IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED THERAPEUTICS CORPORATION,

Plaintiff,

v.

DIANA ESPINOSA, Acting Administrator of U.S. Health Resources and Services Administration, U.S. HEALTH RESOURCES AND SERVICES ADMINISTRATION, XAVIER BECERRA, Secretary of Health and Human Services, and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants.

Case No. 1:21-cv-1686

MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

This case is about a federal program that has run off the rails. In 1992, Congress enacted the 340B Drug Pricing Program (known as the "340B program"), mandating that pharmaceutical manufacturers provide substantial discounts to 15 specified types of healthcare providers. These so-called "covered entities" treat indigent, uninsured, and certain other specific vulnerable patient populations. *See* 42 U.S.C. § 256b. The principal purpose of the program was to provide financial assistance to these covered entities and their patients. Congress anticipated that the covered entities would pass on the drug discounts to the vulnerable patient populations they serve. *See* H.R. Rep. No. 102-384, pt. 2, at 12 (1992). But the program is not operating in remotely that fashion. This is because the federal agency charged with administering the program—the U.S. Health Resources and Services Administration (HRSA)—has taken a series of steps through informal "guidance" that transformed the program from what Congress intended into something very different. Now, rather than providing deeply discounted drugs to select, statutorily specified healthcare providers and their patients, the program has been leveraged as a tool to enhance the profitability of commercial pharmacies that Congress never intended would benefit from it.

The root of the problem is HRSA's "contract pharmacy" guidance. A "contract pharmacy" is not part of any "covered entity" entitled to the statutory 340B drug discounts—it is a separate commercial entity that dispenses drugs to all patients who walk in the door, regardless of whether those patients are linked to covered entities. Indeed, the 340B statute does not identify any role in the 340B program for contract pharmacies at all. As one court recently explained: "It 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." *Astrazeneca Pharms. LP v. Becerra*, No. 21-cv-27, 2021 WL 2458063, at *10 (D. Del. June 16, 2021).

The agency's initial 1996 guidance provided that a covered entity that did not have an in-house pharmacy (and thus could not pass on the benefits of 340B discounts) could contract with *one* outside pharmacy to act functionally as if it were indeed an in-house pharmacy—dispensing drugs to the covered entity's patients. *See* HRSA, *Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services*, 61 Fed. Reg. 43,549, 43,555 (Aug. 23, 1996). And the 1996 HRSA guidance identified specific protocols to ensure that the benefits of the program *only* reached the covered entity's patients. *See id.* at 43,553-55. In 2010, however, HRSA radically altered this guidance, allowing covered entities to engage an *unlimited* number of contract pharmacies to fill patient prescriptions without effective safeguards. *See infra* at 11-12.

HRSA's 2010 policy change had a significant and predictable effect: Over time, tens of thousands of pharmacies (including the nation's largest pharmacy chains) developed a business model that leveraged the 340B program for profit. These pharmacies signed up covered entities as contract partners so that they could take advantage of 340B discounts. Under this scheme, the contract pharmacies (or other third parties working with them) would perform their own undisclosed data analyses and claim the right to 340B discounts. And these 340B discounts would then apply to drugs that the contract pharmacies had already purchased and dispensed to their customers—apparently on the theory that a percentage of those customers had some form of existing or prior relationship with a covered entity sufficient to rationalize a 340B discount. *See infra* at 13-15. This effort paid off for the contract pharmacies. The pharmacies received a windfall: a share of after-the-fact 340B discounts for drugs that they had previously dispensed and been reimbursed for, at materially higher prices. *See id.* (discussing "replenishment" model). One national pharmacy gained such a significant windfall from this business model that it publicly

reported that any legal change disallowing the practice would be "material" to its business. *See infra* at 15.

Under HRSA's 2010 policy, the number of claims for 340B discounts nationwide tripled between 2014 and 2019. *See infra* at 13. Plaintiff United Therapeutics Corporation (UT) felt the specific impact of HRSA's 340B policy changes. For example, UT data demonstrate that between 2018 and 2020 the number of 340B discount claims for certain UT drugs grew substantially. Decl. of David Barton in Supp. of Pl.'s Mot. for Summ. J. (Barton Decl.) ¶ 9. UT is aware of no appropriate rationale for this increase in 340B utilization. *Id.* ¶ 10. Multiple government audits and reports have identified significant problems associated with HRSA's contract pharmacy policy, including evidence that covered entities and contract pharmacies were engaging in statutorily forbidden "diversion"—selling 340B drugs to non-340B patients. *See infra* at 16-17.

UT is one of seven pharmaceutical manufacturers who have begun to institute measures to stem 340B program abuses. UT's measures consist of two policies for covered entities that use contract pharmacies, both of which are carefully constructed to be consistent with 42 U.S.C. § 256b(a) and the agreement entered between HRSA and UT pursuant to that provision.

(1) UT's Contract Pharmacies Policy: UT's contract pharmacies policy applies to a small number of UT outpatient drug products, and each of those products is only sold through one of two specialty pharmacies that deliver those drugs by mail. *See infra* at 18-19. Virtually all the covered entities with health care providers that prescribe these drugs have long had contract pharmacy relationships with one of these specialty pharmacies. Under UT's policy, UT will continue to ship drug orders to the relevant specialty pharmacy for every covered entity that utilized that pharmacy as a contract pharmacy during the first three full quarters of the 2020 calendar year (January 1 through September 30). UT will also allow any other covered entities

the opportunity to designate a relevant specialty pharmacy for shipment, so long as those covered entities do not have their own pharmacy in house.

(2) UT's Claims Data Portal Policy: UT has also identified, but not yet implemented, a plan to require that orders placed for the drugs at issue identify certain claims data—through an easy-to-use portal—that will allow UT to ensure that the orders placed are *bona fide* and do not double-count other discounts. Nothing in the statute can plausibly be read to forbid this.

On May 17, 2021, HRSA began issuing the letter decisions challenged here containing specific threats of enforcement. HRSA has admitted that these letter decisions are "final agency action" subject to judicial review. *See infra* at 24. And all six of the May 17 letter decisions HRSA sent to drug manufacturers make the same core allegations using basically the same text. Indeed, some allegations in the letter to UT appear simply to be copied and pasted from other HRSA letters to other drug manufacturers, even though UT's policies on contract pharmacies are materially different.

HRSA's letter decision with respect to UT concludes that UT's policies are illegal under the statute and "have resulted in overcharges" giving rise to penalties. VLTR_000011-12.[1] Although HRSA asserted that the agency conducted "an analysis of the complaints" regarding UT, HRSA provided no "complaints" or "analysis" with its decision. The administrative record now demonstrates that: (1) nothing in HRSA's possession substantiates any claim that UT's policies are actually unlawful; and (2) contrary to the express statements in its May 17 letter, HRSA apparently conducted *no analysis* of any supposed "complaints" regarding UT that could justify its conclusions. Indeed, UT is aware of *no data* that could conceivably show its current policies

[1] All citations to documents starting as "VLTR" are to the administrative record, excerpts of which will be filed as a Joint Appendix pursuant to the Court's July 8, 2021 Minute Order.

are improperly reducing 340B utilization in any way. To the contrary, in aggregate, the number of UT's 340B discounts has *risen* since its policy was instituted, and nothing in the record demonstrates otherwise. *See infra* at 25.

UT responded to HRSA's May 17 letter and a subsequent May 28 HRSA letter (collectively, HRSA's "Violation Determination"), by raising significant concerns and asking HRSA to withdraw its decision and threat of enforcement. *See* Barton Decl., Ex. E (June 10 UT letter). But HRSA failed to respond. The threats in these letters are very serious. One possible consequence is being terminated from the 340B program, and if that happens, the manufacturer is, by statute, unable to participate in the Medicaid and Medicare Part B programs. This outcome would not only be detrimental to UT but would deprive beneficiaries under these programs of access to lifesaving therapies. HRSA posted its letter decisions declaring that UT and the other manufacturers "are in direct violation of the 340B statute" on its website, along with an additional announcement of that finding.[2]

UT seeks summary judgment on the following grounds:

First, HRSA's legal interpretation, implemented through its Violation Determination, contravenes the plain text of Section 340B. UT is not required by the 340B statute to deal with *any* contract pharmacy (although it voluntarily does so, as described above), let alone in the manner dictated by HRSA. The 340B statute requires participating manufacturers to "offer each *covered entity*" discounted 340B drugs. 42 U.S.C. § 256b(a)(1) (emphasis added). The statute contains a comprehensive list of entities that qualify as a "covered entity," and that list does not include

[2] HRSA, Off. of Pharmacy Affs., *340B Drug Pricing Program: Program Integrity* (May 2021), https://www.hrsa.gov/opa/program-integrity/index.html (listing letters); HRSA, Off. of Pharmacy Affs., *340B Drug Pricing Program* (May 2021), https://www.hrsa.gov/opa/index.html (announcement).

contract pharmacies. *Id.* § 256b(a)(4). And HRSA cannot circumvent that fact by claiming that contract pharmacies are operating in concert with their covered entity partners because the statute also expressly bars the "transfer" of any 340B drug to any entity or person other than a covered entity and its patients.

Second, HRSA's stated conclusion—that UT's two contract pharmacy policies violate the statute—is also invalid because it rests on no valid legal or factual foundation. The Violation Determination appears to rest on reasoning from an HHS General Counsel Advisory Opinion that one court has already concluded was invalid and vacated. And if that is not the agency's rationale, then the Violation Determination appears to rest on no rationale at all. In addition, the administrative record as a whole contains no evidence that could otherwise establish that contract pharmacies are legally one-and-the-same as covered entities, much less that, in UT's unique limited distribution model involving specialty pharmacies, UT has failed to provide the 340B price to covered entities.

Third, the Violation Determination is arbitrary and capricious because it failed to acknowledge, let alone explain, the agency's sudden change in policy that manufacturers are now *legally bound* to ship 340B drugs to a limitless number of contract pharmacies.

