 42 U.S.C. § 256b(a)(5)(B), which means that covered entities may not provide discounted drugs for use by non-patients or non-covered providers for prescribing to their own patients. That straightforward limitation on use of 340B drugs cannot be stretched into an implicit prohibition on eligible patients physically attaining those drugs at neighborhood pharmacies where most Americans receive prescription drugs. Pharmacies only store and handle the medications on behalf of eligible patients of eligible covered entities; the drugs are not "transferred" for the pharmacy's own use. As explained above, each order for 340B drugs is explicitly tied to distributions of those drugs to eligible patients, and the proper understanding of the prohibition on transfer is only that "[c]overed entities are required not to resell or otherwise transfer outpatient drugs purchased at the statutory discount to an individual who is not a patient of the entity." *See* 59 Fed. Reg. at 25,112–13; *see also supra* § I.

Moreover, the Violation Letter does, in fact, "grapple" with the purported "diversion problem." *See* UT Mot. 38. The Violation Letter acknowledges that UT's "rationale for its restrictive action is to prevent diversion and duplicate discounts." VLTR_12. HRSA then goes on to explain that the "340B statute provides a mechanism by which a manufacturer can address these concerns"—by conducting an audit and proceeding through the administrative dispute-resolution process—and that

the statute "does not permit a manufacturer to impose industry-wide, universal restrictions." *Id.* Though UT surely disagrees with HRSA's conclusion, UT cannot reasonably argue that HRSA did not consider diversion in issuing the Violation Letter.

UT's reference to HRSA's 1996 and 2010 Guidances does not undermine the reasonableness of HRSA's determination. HRSA's conclusions need only be "reasonable and reasonably explained," based on consideration of "the relevant issues." *Prometheus*, 141 S. Ct. at 1158. UT claims that the Violation Letter is in conflict with non-binding guidance issued in 1996 and 2010 providing sample contract provisions for covered entities use in their arrangements with contract pharmacies. UT Mot. 39–40. Yet, along with the sample provisions, HRSA explicitly stated that the provisions were only "included for illustrative purposes" and were "not intended to be comprehensive, exhaustive or required." 75 Fed. Reg. at 10,279. UT fails to offer any explanation as to why this non-binding guidance is relevant to HRSA's determination that UT's policy is unlawful. Because reliance on an agency's failure to consider irrelevant factors is not a ground on which to find agency action arbitrary and capricious, UT's argument is meritless. *See Confederated Tribes of Coos, Lower Umpqua & Siuslaw Indians v. Babbitt*, 116 F. Supp. 2d 155, 165 (D.D.C. 2000) ("Although the agency did not consider other possible interpretations, it was not arbitrary and capricious to not consider materials, which under the interpretation being employed, were irrelevant.").

D. HRSA reasonably concluded that UT's claims-data policy is unlawful.

UT also attacks HRSA's determination that its claims-data policy is unlawful. UT Mot. 40–43. But the relevant question for this Court is not, as UT appears to suggest, the merits of UT's particular policy. The question is whether HRSA's determination is reasonable, and HRSA's determination easily meets that standard.

As an initial matter, UT's argument that it may place any conditions on delivery to contract pharmacies because recognition of these arrangements is "voluntary" is incorrect. *See* UT Mot. 40. To the contrary, and as explained *supra* § I, manufacturers are statutorily required to provide discounted drugs to covered entities, regardless of the delivery mechanism they use, including contract-pharmacy

arrangements. Thus, UT is not empowered to create its own extra-statutory conditions outside of those which Congress directed.

Moreover, historic evidence demonstrates that HRSA always has understood the statute (and so have manufacturers) to prohibit drug makers from placing restrictive conditions on covered entities' access to 340B discounts. As explained above, *see supra* § I.C., HRSA's confirmed in its 1994 Guidance that manufacturers *may not* place conditions, even those which purport only to "require [covered] entity compliance" with the statute, before fulfilling 340B orders. 59 Fed. Reg. at 25,112–14. This guidance drew the distinction between manufacturer requirements that *facilitate* access to 340B-discounted drugs and those that *restrict* such access: While manufacturers are permitted to require "covered entities to sign a contract containing" provisions reflecting "the manufacturer's normal business policies (e.g., routine information necessary to set up and maintain an account)," *id.* at 25, 112, HRSA made clear that "[m]anufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective," nor can they "place limitations on the transactions … which would have the effect of discouraging entities from participating in the discount program." *Id.* 25,113. Accordingly, "[a] manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions," nor may a manufacturer condition 340B sales on covered entities "submitting information related to drug acquisition, purchase, and inventory systems." *Id.* at 25,113–14. HRSA thus made plain in 1994 that manufacturers cannot impose their own conditions generally on whether, and when, they will fulfill 340B orders.