Fourth, the Violation Determination is arbitrary and capricious because it failed to consider and address a significant part of the regulatory problem: The severe risks that multiple government investigators have substantiated regarding how the 340B system is being widely abused. HRSA is either unable or unwilling to conduct genuine audits of the contract pharmacies and third-party administrators involved with this abuse, and provides manufactures no ability to do so either.

Fifth, the Violation Determination's specific conclusion that UT's claims data portal policy is unlawful and independently violates the statute and the Administrative Procedure Act (APA) for the additional reason that, even if the agency can force manufacturers to deal with contract pharmacies, there is no plausible argument that it can prohibit them from seeking basic *information* from covered entities about the prescriptions that those pharmacies will fill. Nor has the agency articulated any reasonable rationale for such a prohibition.

Sixth, the Violation Determination is unlawful because it concluded that UT may be subject to civil monetary penalties for "overcharges" to covered entities. But UT *does not overcharge covered entities*—even if they fail to comply with UT's contract pharmacy policies. This conclusion appears to be predicated on "complaints," but as noted, the agency appears to have done no analysis at all of any "complaints" actually relating to UT.

The Court should set aside the Violation Determination, declare that UT's policies do not violate Section 340B, and grant any other relief as appropriate.

STATEMENT OF FACTS

A. Statutory And Regulatory Framework

In 1992, Congress established the 340B Drug Pricing Program. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71 (Nov. 4, 1992) (codified as amended at 42 U.S.C. § 256b). "Under the 340B Program, certain hospitals and clinics ('covered entities') may purchase prescription drugs for their patients at or below maximum prices set by statute." *Astrazeneca*, 2021 WL 2458063, at *1. The term "covered entity" is a statutory term of art that sweeps in 15 enumerated types of facilities. *See* 42 U.S.C. § 256b(a)(4). Congress defined the types of facilities it intended to benefit at a fine level of granularity. *See, e.g., id.* § 256b(a)(4)(G) (providing that one type of "covered entity" is a "comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act").

The unifying feature of the covered entities is that they all "generally care for underserved populations." *Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 822 (D.C. Cir. 2020); *see also* H.R. Rep. No. 102-384, pt. 2, at 12. HRSA has explained that the 340B discount is intended to benefit uninsured and underserved populations in two ways. First, covered entities can "pass all or a significant part of the discount to their patients." 61 Fed. Reg. at 43,551. Second, they can "set the price [of the drug] slightly higher" than the discount cost they acquired it at, charge the patient (or their insurer), and then use the net proceeds "to reach *more* eligible patients and provide *more* comprehensive services." *Id.* (emphases added).

The 340B statute requires participating pharmaceutical manufacturers to supply drugs to these covered entities, but not to any others. The statute accomplishes this goal through a contractual mechanism—HHS is directed to "enter into an agreement" with pharmaceutical manufacturers under which the amount a "covered entity" is "required" to pay for certain of the manufacturer's prescription drugs "does not exceed" a certain maximum ceiling price, calculated under a statutory formula. 42 U.S.C. § 256b(a)(1). This contract is known as the "Pharmaceutical Pricing Agreement" (PPA). *See Astra U.S.A., Inc. v. Santa Clara Cnty., Cal.*, 563 U.S. 110, 113 (2011). The PPA's terms are "no[t] negotiable," and they mirror the statute's requirements. *Id.* at 118 ("The statutory and contractual obligations, in short, are one and the same." (citation omitted)). Nothing in the PPA mentions contract pharmacies, or any manufacturer obligation to sell or ship to them. Although it is nominally optional for pharmaceutical manufacturers to participate in the 340B program, *see id.* at 117-18, they have no choice as a practical matter: "[I]f drug manufacturers wish to receive reimbursements for their drugs under Medicare Part B and Medicaid programs, [they] *must* permit covered entities to buy those drugs at the 340B Program's discounted rates." *Astrazeneca*, 2021 WL 2458063, at *1 (emphasis added); 42 U.S.C. § 1396r-8(a)(1), (5).

Congress also enacted provisions to ensure that the 340B program was not manipulated. Under the 340B statute, a covered entity may not cause "duplicate discounts or rebates," which occur, for example, when a manufacturer sells a unit of covered outpatient drug to a covered entity at the 340B discounted price and then also is invoiced for a Medicaid rebate on the same unit. 42 U.S.C. § 256b(a)(5)(A). Among other restrictions, covered entities cannot dispense 340B drugs to Medicaid beneficiaries (thereby triggering a manufacturer rebate obligation to Medicaid) without taking certain steps to guard against a duplicate discount. Covered entities are also forbidden from engaging in "diversion"—*i.e.*, "resell[ing] *or* otherwise transfer[ring] [a 340B discounted] drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B) (emphasis added). Moreover, *covered entities* must permit both HHS and manufacturers to "audit" "the records of the entity that directly pertain to the entity's compliance with the" bars on duplicate discounting and diversion. *Id.* § 256b(a)(5)(C). Nothing in the statute obligates contract pharmacies, or other third-party administrators involved in seeking 340B discounts, to subject themselves to audits.

In 2010, Congress added specific provisions for sanctioning either covered entities or pharmaceutical manufacturers who violate the terms of the 340B statute. *Id.* § 256b(d). Penalties against manufacturers can be triggered if a manufacturer "knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum" price permitted under the statute. *Id.* § 256b(d)(1)(B)(vi).

B. HRSA Authorizes Covered Entities to Use Contract Pharmacies

During the first four years of the 340B program, covered entities were supposed to obtain and dispense 340B drugs only through their own in-house pharmacies. In 1996, however, HRSA issued guidance that purported to open the door to contract pharmacy use. *See* 61 Fed. Reg. 43,549.

But this doorway was quite narrow. Covered entities could contract with only a *single* contract pharmacy location—for the purpose of "facilitat[ing] program participation for those eligible covered entities that do not have access to appropriate 'in-house' pharmacy services." *Id.* at 43,551; *see also* HRSA, *Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services*, 72 Fed. Reg. 1,540 (Jan. 12, 2007) (confirming that the state of play under the 1996 guidance was that a "covered entity could contract with *only one* pharmacy to provide all pharmacy services for any particular site of the covered entity" (emphasis added)). The 1996 guidance also did not *obligate* manufacturers to sell or ship to contract pharmacies but conveyed only HRSA's non-binding interpretation of how covered entities could choose to do business; it specifically confirmed that its guidelines "create no new law and create no new rights or duties." *See* 61 Fed. Reg. at 43,550. The guidance also did not identify statutory support for its recognition of contract pharmacies. Instead, HRSA candidly admitted that "[t]he statute is silent as to permissible drug distribution systems." *Id.* at 43,549.

That said, the guidance contained multiple important parameters on contract pharmacies' ability to dispense 340B drugs. HRSA explained that a contract pharmacy should only dispense a 340B drug either (a) "[u]pon presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient, and the signature of a legally qualified health care provider affiliated with the covered entity" or (b) after "receipt of a prescription ordered by telephone on behalf of an eligible patient by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an eligible patient." *Id.* at 43,556. HRSA stated those requirements were added because "[t]he contractor should have some type of assurance that the patient to whom the contractor is dispensing the 340B drug is a patient of a covered entity participating in the 340B Program[]" at the time of the transaction. *Id.*

at 43,553. HRSA set forth a list of "[s]uggested [c]ontract [p]rovisions" to govern covered entity arrangements with contract pharmacies—*i.e.*, that the "covered entity [not the contract pharmacy or any other third-party] will order covered drugs directly." *Id.* at 43,556. Under the 1996 guidance, many contract pharmacies maintained a separate physical inventory of 340B drugs that it would dispense only to the covered entity's patients.

In 2010, without any intervening change in the 340B statute, HRSA shifted course and issued guidance that fundamentally changed its policy. HRSA, *Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services*, 75 Fed. Reg. 10,272 (Mar. 5, 2010). Under that guidance, rather than just using *one* contract pharmacy location, covered entities could instead enter arrangements with an *unlimited* number of contract pharmacies. *Id.* HRSA identified no statutory basis for its new 2010 guidance but claimed that the guidance "impose[d] [no] additional burdens upon manufacturers." *Id.* at 10,273.

Although HRSA's 2010 guidance dramatically expanded the scope of contract pharmacy use under the 340B program, the agency mostly deferred to *covered entities* to determine how to implement this significant new change. On the one hand, the guidance established that covered entities must include certain "essential elements" in their contract pharmacy arrangements, including that the covered entity "*maintain title* to the drug and *assume responsibility for establishing its price*." *Id.* at 10,277 (emphases added). But it gave covered entities substantial discretion in practice on how to structure their agreements with contract pharmacies. Specifically, the agency again set forth a (modified) list of "*suggested* contract provisions" to govern these arrangements but once again failed to make any of the provisions mandatory. *Id.* at 10,279. For example, HRSA indicated that the parties' contract should reflect that "[t]he covered entity owns covered drugs." *Id.* But HRSA has apparently made no effort to require this, and as a matter of

practice, covered entities frequently exercise no authority over the drugs that would commonly be associated with "ownership."

Indeed, HRSA has apparently made no effort to confirm if any of its suggested contract provisions (or similar restrictions on pharmacy sales) were actually incorporated in any contract pharmacy arrangements. And HRSA's administrative record fails to demonstrate whether they were or were not. To the contrary, HRSA knows that contract pharmacies often operate on a "replenishment" model, where title to the drugs shipped to the pharmacy *does not* remain in the hands of the covered entity, and the covered entity has *no responsibility at all for setting drug prices* or no control over any other detail of how, when, or to whom the drugs are actually dispensed. *See* VLTR_007977 (many "covered entities use administrators that determine 340B eligibility *after* drugs are dispensed, which means that their contract pharmacies do not know at the time they dispense the drugs whether patients' prescriptions are 340B-eligible.").

C. Abuses in the Contract Pharmacy System

HRSA's 2010 guidance caused a proliferation of contract pharmacy uses (and abuses) under the 340B program.