UT suggests that its claims policy is lawful because it "simply provides UT a mechanism to confirm that an entity seeking 340B discounts is, in fact, a statutory covered entity," by confirming the entity is complying with the prohibition on duplicate discounts. UT Mot. 41. But the statute provides the remedy for concerns by manufacturers that a covered entity is violating its own statutory obligations. That is, manufacturers must audit the covered entity and then utilize the administrative dispute-resolution process. 42 U.S.C. § 256b(d)(3). Nothing in the statute allows UT to make an end run around the congressionally mandated audit and dispute-resolution process by implementing UT's

own self-help measures. In light of the statutory scheme and HRSA's historical understanding, its determination that UT's claims data policy is unlawful is eminently reasonable.

E. UT's attempt to pre-litigate the propriety of civil monetary penalties should be rejected.

UT's attempt to pre-litigate whether its overcharges constitute "knowing and intentional" violations sufficient to support sanctions should be rejected. *See* UT Mot. 43–45. As an initial matter, HRSA has made clear that UT's overcharges *may* lead to sanctions, but has not yet imposed any penalties, so any dispute over yet-to-be-determined penalties is unripe. *See* VLTR_12. For that reason, the government omits here substantive discussion as to whether UT's overcharges are knowing and intentional (but certainly does not concede the issue). UT's underlying theory, however, is meritless.

According to UT, it cannot possibly "overcharge" a covered entity because "when UT denies a 340B contract pharmacy order under its policies," it "declines the fill the order altogether." UT Mot. 44. HRSA has long made clear, however, that evidence of overcharges may include "cases where refusal to sell at the 340B price has led to the purchase of the covered outpatient drug outside of the 340B Program." *See* 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57,233, 57,234 (Sept. 20, 2010); *see also* 42 C.F.R. § 10.21(c)(1) (recognizing that, through 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"); 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210, 1,226 (Jan. 5, 2017) ("When a manufacturer's documented refusal to sell or make drugs available at the 340B ceiling price results in the covered entity purchasing at the non-340B price, a manufacturer's sale at the non-340B price could be considered an instance of overcharging."). Although UT claims not to automatically "convert" 340B orders to commercial orders, the fact that the covered entity does not have access to the statutory ceiling price and the covered entity had to forego the 340B benefit constitutes an overcharge. And although UT may disagree, HRSA's position on manufacturers' obligations has remained consistent over time. *See supra*, § II.B.

It is certainly the case that the 340B statute does not allow contract pharmacies to participate in or become beneficiaries of the 340B Program, and that UT has no obligation to sell discounted drugs to *any* pharmacies. But the statute conditions Medicaid and Medicare Part B access on UT's agreement to provide its discounted drugs to covered entities, and does not authorize UT to place barriers that make those purchases inaccessible in practice. HRSA's review of the evidence has demonstrated that UT is denying 340B sales *to covered entities* when those providers dispense drugs to patients through their contract pharmacies.

CONCLUSION

Because each of UT's claims is meritless, the Court should grant summary judgment in favor of HHS and deny UT's motion for summary judgment.

Dated: August 10, 2021

Respectfully submitted,

BRIAN D. NETTER
Deputy Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Jody D. Lowenstein
JODY D. LOWENSTEIN
Mont. Bar No. 55816869
KATE TALMOR
RACHAEL L. WESTMORELAND
Trial Attorneys
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street NW
Washington, D.C. 20005
Phone: (202) 598-9280
Email: jody.d.lowenstein@usdoj.gov

Attorneys for Defendants

Exhibit 1

DECLARATION OF KRISTA M. PEDLEY

I, Krista M. Pedley, declare as follows pursuant to 28 U.S.C. § 1746:

1. I currently serve as Director of the Office of Pharmacy Affairs (OPA), Health Resources and Services Administration (HRSA), United States Department of Health and Human Services (HHS). OPA is the component within HRSA with primary responsibility for the day-to-day administration of the 340B Program. I have worked at OPA since 2007 and served as Director since 2010. In my role at OPA, I have acquired deep knowledge of and experience with the functioning of all facets of the 340B Program, including covered entities' use of contract pharmacies.