First, following the 2010 guidance, the nature and the number of such arrangements radically changed. Many pharmacies and consultants recognized the opportunity for profit from 340B discounts. Aaron Vandervelde et al., BRG, *For-Profit Pharmacy Participation in the 340B Program* at 4 (Oct. 2020), https://bit.ly/3eqIDWl (Vandervelde), attached as Exhibit A to the Declaration of Ryan S. Baasch (Baasch Decl.). In 2018, for example, the U.S. Government Accountability Office (GAO) found that the use of contract pharmacies had "increased more than fifteen-fold, from about 1,300 to approximately 20,000 [as of 2018]." GAO, GAO-18-840, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs*

Improvement at 10 (June 2018), https://www.gao.gov/assets/gao-18-480.pdf (2018 GAO Rep.). A 2020 study put the increase at **4,228%**, with now "more than 27,000 individual pharmacies (almost one out of every three pharmacies)" participating in the 340B program as contract pharmacies. Vandervelde at 4. By 2020, instead of using just one contract pharmacy, covered entities were using an average of 22 contract pharmacies. *Id.* at 7.[3] And the number of claims for 340B discounts nationwide tripled between 2014 and 2019. *See* Adam J. Fein, *New HRSA Data: 340B Program Reached $29.9 Billion in 2019; Now Over 8% of Drug Sales*, Drug Channels (June 9, 2020), https://bit.ly/3eq5Fwy, attached as Ex. B to Baasch Decl. At the same time, the average distance between a covered entity and its contract pharmacies also changed dramatically: Instead of an average of 34 miles in 2010, covered entities are now separated from their contract pharmacies by an average of *334* miles—suggesting that many contract pharmacies are not dispensing medication to the covered entity's patients. Vandervelde at 7.

Second, the specific business arrangements between contract pharmacies and covered entities have markedly evolved. Under the 1996 guidance, contract pharmacies were a mere conduit for a covered entity's drugs where the covered entity purchased the drugs and specified that the drugs would be shipped to the contract pharmacy for dispensing only to the covered entities' patients. *See* 61 Fed. Reg. at 43,552; *see also id.* at 43,550 ("This situation is akin to a covered entity having its own pharmacy."). But under the "replenishment model" now in widespread use, the contract pharmacy literally dispenses drugs from one common inventory to whomever walks in the door—340B and non-340B patients alike. *See* Decl. of Krista M. Pedley (Pedley Decl.) ¶¶ 9, 12, *Sanofi-Aventus U.S., LLC v. U.S. Dep't of Health & Human Servs.*, No.

[3] UT has likewise experienced a substantial increase in 340B activity. The number of 340B discount claims UT has received grew substantially between 2018 and 2020. *See* Barton Decl. ¶ 9. UT is aware of no appropriate cause for such an immense increase. *Id.* ¶ 10.

21-cv-634 (D.N.J. June 24, 2021), ECF No. 93-2 (HRSA Director of Office of Pharmacy Affairs stating that under the replenishment system, contract pharmacies use stock replenished at 340B prices as "neutral inventory" that "may be dispensed to any subsequent patient"); *see also Examining Oversight Reports on the 340B Drug Pricing Program, Hearing of the S. Comm. on Health, Educ., Labor, & Pensions*, 115th Cong. 11 (May 15, 2018) (testimony of Ann Maxwell, Assistant Inspector Gen. for Evaluation & Inspections, Off. of Inspector Gen. (OIG)) (OIG Test.) (testifying "many contract pharmacies dispense drugs to all of their customers—340B-eligible or otherwise—from their regular inventory"). In other words, in such situations, the covered entity does not take or hold title to any particular drug shipment to the covered pharmacy. *See Astrazeneca*, 2021 WL 2458063, at *11 n.19.

HRSA appears to lack detailed knowledge of how the replenishment model works in many contexts, including how it works for the covered entities who use the mail delivery specialty contract pharmacy that does business with UT. Nothing in HRSA's administrative record provides this information, but what *is* clear is that, *after* a drug is dispensed (maybe to a 340B patient, or maybe not), contract pharmacies or a "third-party administrator" will generally use some kind of black-box software "algorithm" to conclude whether that patient should trigger a 340B discount. *See id.*; *see also* Pedley Decl. ¶ 6 (HRSA Office of Pharmacy Affairs Director acknowledging that "[v]arious 340B-tailored software programs exist" to perform this function); *see also* 2018 GAO Rep. at 2 (explaining how some "covered entities hire and pay a private company, referred to as a third-party administrator (TPA), to help determine patient eligibility and manage 340B inventory"). HRSA does not appear to know how these algorithms work in general, or how the specific algorithm works for UT drugs. And the algorithms likely stretch the concept of who is and who is not a 340B patient beyond any legally justifiable definition. *Cf.* Pedley Decl. ¶ 3

(conceding that "contract-pharmacy arrangements vary, and [HRSA] cannot speak to the exact details of every existing relationship"). The contract pharmacies or other third-party administrators (not the covered entities) then use this determination to order stocks at the 340B price to "replenish[]" those that were dispensed. *Id.* ¶ 11.

Third, contract pharmacies can now profit in multiple ways from their arrangement with covered entities. Typically, a contract pharmacy will bill a patient's third-party insurer at full price, or else charge the patient out of pocket, for a 340B drug that the contract pharmacy obtained at a fraction of that price. *See* Vandervelde at 4. Sometimes, the contract pharmacy and covered entity enter a percentage-based profit sharing scheme, where the contract pharmacy receives "a fee based on a percentage of revenue generated for each 340B prescription," and other times, the contract pharmacy collects a flat fee per dispensed prescription. *See* VLTR_008004 (GAO finding showing that percentage-based fees range from 12 to 20 percent of revenue generated, and that some flat fees for brand drugs are as high as $1,750 per dispense); 2018 GAO Rep. at 20 (finding, among other things, that majority (75%) of 340B contract pharmacies are chain pharmacies). At least one national pharmacy chain publicly disclosed that 340B profits were material to its business operations. *See* Walgreens Boots Alliance, Inc., Annual Report (Form 10-K) at 23 (Oct. 15, 2020), https://bit.ly/2MoLX9d, attached as Ex. C to Baasch Decl.; *but see* Letter from Senator Charles Grassley to Gregory Wasson, President and CEO, Walgreens (July 31, 2013), https://bit.ly/3krmVoP (explaining the 340B program "is not intended to subsidize pharmacies that team up with covered entities to turn a profit"), attached as Ex. D to Baasch Decl. Contract pharmacies frequently share none of this profit with the patients that Congress intended to benefit. *See* 2018 GAO Rep. at 30 (finding that only 54 percent of covered entities who responded to its request for data reported offering some discount on 340B drugs to low-income, uninsured patients

in their contract pharmacy arrangements). HRSA knows that the 340B discounts are now being distributed across for-profit entities that Congress never intended to benefit but does not seem to believe it can do anything about it. *See Examining HRSA's Oversight of the 340B Drug Pricing Program; Hearing Before the H. Subcomm. on Oversight & Investigations of the Comm. on Energy and Commerce*, 115 Cong. 79 (July 18, 2017) (July 18, 2017, H. Subcomm. Hr'g) (testimony of Krista M. Pedley, current Director of HRSA's Office of Pharmacy Affairs, that contract pharmacy arrangements are "a business matter between the parties and their contract," and conceding that HRSA does not prohibit contract pharmacies from sharing the spread between the 340B discount and the reimbursement). And, again, HRSA does not appear to know how the contract pharmacy arrangements work for the specialty pharmacies at issue here for UT; nothing in the administrative record even begins to answer this question.

Fourth, although there is little transparency regarding how the retrospective identification of 340B patients (and therefore 340B units) is performed, available evidence indicates that third-party administrators are strongly incentivized to broadly interpret which contract pharmacy patients might have been patients of 340B covered entities. *See* 2018 GAO Rep. at 26 (describing findings regarding third-party administrator fees, with a smaller fee typically charged when the prescription that may not be eligible for a 340B discount). HRSA has identified hundreds of instances of diversion, notwithstanding that it exercises very limited oversight. *Id.* at 37; *see also* GAO, GAO-11-836, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement* at 28 (Sept. 2011), https://www.gao.gov/assets/gao-11-836.pdf ("Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in house pharmacies."); 2018 GAO Rep. at 44 (diversion involving contract pharmacies). Congress has recognized that the number of audits finding violations is

"staggering"—with over 80 percent of audited covered entities showing non-compliance in certain audit years. *See* July 18, 2017, H. Subcomm. Hr'g at 79.

HRSA, however, has failed to remedy these abuses. *See* VLTR_007965; 2018 GAO Rep. at GAO Highlights (each setting forth findings as to ineffective HRSA oversight). Indeed, HRSA does not appear to police the detailed contractual relationships between covered entities, third-party administrators, and contract pharmacies. It also lacks statutory authority to audit contract pharmacies or other third parties or compel them to submit to a statutory audit by manufacturers. *See* 42 U.S.C. § 256b(a)(5)(C) (requiring only that a *covered entity* permit the government or the drug manufacturer to audit *the covered entity's* records directly pertaining to compliance with the diversion and duplicate discount prohibitions). HRSA has also explained that it does not issue audit findings against covered entities "for a failure to oversee 340B Program compliance *at contract pharmacies* through internal audits and other measures as set forth in guidance *because the 340B statute does not address contract pharmacy use*." GAO, GAO-21-107, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance With 340B Requirements* at 15-16 (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf (2020 GAO 340B Rep.) (emphases added). And even where HRSA does audit covered entities to ensure compliance and discover violations, HRSA does "not require all covered entities to provide evidence that they have taken corrective action and are in compliance with program requirements prior to closing an audit." *Opportunities to Improve the 340B Drug Pricing Program*, *Hearing Before the H. Subcomm. on Health*, 115th Cong. at 54 (July 11, 2018) (testimony of Rep. H. Morgan Griffith) (July 11, 2018, H. Subcomm. Hr'g). Even in the very limited cases where HRSA conducted re-audits of covered entities who had compliance issues, it found repeated instances of similar noncompliance. *See id.* at 55 (GAO witness testifying that HRSA should require "more rigorous information . . . from the

covered entities as to what they've done"). HRSA also almost never terminates a covered entity's ability to participate in the 340B program for non-compliance. *See* July 18, 2017, H. Subcomm. Hr'g at 79 (HRSA witness indicating that the agency had "terminated one covered entity" as of 2017); *see also Genesis Health Care, Inc. v. Azar*, 2019 WL 6909572, at *2 (D.S.C. Dec. 19, 2019) ((HRSA "vacated its decision to remove [covered entity] from the 340B Program and promptly reinstated [covered entity] into the 340B Program" after the covered entity initiated litigation) (citation omitted)). And there is nothing at all in the record in this case reflecting any HRSA audit relevant to covered entities or contract pharmacies and UT's specific drugs.

D. Pharmaceutical Manufacturers Attempt to Mitigate the Abuses

Given HRSA's consistent failure to address the abuses of the 340B program, and the absence of any requirement under statute or guidance of manufacturers to sell or ship to contract pharmacies, UT and six other pharmaceutical manufacturers issued varying contract pharmacy policies in their own efforts to combat the abuses in the program.

On November 13, 2020, UT notified HRSA that it would begin implementing two narrowly tailored policies for covered entities that use contract pharmacies with the goal of stemming abuses going forward without upsetting the status quo or creating hardship for covered entities or their patients. VLTR_007737-39. UT's policies apply to its outpatient drugs, and, because of their unique features, each of these drugs is dispensed either by an in-house pharmacy within the covered entity, or by one or two outside specialty pharmacies that delivers the drugs by mail. *See* Barton Decl. ¶¶ 5, 17-19.[4] In practice, only one of these two outside specialty pharmacies has

[4] Consistent with applicable caselaw in this APA context, UT is submitting the Declaration of David Barton and limited other material to provide important "background information needed to determine whether the agency considered all the relevant factors." *See e.g. Oceana, Inc. v. Ross*, 454 F. Supp. 3d 62, 69 (D.D.C. 2020) (considering such a declaration in APA case); *see also*

been dispensing these drugs in recent years. *See id.* ¶ 25. (UT's policies also apply to a fourth drug that is prescribed on an *inpatient basis only*, and so should never be subject to requests for 340B discounts. UT, however, has received multiple inexplicable requests for 340B discounts on that drug, and so has previously included that drug in its contract pharmacy policies. *Id.* ¶ 19.)[5]

UT's first policy (the "contract pharmacies policy") applies to relevant orders for the subject drugs placed on or after November 20, 2020. *See id.* ¶¶ 17-19. Under that policy, UT accepts the order only if the particular contract pharmacy was utilized by the relevant covered entity in making a valid 340B purchase of a UT covered outpatient drug during the first three quarters of the 2020 calendar year (January 1 through September 30, 2020). *See id.* ¶¶ 21-25. This policy will have an extremely limited effect on the marketplace because virtually all covered entities with health care providers who prescribe these drugs have long had a contract pharmacy relationship with at least one of the two specialty pharmacies that UT uses for distribution. *See id.* ¶ 25. In addition, in the few potential cases where a covered entity did not have a contract pharmacy arrangement in place during the first three quarters of 2020, that covered entity may ask UT to designate one of the specialty 340B contract pharmacies that dispenses its drugs. *See id.* ¶ 26. This policy has one exception—if one of those few entities seeking to designate a 340B contract pharmacy has its own in-house pharmacy, then it cannot designate a new contract pharmacy. *See id.* ¶ 26. This policy is consistent with HRSA's 1996 guidance, which envisioned

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Center for Biological Diversity v. U.S. Army Corps, 2020 WL 5642287, at *14 (D.D.C. Sept. 22, 2020) (similar). Specifically, UT's business model and policies are by definition a relevant factor in determining whether UT has violated the 340B statute, as HRSA contends. But the administrative record does not contain any information describing UT or its policies in any relevant respect.

[5] UT has another outpatient drug—Adcirca® (tadalifil)—that is distributed through a different framework and is not subject to UT's policies for covered entities that use contract pharmacies. Barton Decl. ¶ 18.

that covered entities would contract with a single third-party pharmacy—a limitation that HRSA considered to be consistent with the 340B statute. *See* 61 Fed. Reg. 43,549.

UT's second policy (the "claims data portal policy") is directed at ensuring the integrity of the 340B program by enabling UT to confirm that 340B drug orders are *bona fide*, including through the detection of unlawful duplicate discounts. *See* Barton Decl. ¶¶ 28-31. A "duplicate discount" occurs where a covered entity obtains and prescribes a 340B discounted drug, a claim for payment is submitted to Medicaid for the drug, and the state Medicaid agency then seeks a rebate from the manufacturer for the same, already discounted, drug. Covered entities are statutorily directed to not allow duplicate discounting to occur, 42 U.S.C. § 256b(a)(5)(A)(i), and Congress directed HHS to "establish a mechanism" to defeat the possibility of duplicate discounts, *id.* § 256b(a)(5)(A)(ii). It is well-known, however, that duplicate discounting is rampant in the 340B program. A recent GAO report, for example, found serious limitations in federal oversight of this problem. *See* GAO, GAO-20-212, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement* (Jan. 2020), https://www.gao.gov/assets/gao-20-212.pdf (2020 GAO Medicaid Rep.). On the Medicaid side, the Center for Medicare and Medicaid Services (CMS) "conducts limited oversight of state Medicaid programs' efforts to prevent duplicate discounts[]" and "does not have the information needed to effectively ensure that states exclude 340B drugs from Medicaid rebate requests." *Id.* at GAO Highlights. As for 340B, HRSA "audits are unable to determine whether covered entities are following state requirements, and taking the necessary steps to comply" with the duplicate discount prohibition. *Id.*[6] Contract pharmacies make this situation significantly worse. *See* 2018

[6] Matters are even worse under Medicaid managed care. "[U]nlike Medicaid fee-for-service, when duplicate discounts in Medicaid managed care claims are identified, HRSA *does not require*

GAO Rep. at 45 ("The expansion of contract pharmacies . . . increases potential risks to the 340B Program, such as risks related to diversion and duplicate discounts."). As just one example, HRSA maintains a Medicaid Exclusion File (MEF) that helps manufacturers identify duplicate discounts by containing provider numbers used by covered entities that may prescribe 340B drugs to Medicaid beneficiaries. But the MEF "does not include information on whether covered entities are using 340B drugs for Medicaid managed care," and also "may not include information on *contract pharmacies* that are dispensing these drugs to Medicaid beneficiaries on covered entities' behalf." 2020 GAO Medicaid Rep. at 32 (emphasis added). At bottom, as the GAO recognized, the resulting state of affairs is that "manufacturers lack complete information on the extent to which covered entities use 340B drugs for Medicaid beneficiaries." *Id.*

To address this problem, UT's claims data portal policy requires covered entities using a contract pharmacy to regularly provide general, de-identified claims data to UT via a third-party platform, allowing UT to confirm that each order of a covered outpatient drug through contract pharmacies has not resulted in, or will not result in, a statutorily prohibited duplicate discount. The data will include basic prescription information, including Rx Number, prescribed date, fill date, NDC (a unique number and universal product identifier for human drugs in the United States), quantity, pharmacy ID, prescriber ID, wholesaler invoice number, and 340B covered entity ID. Barton Decl. ¶ 29. The submission of this claims data will achieve UT's goal of policing duplicate discounts because it will give UT a ledger that it can compare Medicaid rebate requests against to determine if a duplicate discount is being requested. *See id.* ¶ 30. In addition, because the prescription ID field on the portal includes data about prescribers, it will be possible for UT to

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covered entities to address them or work with manufacturers to repay them," and that, "[a]s a result, *manufacturers may be subject to duplicate discounts for drugs provided under managed care*." 2020 GAO Medicaid Rep. at GAO Highlights (emphases added).

determine whether the prescribers at issue are genuinely affiliated with covered entities or not. *See id.* ¶ 31. UT's claims data policy is currently scheduled to take effect September 1, 2021, *see id.* ¶ 33, but UT anticipates that the date will be reset for November 15 and will provide an appropriate notification when that happens.

Together, these reasonable measures—the contract pharmacies policy and the claims data portal policy (collectively, "UT's policies")—have the potential to ameliorate the most problematic contract pharmacy aspects of the 340B program in its current form.

E. HHS General Counsel Interprets the Statute

On December 30, 2020, HHS's General Counsel issued an "Advisory Opinion" on contract pharmacies. *See* VLTR_008048-56 ("Recently, certain drug manufacturers participating in the 340B Program are declining to distribute covered outpatient drugs through contract pharmacies at the ceiling price.").

The Advisory Opinion made several important new pronouncements. *First*, the Advisory Opinion marked the first time a government agency concluded that pharmaceutical manufacturers are "obligated" to transmit their drugs at the 340B discounted price to an unlimited number of contract pharmacies. More specifically, the Advisory Opinion explicitly recognized that this purported obligation was limited; it only applied "to the extent [that the contract pharmacies or third-party administrators] are acting as agents of a covered entity." VLTR_008048; *see also Astrazeneca*, 2021 WL 2458063, at *6 ("The [Advisory] Opinion is the first document in which HHS explicitly concluded that *drug manufacturers* are required *by statute* to provide 340B drugs to *multiple* contract pharmacies." (emphases in original) (footnote omitted)). The Advisory Opinion identified no evidentiary basis for concluding that any contract pharmacy is actually

acting as an agent of a covered entity, much less that all 27,000 are. VLTR_008048; *see infra* at 34-35.

Second, in addition to relying on the concept of "agency," the Advisory Opinion conditioned a manufacturer's purported obligation to do business with contract pharmacies on the notion that a covered entity purchases and holds "title" to all 340B drugs dispensed to patients throughout all of the transactions at issue. *See* VLTR_008050.

Third, in a footnote, the Advisory Opinion expressly blessed the replenishment model that is in widespread use by contract pharmacies but made no genuine effort to explain how that model could be reconciled with the concepts of "agency" and "[t]itle" on which the Advisory Opinion was predicated. VLTR_008053 n.6.