2. I submit this Declaration to respond to certain factual representations that I understand have been made by drug manufacturers and a consultant for the pharmaceutical industry, Aaron Vandervelde, in litigation involving the issue of contract-pharmacy use. Specifically, Mr. Vandervelde has submitted amicus briefs in various cases that describes the "replenishment model" used in some contract-pharmacy arrangements. *See* Br. of 340B Expert Aaron Vandervelde as Amicus Curiae in Support of Neither Party, *Eli Lilly and Company et al. v. HHS et al.*, 21-cv-81 (S.D. Ind. May 12, 2021), Dkt. 92-1 at 13-14; *AstraZeneca Pharmaceuticals LP v. Becerra et al.*, 21-cv-27 (D. Del. Apr. 16, 2021), Dkt. 46; *Sanofi-Aventis U.S., LLC v. HHS et al.*, 21-cv-634 (D.N.J. May 13, 2021), Dkt. 71-2. The drug manufacturers, in reliance on Mr. Vandervelde's brief, have also made assertions about how contract-pharmacy arrangements work. *See* Tr. of May 27, 2021 Hrg., *AstraZeneca Pharmaceuticals LP v. Becerra et al.*, 21-cv-27 (D. Del.), 10:6-14:6; Tr. of May 27, 2021 Hrg., *Eli Lilly and Company et al. v. HHS et al.*, 21-cv-81 (S.D. Ind.), 20:9-15, 22:21-25, 67:8-14.

3. The following paragraphs describe my understanding of how, in general, contract-pharmacy arrangements work under the replenishment model. Of course, contract-pharmacy arrangements vary, and I cannot speak to the exact details of every existing relationship between a covered entity and contract pharmacy. But at its most basic level, under the replenishment model, to the extent that

an individual is determined to have been a 340B patient of the covered entity, the contract pharmacy's drug inventory is "replenished" with a drug purchased directly by a covered entity at the 340B discount after a drug is dispensed.

4. As an initial matter, for all contract-pharmacy arrangements (replenishment or otherwise), a covered entity may establish a relationship directly with a pharmacy, or it may elect to employ a third-party vendor or administrator (TPA) to facilitate data-capture and reporting in the administration of a covered entity's contract-pharmacy program. In the former situation, the covered entity sends data feeds about its patients' 340B eligibility directly to the contract pharmacy; in the latter, it sends that data to the TPA.

5. The replenishment model proceeds in three steps. First, a contract pharmacy dispenses a certain drug in a certain amount—say, 90 tablets of Amoxicillin—to a patient (the dispense). That patient may present a prescription to the pharmacy, or the dispense may result from "e-prescribing," whereby the covered entity directly transmits the prescription to the pharmacy. Either way, the dispensed drug comes from the contract pharmacy's own inventory.

6. Various 340B-tailored software programs exist to evaluate each dispense. That software compares the information about the dispense with eligibility criteria provided from the covered entity, in order to determine if the patient was eligible for 340B product. The software operates under the oversight of the covered entity, in that each 340B-eligible dispense is recorded and reported to the covered entity. And HRSA audits this process: we obtain a random sample of the drugs dispensed, and the covered entity has to provide auditable records that show each dispense that was deemed 340B-eligible is actually tied to a 340B-eligible patient. Each year, HRSA audits approximately 200 covered entities, along with any of the covered entities' contract-pharmacy arrangements.

7. Second, the 340B software notifies the covered entity that it may place a replenishment order for the drug in question—90 tablets of Amoxicillin—under the covered entity's 340B account with the relevant wholesaler. The replenishment order has to be an exact 11-digit match under the National Drug Code (NDC) system for the product that was identified by the software. (The NDC for a product identifies (1) the product's labeler, *i.e.* manufacturer or distributor; (2) the identity of the product, *i.e.* strength, dosage form, and formulation of the drug; and (3) the product's package size and type.)

8. The trigger for a replacement order will not usually be a single dispense. Rather, the TPA and/or contract pharmacy will "accumulate" 340B-eligible dispenses of a specific 11-digit NDC product towards a pre-set package size. So, for example, a package may be 270 tablets of Amoxicillin, which means that it would take 3 dispenses of the 90-tablet bottles to accumulate one package and lead to submission of a replenishment order. Covered entities are provided accumulation reports where they can track each accumulation to a specific patient/dispense.