HHS was sued by many pharmaceutical manufacturers following issuance of the Advisory Opinion. On June 16, 2021, one of the courts adjudicating those claims concluded that the Advisory Opinion was unlawful. *See Astrazeneca*, 2021 WL 2458063. Specifically, the court concluded that the Advisory Opinion was "based on the 'unjustified assumption' that Congress imposed this interpretation as a statutory requirement." *Id.* at *11 (citation omitted). HHS responded by withdrawing the Advisory Opinion. *See* Notice of Withdrawal at 2, *Eli Lilly & Co. v. U.S. Dep't of Health & Human Servs.*, No. 21-cv-81 (S.D. Ind. June 18, 2021), ECF No. 119-1 (Advisory Opinion Withdrawal) ("The Office of the General Counsel (OCG) is withdrawing Advisory Opinion 20-06."). The Court then vacated the Advisory Opinion. *See* Mem. Order at 3, *Astrazeneca Pharms. LP v. Becerra*, No. 21-cv-27 (D. Del. June 30, 2021), ECF No. 83.

F. HRSA Issues The Violation Determination To UT

On May 17, 2021—before its Advisory Opinion was declared invalid, withdrawn, and then also vacated—HRSA sent a letter to UT stating that HRSA had determined that UT's policies

violate the 340B statute. *See* VLTR_000011-12. HRSA also sent decisions that made the same core allegations and used the same text to five other pharmaceutical manufacturers. *See* VLTR000001-10. HRSA has stated that these letters marked the "culmination" of the agency's "review" of each manufacturer's policies, and that they are final agency action. *See* Hr'g Tr. at 21:13-16, 30:19-21, *Astrazeneca Pharms. v. Becerra*, No. 21-cv-27 (D. Del. May 27, 2021), ECF No. 76.

The May 17 letter contained HRSA's Violation Determination and made multiple critical claims: (1) The Violation Determination determined that the obligation to ship 340B discounted drugs to a covered entity "is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs"—thus, UT's contract pharmacies policy limiting the contract pharmacy arrangements it will honor is not lawful in HRSA's view; (2) the Violation Determination determined that "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfilment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities"—thus, UT's claims data portal policy requiring claims data to mitigate duplicate discounts is not lawful in HRSA's view; and (3) the Violation Determination asserted that UT's "actions have resulted in overcharges and are in direct violation of the 340B statute." VLTR_000011.

HRSA claimed that its Violation Determination was based on its "review" of UT's policies, and on its analysis of "complaints" it received from *covered entities*. *Id.* But there is no HRSA analysis of *bona fide* complaints or any other documents in the administrative record that substantiate this, and HRSA appears to have copy-pasted this language about "complaints" and the agency's "review" from its letters to other manufacturers. *See* VLTR_000001-12 (reflecting the identical language in letters to each manufacturer). There are three complaints in the

administrative record from *covered entities* that specifically mention UT's policies. One of those complaints (from UC Davis medical center) is generic, cites a news report, identifies multiple manufacturers, and does not contain any specific allegations regarding UT. VLTR_005708. The other two complaints (UCLA Santa Monica, and UCLA Ronald Reagan medical centers) likewise contain very limited details and appear to be directed towards UT's claims data portal policy, which has not yet gone into effect. VLTR_005765-67; VLTR_005769-70. That is evident because both complaints specified May 13, 2021 as the date which they would experience trouble obtaining 340B discounted drugs from UT, VLTR_005767, VLTR_005770, and that was the original (now, postponed) date for the claims data portal policy. While there are documents in the record purporting to address other manufacturers' policies, none of those are relevant to UT.

In addition, and in further contrast to HRSA's determinations, UT's 340B orders have *increased* since it implemented its policies. Barton Decl. ¶ 27. Although the administrative record also contains multiple agency-created financial charts regarding the manufacturers purporting to show such things as the "lost savings" that contract pharmacies experienced because of the manufacturers' policies, the agency's charts contain literally no comparable arguments or data relevant to UT. *See* VLTR_007936-43.

The Violation Determination also did not contain any meaningful legal analysis. Instead, it appeared to reiterate the bottom line conclusion from the Advisory Opinion that manufacturers are bound to provide covered drugs to contract pharmacies. The Violation Determination *did not* find that the two specialty pharmacies that distribute UT's outpatient drugs at issue (*see supra* at 18-19), are "agents" for *any* covered entities, nor that the covered entities retain "title" to 340B drugs when dispensed by these specialty pharmacies. *See* VLTR_000011-12. Finally, HRSA "request[ed] that [UT] provide an update on its plan to restart selling, without restriction, 340B

covered outpatient drugs at the 340B price to covered entities with contract pharmacy arrangements by June 1, 2021." VLTR_000012.

On May 28, 2021, HRSA wrote again to restate the basis for its Violation Determination and to give UT until June 10 to respond. *See* Barton Decl., Ex. C. On June 10, 2021, UT submitted a letter to HRSA attempting to clarify how its policies complement the purposes of the 340B program, how the policies are designed to operate, and why they are consistent with the statute. *See* Barton Decl., Ex. E. HRSA has taken no steps to rescind the erroneous Violation Determination or otherwise withdraw its conclusion that it may commence enforcement.

ARGUMENT

UT is entitled to summary judgment. The APA requires courts to "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2)(A). The Violation Determination is unlawful because it is inconsistent with Section 340B and the APA's requirement of reasoned, evidence-based decision-making. Because the full administrative record demonstrates that UT is correct on the merits, the Court should issue a summary judgment vacating the Violation Determination. *See Roberts v. United States*, 883 F. Supp. 2d 56, 62-63 (D.D.C. 2012) (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" (citations omitted)).

I. THE VIOLATION DETERMINATION CONFLICTS WITH THE 340B STATUTE

"In addressing a question of statutory interpretation, [the Court] begin[s] with the text," presuming that the "legislature says in a statute what it means and means in a statute what it says there." *Eagle Pharms., Inc. v. Azar*, 952 F.3d 323, 330 (D.C. Cir. 2020) (internal quotation marks

and citations omitted). As relevant here, the statute contains three features worded in plain and unambiguous terms. First, it imposes a specific obligation on drug manufacturers to offer 340B prices to particular entities: "[T]he manufacturer [shall] *offer each covered entity* covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1) (emphasis added). Second, it enumerates who qualifies as a "covered entity" eligible to receive an offer at the 340B price, listing 15 specific types of medical facilities. *Id.* § 256b(a)(4). Third, it expressly prohibits a covered entity from transferring a drug purchased at the 340B price to anyone other than its patients: "With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell *or otherwise transfer* the drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B) (emphasis added). Applying the ordinary tools of statutory interpretation to those provisions resolves this case.

To start, the statute by its terms does not require UT to provide 340B drugs to contract pharmacies. Indeed, the statute makes no reference to "contract pharmacies" at all. *Astrazeneca*, 2021 WL 2458063, at *9 ("Pharmacies are not mentioned anywhere in the statutory text."). Instead, it requires UT to offer 340B drugs to 15 types of explicitly defined "covered entities." And "[i]t is axiomatic that the statutory definition of [a] term excludes unstated meanings of that term." *Meese v. Keene*, 481 U.S. 465, 484 (1987); *Colautti v. Franklin*, 439 U.S. 379, 392 n.10 (1979) ("[A] definition which declares what a term 'means' excludes any meaning that is not stated." (cleaned up)); *see also Burgess v. United States*, 553 U.S. 124, 129-30 (2008) (same). Congress has thus categorically ruled out interpreting "covered entity" as encompassing contract pharmacies. *See Astrazeneca*, 2021 WL 2458063, at *10 ("It 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."). HRSA has long understood this. *See* VLTR_007589 ("Contract pharmacies . . . [are] not independent covered entities."). UT accordingly has no obligation to offer 340B pricing to contract pharmacies.

To circumvent the plain language of the statute, the agency has developed a series of rationales conflating contract pharmacies and covered entities, so that it can attempt to claim that drugs received by contract pharmacies are nonetheless still "offered" to "covered entities." The agency's current rationale, as articulated in the Violation Determination, is that contract pharmacies are merely a method of "distribut[ing]" the covered entity's drugs. VLTR_000011. Putting aside for the moment that that is not true as a factual matter, *supra* at 13-15, the problem for the agency is that the statute expressly bars such a "distribution" relationship. The prohibition on transfers expressly provides that "[w]ith respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell *or otherwise transfer the drug to a person who is not a patient of the entity*." *Id.* § 256b(a)(5)(B) (emphasis added). As a matter of plain English, an entity "transfers" something when it hands it off to another entity. *See, e.g.*, *Transfer*, Oxford American Dictionary 730 (1st ed. 1980) (defining "transfer" as "to convey or move or hand over (a thing) from one place or person or group etc. to another"). And because a contract pharmacy is obviously not a "patient of the [covered] entity," it is statutorily prohibited from receiving 340B drugs.[7]

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[7] It is no answer that the covered entity is merely instructing UT to send drugs to the contract pharmacy, so it is not doing a transfer itself. Covered entities cannot circumvent the statutory prohibition by demanding that manufacturers to violate the statute for them. *See Mainstream Mktg. Servs., Inc. v. FTC*, 284 F. Supp. 2d 1266, 1277 (D. Colo. 2003) (recognizing "substantial body of case law to the effect that a person enjoined cannot do indirectly through another what it is prohibited from doing directly"); *United States v. Coloplast Corp.*, 2016 WL 4483868, at *2 (D. Mass. July 29, 2016) (same under Medicare program); *see also City of Eugene, Or. v. FCC*, 998 F.3d 701, 711 (6th Cir. 2021) (regulated entities "may not 'end-run' the Act's limitations by using

The agency used to understand this, too. For over a decade, HRSA recognized that it could not compel manufacturers to sell or ship to contract pharmacies. That is why, just last year, the agency explained that the purported obligation for manufacturers to deal with contract pharmacies is limited to circumstances where the covered entity and contract pharmacy are in a "principal-agent" relationship. VLTR_008048 ("For the reasons set forth below, we conclude that *to the extent contract pharmacies are acting as agents of a covered entity*, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." (emphasis added)). The 1996 guidance likewise emphasized that to the extent contract pharmacies are permissible it is as "agents" of covered entities. 61 Fed. Reg. at 43,550 ("[E]ntities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients."). Under this theory, there was allegedly no prohibited "transfer" between the covered entity and the contract pharmacy. Because they are in a purported "principal-agent" relationship and "title" always remained with the covered entity, they are (allegedly) legally one and the same. VLTR_008053 (explaining that the prohibition on transfers does not apply because, as principal-agents, "the covered entity and contract pharmacy are not distinct").

The core problem with principal-agency rationalization is that the concepts of agency and title do not appear anywhere in the statute. "Neither the operative provision in § 256b(a)(1) nor the definition of 'covered entity' in § 256b(a)(4) speaks about covered entities' agents." *Astrazeneca*, 2021 WL 2458063, at *10. And it is clear from the statute as a whole that if Congress wanted to make pharmaceutical manufacturers deal with covered entities' agents, it knew exactly

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other . . . entities or other sources of authority to accomplish indirectly what [they] are prohibited from doing directly" (cleaned up)).

how to do so. *Id.* ("Congress knows how to write statutes that cover agents and contractors, but it did not do so in the 340B statute."). For example, the statute specifically refers to "associations or organizations representing the interests" of covered entities, and gives those representatives standing to seek redress on behalf of covered entities in administrative proceedings. 42 U.S.C. § 256b(d)(3)(B)(vi). But Congress did not authorize those associations or organizations—or any other "agents"—to receive 340B drugs on behalf of covered entities. Likewise, Congress swept in agents in another part of the Veterans Health Care Act of 1992 (the same Act that established the 340B program), which provided that manufacturers could not charge certain federal agencies more than a specified amount for covered drugs. *See* Veterans Health Care Act of 1992 § 603(a), 106 Stat. at 4971, 4974. Congress provided that this pricing limitation applies to drugs "purchased under depot contracting systems." 38 U.S.C. § 8126(a)(2). And Congress, in turn, defined "depot" to mean a system through which drugs "procured by an agency of the Federal Government are received, stored, and delivered through a federally owned and operated warehouse system, *or a commercial entity operating under contract with such agency*." *Id.* § 8126(h)(3) (emphasis added). This distinction demonstrates that Congress (1) recognized a difference between entities operating on their own versus operating through an agency relationship and (2) intentionally blessed the former relationship in a different provision but not the one at issue here.[8] Congress plainly knows how to authorize the agency concept when it wishes. And, "when . . . Congress has shown that it knows how to adopt the omitted language or provision," it is impermissible for

[8] In other healthcare contexts, too, Congress explicitly mentions agents when it intends the statutory concept to extend to such entities. *See, e.g.*, 42 U.S.C. § 1320a-7b(b)(3)(C) (providing a safe harbor from penalties for purchases made through a "person authorized to act as a purchasing *agent* for" a healthcare provider (emphasis added)).

agencies or courts to bootstrap that missing language into the statute. *Rotkiske v. Klemm*, 140 S. Ct. 355, 361 (2019).[9]

Congress said that manufacturers must offer 340B prices to covered entities, not contract pharmacies. Nor did it require manufacturers to deal with distribution partners or agents of covered entities. Congress's choice must be respected. *Califano v. Sanders*, 430 U.S. 99, 108 (1977) ("Our duty, of course, is to respect [Congress's] choice."). The Violation Determination is inconsistent with Congress's scheme and must be set aside. *See, e.g., Flint Hills Res. Alaska, LLC v. FERC*, 631 F.3d 543, 544 (D.C. Cir. 2011).

II. THERE IS NO VALID LEGAL OR FACTUAL BASIS IN THE ADMINISTRATIVE RECORD FOR CONCLUDING THAT UT HAS REFUSED TO OFFER COVERED ENTITIES THE 340B PRICE

The Violation Determination is also arbitrary and capricious because it contains no legal or factual justification to support HRSA's conclusion that UT's policies deny covered entities the 340B price.

The agency's recent Advisory Opinion setting forth the "principal-agent" rationalization was vacated by the District of Delaware for lack of reasoned decision-making. *Astrazeneca*, 2021 WL 2458063, at *8. It was subsequently withdrawn by HHS. *See* Advisory Opinion Withdrawal at 2. And, in recent litigation, it now appears that the gency has abandoned that principal-agent

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[9] HRSA may respond by pointing to the recent *Astrazeneca* opinion, where the court—despite holding that the Advisory Opinion was "legally flawed" because it rested on the idea that the statute unambiguously encompassed covered entity agents—noted that "interpret[ing] [] the statute" as permitting agents is "permissible." 2021 WL 2458063, at *8-11. But that *dicta* gets administrative law wrong by concluding that the statute is "silent on the issue" and that this silence renders the statute "ambiguous." *Id.* at *9 (emphasis added). Silence and ambiguity, however, are different things. And if a statute's text "clearly requires a particular outcome, then the mere fact that it does so implicitly rather than expressly does not mean it is 'silent'" in a way that gives rise to agency discretion or lawmaking. *Engine Mfrs. Ass'n v. U.S. EPA*, 88 F.3d 1075, 1088 (D.C. Cir. 1996) (citation omitted); *see also Eagle Pharms.*, 952 F.3d at 331 (same); *H. Lee Moffitt Cancer Ctr. & Rsch. Inst. Hosp., Inc. v. Azar*, 324 F. Supp. 3d 1, 14 (D.D.C. 2018).

rationalization altogether. Hr'g Tr. at 34:10, *Astrazeneca Pharms.*, No. 21-cv-27 (D. Del. May 27, 2021), ECF No. 76 (government attorney contending that agency relationship in Advisory Opinion is merely "illustrative" of permissible contract pharmacy arrangement but is not a "requirement" for those arrangements). That is likely because, after the agency produced its administrative record to other manufacturers in litigation (which is apparently identical to the record in this case), it became abundantly clear that the agency has no—literally, zero—evidence that any contract pharmacy operates in an actual agency relationship (*i.e.*, as a fiduciary) with any covered entity, much less that covered entities retain "title" to 340B drugs held by contract pharmacies. That is unsurprising, because the vast majority of contract pharmacy arrangements operate pursuant to the "replenishment" model. *See, e.g.*, Pedley Decl. Under that model, contract pharmacies do not act as agents merely holding and dispensing drugs owned by the covered entity to the covered entity's patients—rather, the pharmacies dispense from a general inventory of comingled 340B and non-340B drugs to all patients. *Id.* ¶ 11. In short, the "principal-agent" theory was pure fiction.

It seems obvious enough that the Violation Determination was based on the invalid and now-withdrawn reasoning in the Advisory Opinion.[10] The administrative record in this case contains no reasoning other than the Advisory Opinion. The Advisory Opinion was issued by HHS's General Counsel, who has final, legal decision-making authority over the agency. *See Statement of Organizations, Functions, and Delegations of Authority*, 86 Fed. Reg. 6,349, 6,351 (Jan. 21, 2021) (General Counsel "[f]urnishes all legal services" at HHS, "[s]upervises all legal

[10] *Compare, e.g.*, VLTR_000011 (invoking "shall . . . offer" language in 42 U.S.C. § 256b(a)(1) and asserting that "[t]his requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute"), *with* VLTR_008049 (likewise invoking "shall . . . offer" language in 42 U.S.C. § 256b(a)(1) and asserting that "[t]his fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute").

activities," and "[r]eviews and approves all administrative complaints and enforcement actions . . . to ensure that [they are] legally sound.").[11] And before the Advisory Opinion, there was no form of agency authority that required pharmaceutical manufacturers to provide 340B drugs to contract pharmacies—much less to an unlimited number of them, without restriction. After all, the agency's 1996 and 2010 guidance documents expressly *disclaimed* that they created any legal rights or obligations. *See* 61 Fed. Reg. at 43,550 ("[T]hese guidelines create no new law and create no new rights or duties."); 75 Fed. Reg. at 10,273 (same).[12] Because "[a]n agency decision cannot be sustained . . . where it is based . . . on an erroneous view of the law," *Prill v. NLRB*, 755 F.2d 941, 947 (D.C. Cir. 1985), the Violation Determination should be set aside for this reason alone.

HRSA has recently tried to claim that the Violation Determination was meant to stand on its own and that it does not rise or fall solely on the validity of the Advisory Opinion. Advisory Opinion Withdrawal at 1 (stating the Advisory Opinion "was never intended . . . to serve as the predicate for enforcement"). That strains credulity, but in any event does not save the agency. It is a cardinal rule of administrative law that an agency must provide a "reasoned explanation" for its action, *N. Ger. Area Council, Overseas Educ. Ass'n v. Fed. Lab. Rels. Auth.*, 805 F.2d 1044, 1050 (D.C. Cir. 1986), including by articulating "[t]he precise grounds" for its decision, *United*

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[11] And HHS explains on its website that these kinds of advisory opinions are issued "to clarify *the Department's* legal position." Dep't of Health & Human Servs., Off. of the Gen. Counsel (OGC), *HHS Advisory Opinions* (June 24, 2021), https://www.hhs.gov/about/agencies/ogc/advisory-opinions/index.html (emphasis added).

[12] In addition, even if the 1996 and 2010 guidance documents purported to contain binding directives, the Department of Justice could not take the position that an agency enforcement action can be predicated on a violation of agency guidance. *See, e.g.*, Mem. of the Associate Attorney General, *Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases*, at 2 (Jan. 25, 2018) (noting that "[g]uidance documents cannot create binding requirements that do not already exist by statute or regulation."); *see also* DOJ *Justice Manual* § 1.20.100 ("[T]he Department should not treat a party's noncompliance with a guidance document as itself a violation of applicable statutes or regulations.").