9. As noted, the replenishment order will be placed on a covered entity's 340B account with the relevant wholesaler. The 340B account is in the covered entity's name and reflects its financial payment information. That 340B account reflects a "bill to" address and "ship to" address. The covered entity is reflected as the "bill to" party; the contract pharmacy (or sometimes, its warehouse) is reflected as the "ship to" address. The wholesaler invoice shows the covered entity as the purchaser of the product under the "sold to" field. And so, the covered entity pays for and purchases the drug at the 340B discount price from the wholesaler. If the wholesaler's invoice is not paid, it will seek to collect payment from the covered entity directly—not the contract pharmacy.

10. While it is true that the logistics of placing the replenishment order can vary—for example, sometimes the covered entity places the order, sometimes the contract pharmacy orders it as a purchasing agent of the covered entity, sometimes the order is submitted by the TPA—HRSA

understands that the covered entity is the legal purchaser and authorizes the order. If the replenishment order is sent on behalf of the covered entity, the entity should be aware of the replenishment order; indeed, the order is often approved by the covered entity prior to submission to the wholesaler/distributor to ensure accuracy.

11. Third and finally, the drug in question—90 tablets of Amoxicillin—is shipped to the contract pharmacy, where it is placed on the shelf, becomes "neutral inventory," and may be dispensed to any subsequent patient.

12. When utilizing a replenishment model, covered entities must ensure that appropriate safeguards are in place at the contract pharmacy to ensure that the covered entity is replenishing inventory with 340B drugs only in instances where drugs have been provided to qualified 340B patients. The covered entity must have systems in place to be able to demonstrate that the covered entity is properly accounting for 340B purchases in a replenishment system. HRSA ensures that is the case through the audits mentioned above (¶ 6).

13. OPA maintains the 340B Office of Pharmacy Affairs Information System (OPAIS), a database that assists in the functioning of the 340B Program. When registering on OPAIS, a covered entity must list its contract pharmacy(ies), and that listing must reflect a bill-to/ship-to arrangement. Thus, OPAIS clearly shows that the covered entity, as the bill-to party, is the party that purchases the 340B drugs.

Executed on June 16, 2021, in Frederick, MD.

Krista M. Pedley -S

Digitally signed by Krista M. Pedley -S
Date: 2021.06.16 12:41:17 -04'00'

Krista M. Pedley, PharmD, MS
RADM, USPHS
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
United States Department of Health and Human Services

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)

PROPOSED ORDER

Upon consideration of Defendants' Motion for Summary Judgment, Plaintiff's Motion for Summary Judgment, the parties' memoranda of points and authorities, and the administrative record, the Court hereby GRANTS Defendants' Motion for Summary Judgment as to all claims contained in Plaintiff's Complaint for Declaratory and Injunctive Relief and DENIES Plaintiff's Motion for Summary Judgment.

SO ORDERED.

Dated: _____

Signed:_____
The Honorable Dabney L. Friedrich
United States District Judge

NAMES OF PERSONS TO BE SERVED WITH PROPOSED ORDER

Pursuant to LCvR 7(k), the following attorneys are entitled to be notified of the entry of the foregoing proposed order:

Andrew D. Prins
LATHAM & WATKINS LLP
555 11th Street, NW
Suite 1000
Washington, DC 20004-1304
(202) 637-2200
Email: andrew.prins@lw.com

Gregory B. IN Den Berken
LATHAM & WATKINS LLP
555 11th Street, NW
Suite 1000
Washington, DC 20004
(202) 637-2200
Email: Greg.indenBerken@lw.com

Ryan S. Baasch
LATHAM & WATKINS LLP
555 11th St, NW
Suite 1000
Washington, DC 20004
(202) 637-2200
Email: ryan.baasch@lw.com

Philip Jonathan Perry
LATHAM & WATKINS LLP
555 11th Street, NW
Suite 1000
Washington, DC 20004-1304
(202) 637-2244
Email: philip.perry@lw.com

Jody D. Lowenstein
U.S. DEPARTMENT OF JUSTICE
Civil Division, Federal Programs Branch
1100 L Street NW
Washington, DC 20005
(202) 598-9280
Email: jody.d.lowenstein@usdoj.gov