States v. Carolina Freight Carriers Corp., 315 U.S. 475, 488-89 (1942). This ensures that an agency's "erroneous statutory construction" does not escape review merely because it is cloaked in "vague findings." *Id.* at 489.; *see also Am. Lung Ass'n v. EPA*, 985 F.3d 914, 944 (D.C. Cir. 2021) (similar). But with the Advisory Opinion stripped away, the Violation Determination alone fails to contain any "reasons [that] undergird the agency's conclusion." *Celcom Commc'ns Corp. v. FCC*, 789 F.2d 67, 71 (D.C. Cir. 1986); *see also Tripoli Rocketry Ass'n, Inc. v. Bureau of Alcohol, Tobacco, Firearms, & Explosives*, 437 F.3d 75, 77 (D.C. Cir. 2006) ("the process by which [the agency] reaches [its] result must be logical and rational" (citation omitted)). All it contains is conclusions, and wrong ones at that. That is insufficient for reasoned decision-making. *See, e.g.*, *Carolina Freight Carriers*, 315 U.S. at 488-89; *N. Ger. Area Council*, 805 F.2d at 1050.

Moreover, as discussed, the administrative record as a whole contains no evidence that could otherwise establish that contract pharmacies are legally one-and-the-same as covered entities, much less that, in UT's unique limited distribution model involving specialty pharmacies, UT has "fail[ed] to provide the 340B price to covered entities." VLTR_000012. Agencies may not "act on hunches or wild guesses"—their "conclusions must be rationally justified," *Ethyl Corp. v. EPA*, 541 F.2d 1, 28 (D.C. Cir. 1976) (citation omitted), and facts relied upon by the agency must "have some basis in the record," *Nat. Res. Def. Council, Inc. v. SEC*, 606 F.2d 1031, 1053 (D.C. Cir. 1979). The record here contains no analysis or factual support indicating that UT has ever refused to give any covered entity the 340B price.

HRSA may respond that the Violation Determination explains that it relied on "specific complaints from covered entities regarding their inability to purchase several United Therapeutics covered outpatient drug products at or below the 340B ceiling price through the pharmacies that dispense medications to their patients." Barton Decl., Ex. C at 1. But, again, this language appears

to be part of HRSA's cut-and-paste job from its determinations to the other five pharmaceutical manufacturers. That administrative record appears to contain *no such complaints about UT*, much less any analysis of any such complaints. *See supra* at 24-25 (explaining the context for the three isolated complaints about UT in the record). And again, UT operates on a different distribution model from the other manufacturers that received violation determinations. Because UT's drugs require additional patient education and support beyond mere dispensing, UT relies on two specialty pharmacies to dispense the drugs subject to the policies at issue here. *See* Barton Decl. ¶ 5. Almost all covered entities that purchase from UT were *already* using one of those specialty pharmacies as a contract pharmacy when UT instituted its contract pharmacies policy. *See id.* ¶ 25. Therefore, under the terms of that policy, those covered entities would not have been affected by UT's decision and would still have been able to direct 340B discounted drug purchases to their contract pharmacy. *See id.* And, as HRSA knew when it issued the Violation Determination, UT's claims data portal policy has not yet been implemented, and so could not have been the foundation for any *bona fide* complaints.

There is nothing in the record supporting the Violation Determination's conclusion with respect to UT. That is quintessential arbitrary and capricious decision-making. *See Spirit Airlines, Inc. v. DOT*, 997 F.3d 1247, 1257 (D.C. Cir. 2021).

III. THE VIOLATION DETERMINATION ARBITRARY AND CAPRICIOUS FOR MULTIPLE ADDITIONAL REASONS

The Violation Determination's conclusion about UT's policies is also arbitrary and capricious for multiple additional reasons.

A. The Violation Determination Fails to Acknowledge, Let Alone Rationally Explain, HRSA's Sudden Change in Policy on Contract Pharmacies

HRSA's Violation Determination is arbitrary and capricious because the agency failed to acknowledge (let alone justify) its change in position on the obligations of pharmaceutical manufacturers vis-à-vis contract pharmacies. The APA's requirement that an agency "provide [a] reasoned explanation for its action" generally mandates that the agency at least "display awareness that it *is* changing position." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (emphasis in original). And agencies must also "provide 'a reasonable analysis indicating that prior policies and standards are being deliberately changed, not casually ignored." *Ramaprakash v. FAA*, 346 F.3d 1121, 1124-25 (D.C. Cir. 2003) (citation omitted).

Here, HRSA flouted these basic requirements. In 1996, HRSA asserted that it was "clear that there were many gaps" in the 340B statute, 61 Fed. Reg. at 43,550, and concluded that covered entities could use only *one* contract pharmacy, *see id.* at 43,555 (acknowledging "limitation of one pharmacy contractor per entity"). HRSA's 2010 guidance eliminated this limitation, but that guidance did not purport to bind or impose any obligations on pharmaceutical manufacturers. *See* 75 Fed. Reg. at 10,273 ("This guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law."); *see also Astrazeneca*, 2021 WL 2458063, at *6-7 (detailing HRSA's evolving positions).[13] Yet HRSA's Violation Determination

[13] *See also* Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020), https://bit.ly/36I9fxu (quoting HRSA's statement that "guidance is not legally enforceable. Regarding the 340B program's guidance documents, HRSA's current authority to enforce certain 340B policies contained in guidance is limited unless there is a clear violation of the 340B statute."), attached as Ex. E to Baasch Decl.; VLTR_007590 ("HRSA has published contract pharmacy advice in guidance, rather than through binding regulations."); *Eli Lilly* Second Am. Compl., Ex. L, HRSA Letter to Maureen Testoni at 1 (Dec. 9, 2020), *Eli Lilly & Co.*, No. 1:21-cv-81 (S.D. Ind. June 11, 2021), ECF No. 103-13 ("The 340B statute does not specify the mode by which 340B drugs may be dispensed.").

(and the Advisory Opinion on which it is based) wholly fails to acknowledge (and justify) the agency's present shift in policy from the 1996 and 2010 guidance documents. To do so, the agency would have had to at a minimum explain how manufacturers were suddenly *bound* to supply 340B drugs to an unlimited number of contract pharmacies (not merely that covered entities had permission to use contract pharmacies), and where the agency found its newfound source of purported authority to penalize manufacturers for not engaging with contract pharmacies. *Grace v. Barr*, 965 F.3d 883, 900 (D.C. Cir. 2020) (agencies may not "gloss over" or "swerve from" previous positions "without discussion") (alterations and citations omitted)). But it failed to do that.

B. The Violation Determination Failed to Consider and Address the Severe Risks for Diversion and Abuse Arising from Forcing UT to Deal with an Unlimited Number of Contract Pharmacies

The Violation Determination's conclusion about UT's policies also contravenes the APA because it fails to consider multiple "important aspect[s] of the [regulatory] problem." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). A mountain of public evidence shows that the contract pharmacy model has facilitated diversion, and UT's policies are designed to further key statutory purposes by mitigating diversion and duplicate discounts. In addition, the administrative record contains no evidence that contract pharmacies are validating *upfront* whether any patients are 340B eligible, even though HRSA's own guidance previously indicated that such steps should be a central feature of any contract pharmacy relationship. *See infra* at 39-40.

Here, the 340B statute itself provides that preventing "diversion" and "duplicate discounts" are important aspects of any drug dispensation model under the 340B program. *See* 42 U.S.C. § 256b(a)(5)(A), (B); *Carlson v. Postal Regul. Comm'n*, 938 F.3d 337, 343-44 (D.C. Cir. 2019)

("statutory objectives and factors" setting bounds for an agency program are an important aspect of the regulatory problem). But a substantial amount of publicly available evidence—including from HHS's own Inspector General and the U.S. Government Accountability Office—shows that there is a significant risk of diversion under the contract pharmacy distribution model. Indeed, the Government Accountability Office last year reported that HRSA's own audits have found over 1,500 cases of noncompliance with 340B program requirements since fiscal year 2012. 2020 GAO 340B Rep. And in 2018, the Government Accountability Office reported that "HRSA does not have a reasonable assurance that covered entities have adequately identified and addressed noncompliance with 340B Program requirements." 2018 GAO Rep. at GAO Highlights. In addition, as explained *supra* at 20-21, HRSA is doing next-to-nothing to police duplicate discounting. 2020 GAO Medicaid Rep. at GAO Highlights page. (HRSA "audits are unable to determine whether covered entities are following state requirements, and taking the necessary steps to comply" with the duplicate discount prohibition).

As UT explained in its November 2020 letter to HRSA, its policies were designed to thwart these problems. Barton Decl., Ex. A at 1. The contract pharmacies policy does that because under its express terms it limits the number of contract pharmacies (albeit modestly) that covered entities can direct (*i.e.*, divert) their 340B discounted drugs to. *See supra* at 19-20. And the claims data portal policy will not only allow UT to detect and limit duplicate discounting by providing a ledger of specific 340B discounted drug purchases that UT can compare against Medicaid rebate invoices, it should also help UT to determine if 340B discounts are being sought for prescriptions not actually written by covered entity prescribers. *See supra* at 21-22.

The Violation Determination (and the Advisory Opinion on which it is based) fails entirely to grapple with the diversion problem, and in fact facilitates rampant diversion within the 340B

program and prevents pharmaceutical manufacturers like UT from taking any reasonable steps to combat diversion, without providing any explanation (much less a reasoned one) for this perverse outcome. HRSA may respond that if UT is concerned about diversion and duplicate discounting its remedy is not to stop those things *ex ante*, but to conduct audits to detect them *ex post*. VLTR_000012. But that is no solution because neither UT nor even HRSA has statutory authority to audit contract pharmacies or the third-party administrators who use undisclosed algorithms to determine who is entitled to 340B discounts. *See* 42 U.S.C. § 256b(a)(5)(C) (providing authority to audit only covered entities); *see also supra* at 14-15 (discussing contract pharmacy and third-party administrator algorithms). While covered entities can and should in theory audit contract pharmacies, HHS's own Inspector General conducted that "most covered entities [it studied] do not" effectively do so. VLTR_007965; *see also* July 11, 2018, H. Subcomm. Hr'g at 54 (Rep. H. Morgan Griffith) (noting HRSA does "not require all covered entities to provide evidence that they have taken corrective action and are in compliance with program requirements prior to closing an audit").

In addition, HRSA previously explained on multiple occasions that covered entities should require contract pharmacies to verify *upfront* that a specific patient is in fact a patient from a 340B covered entity. HRSA's 1996 and 2010 guidance documents stated flatly that covered entities should ensure that a contract pharmacy dispenses a 340B drug only either (a) "[u]pon presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient, and the signature of a legally qualified health care provider affiliated with the covered entity" or (b) after "receipt of a prescription ordered by telephone on behalf of an eligible patient by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an eligible patient." 61 Fed. Reg. at 43,556; *see also*

75 Fed. Reg. at 10,279. But the administrative record contains no evidence that this happens as a matter of fact, and it is logically implausible that it would occur under the replenishment model, which is based on an *after-the-fact* determination of eligibility through the algorithms discussed *supra* at 14-15. HRSA was obligated to explain why it permits contract pharmacy arrangements that do not contain this critical feature, but it failed to do so.

The Violation Determination has accordingly failed to consider and address multiple important aspects of the regulatory problem here and is arbitrary and capricious. *See, e.g.*, *Mfrs. Ry. Co. v. Surface Transp. Bd.*, 676 F.3d 1094, 1097 (D.C. Cir. 2012) (Kavanaugh, J.) ("We must vacate" where agency "failed to reasonably explain and justify" its decision.).

IV. THE VIOLATION DETERMINATION'S CONCLUSION THAT UT'S CLAIMS DATA POLICY IS UNLAWFUL ALSO VIOLATES THE 340B STATUTE AND THE APA

Even if HRSA could compel UT to deal with contract pharmacies, the Violation Determination also contravened the 340B statute and the APA by concluding that UT's claims data policy is unlawful. *See* VLTR_000011 ("[T]he 340B statute does not permit manufacturers to impose conditions on covered entities' access to 340B pricing, including the production of claims data."). This policy alone does not prevent covered entities from using contract pharmacies in any respect. It simply requires that if they do use contract pharmacies, the covered entities must submit certain "claims data" (*i.e.*, prescription numbers, prescriber IDs, and covered entity IDs) to UT through a third-party portal. As noted *supra* at 21-22, this policy allows UT to confirm that 340B drug orders are *bona fide* and, among other things, will help UT detect duplicate discounts, and should help UT identify prescriptions written by healthcare providers not covered by 340B. In a single sentence, the Violation Determination determined this policy was unlawful because "the 340B statute does not permit manufacturers to impose conditions on covered entities' access

to 340B pricing, including the production of claims data." VLTR_000011. That is wrong. As an initial matter, because the statute does not require manufacturers to deal with contract pharmacies or third-party administrators, *supra* at 27-31, it necessarily follows that when a manufacturer voluntarily chooses to do so it can place conditions on those dealings. But in any event, the agency's conclusion has multiple additional flaws.

To start, nothing in the statute prevents manufacturers from properly vetting covered entities to ensure 340B sales are *bona fide*. To be sure, a manufacturer is obligated to "offer" 340B drugs to covered entities—but only to covered entities. 42 U.S.C. § 256b(a). And under the plain text of the statute, a facility that engages in duplicate discounting *is definitionally not a covered entity*. *Id.* § 256b(a)(4) ("[T]he term 'covered entity' means an entity that meets the requirements described in [the] paragraph [forbidding duplicate discounts]."). So UT's claims data policy simply provides UT a mechanism to confirm that an entity seeking 340B discounts is, in fact, a statutory covered entity.

Even if the statute could in theory sustain the Violation Determination's conclusion about UT's claims data policy (it cannot), the Determination's one-sentence conclusion lacks a reasoned explanation. *See N. Ger. Area Council*, 805 F.2d at 1050 (agency must provide "reasoned explanation" for its action). In addition, this conclusion failed to grapple with an important aspect of the problem—duplicate discounting. *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43 (agency must address each important aspect of the regulatory problem). Duplicate discounting is a serious problem. As explained *supra* at 20-21, it occurs when a pharmaceutical manufacturer provides a 340B discount on a drug to a covered entity and then, at some point after the drug is prescribed, a state Medicaid program seeks a rebate under Medicaid for its coverage of that drug. Both the 340B discount and the Medicaid rebate *alone* can make up "25 to 50 percent of the cost of the drug[]."

2020 GAO Medicaid Rep. at 1. So, when a manufacturer is erroneously subject to *both*, it can be financially crushing. The GAO has concluded that HRSA's "audits are unable to determine whether covered entities are" complying with the bar on duplicate discounts. *Id.* at GAO Highlights page. And contract pharmacies are worsening the situation. *See* 2018 GAO Rep. at 45. It defies logic and all fundamental aspects of reasoned decision-making that HRSA could just force pharmaceutical manufacturers to accept and tolerate this problem. But if that is HRSA's intent then it must at a bare minimum grapple with this problem and clearly articulate its position.

HRSA may respond that it articulated an applicable position in 1994—26 years before UT announced its claims data portal policy—in a document providing "guidelines regarding eligible covered entities." HRSA, *Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines*, 59 Fed. Reg. 25,110 (May 13, 1994). That document purported to make it unlawful for manufacturers to impose "conditions" on covered entity access to 340B drugs. But that document did not identify any statutory authority for its prohibition on conditions. The agency may also claim that the statutory requirement to "offer" 340B drugs to covered entities provides support for the agency's 1994 policy. *See* VLTR_000108-09. But that would make little sense because the concept of an "offer" does not preclude the existence of "conditions." Conditions are a common feature of contract law. *See Comcast Corp. v. Nat'l Ass'n of Afr. American-Owned Media*, 140 S. Ct. 1009, 1016 (2020) ("[W]e generally presume that Congress legislates against the backdrop of the common law." (citation omitted)).[14] And as a matter of basic logic, pharmaceutical manufacturers must impose at least *some* conditions on purchase of 340B drugs—

[14] When a pharmaceutical manufacturer sells a drug it is common for multiple "conditions" to first be satisfied—for example, it is common to ask for a copy of the pharmacy (or like) license, to validate that the drug is being sent to someone authorized to receive and distribute it. The manufacturer also needs accurate accounting information and shipment information—for example, how the drug will be stored (such as temperature controls).

such as the condition that the purchasing entity *is* 340B eligible. In addition, even on the terms of HRSA's 1994 document, UT's claims data portal policy is permissible. HRSA explained that manufacturers were not allowed to impose "restrictive conditions that would undermine the statutory objective." 59 Fed. Reg. at 25,113. But UT's claims data portal policy does not do that—in fact, it *advances* the statutory objective of limiting duplicate discounts, among other things. 42 U.S.C. § 256b(a)(5)(A). In addition, HRSA expressly explained that manufacturers were allowed to "request standard information." 59 Fed. Reg. at 25,113. That is exactly what UT's claims data portal policy requests—barebones prescription information that suffices to give UT the tools to detect duplicate discounts and identify other improprieties, and that is very similar to the data that HRSA has recommended that covered entities require contract pharmacies to identify before dispensing a 340B drug. *See* 61 Fed. Reg. at 43,556 (recommending that covered entities instruct contract pharmacies to dispense only "[u]pon presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient, and the signature of a legally qualified health care provider affiliated with the covered entity" or a similar telephone prescription).

V. THE VIOLATION DETERMINATION LACKS ANY PLAUSIBLE BASIS TO JUSTIFY CIVIL MONETARY PENALTY PROCEEDINGS

Finally, the Violation Determination violates Section 340B and the APA by determining that UT is subject to civil monetary penalties without any factual or legal basis. Even if HRSA's entire contract pharmacy regime were lawful (it is not), the 340B statute authorizes the imposition of civil monetary penalties only for "knowing[] and intentional ***[over]charges***." 42 U.S.C. § 256b(d)(1)(B)(vi) (emphasis added). UT, however, has not overcharged anyone (much less knowingly and intentionally).

First, as UT explained to HRSA, even under its contract pharmacy and claims data policies it does not, and will not, "overcharge" a covered entity. That is because when UT denies a 340B contract pharmacy order under its policies, it *does not* convert the order to a commercial order that is priced higher than the 340B ceiling price. Instead, it simply declines to fill the order altogether. *See* Barton Decl., Ex. E. There is no plausible way to characterize that as an "overcharge," and, although HRSA claimed that it has received "complaints" substantiating its determination, as shown *supra* at 24-25, the very few complaints in the administrative record do not substantiate that an "overcharge" ever occurred.

HRSA may respond that a failure to honor a request for 340B pricing is itself an "overcharge." But even if that is right (and it is not), that would still not mean UT has *knowingly and intentionally* overcharged anyone. "Where, as here, the statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a knowing or reckless violator." *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 70 n.20 (2007). As discussed above, HRSA's own position—since issuing its 1996 guidance and throughout the 340B program's existence—had been that manufacturers have no legal obligation to work with contract pharmacies and that HRSA had no statutory authority to impose such an obligation. *See supra* at 36-37 & n.12. UT's policies and conduct are thus consistent with HRSA's own longstanding views of what the law demands. It was only in the last year that HRSA—first in the Advisory Opinion and then in the Violation Determination—declared its view that the 340B statute requires manufacturers to work with an unlimited number of contract pharmacies and prevents manufacturers from using reasonable measures to prevent abuses of the program. *See Astrazeneca*, 2021 WL 2458063, at *6 (Advisory Opinion was "the first document in which HHS explicitly concluded that drug

manufacturers are required by statute to provide 340B drugs to multiple contract pharmacies" (emphases and footnote omitted)). But the only court yet to have substantively evaluated that change in policy concluded it was invalid. *See id.* at *11. At most UT's policies represent good faith disputes about its legal requirements under Section 340B. That does not amount to "knowing and intentional" violations. *See Berry v. Schulman*, 807 F.3d 600, 615 (4th Cir. 2015) (following "agency guidance" could not result in "willful" violation of law); *Shaw v. Experian Info. Sols.*, 891 F.3d 749, 761 (9th Cir. 2018) (similar).

CONCLUSION

For the foregoing reasons, UT's motion should be granted and the Court should issue a summary judgment in UT's favor, vacating the Violation Determination, declaring that UT's policies do not violate Section 340B, and granting any other appropriate relief.

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Respectfully submitted,

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