**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

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| UNITED THERAPEUTICS CORPORATION,<br><br>Plaintiff,<br><br>v.<br><br>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,<br><br>Defendants. | Case No. 1:21-cv-01686 |

**PLAINTIFF UNITED THERAPEUTICS CORPORATION'S MOTION FOR SUMMARY JUDGMENT**

Plaintiff United Therapeutics Corporation (UT) respectfully moves this Court for summary judgment pursuant to Federal Rule of Civil Procedure 56(c). For the reasons set forth more fully in UT's accompanying memorandum, UT requests that the Court enter summary judgment in its favor, vacate HRSA's May 17 and 28, 2021 determination that UT is violating 42 U.S.C. § 256b, declare that UT's policies do not violate 42 U.S.C. § 256b, and grant any other appropriate relief.

Date: July 16, 2021

Respectfully submitted,

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| UNITED THERAPEUTICS CORPORATION,<br><br>Plaintiff,<br><br>v.<br><br>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,<br><br>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.

Date: July 16, 2021

Respectfully submitted,

*/s/ Philip J. Perry*

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*Attorneys for Plaintiff*

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

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|---|---|
| UNITED THERAPEUTICS CORPORATION,<br><br>Plaintiff,<br><br>v.<br><br>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,<br><br>Defendants. | Case No. 1:21-cv-1686 |

**DECLARATION OF RYAN S. BAASCH**

I, Ryan S. Baasch, declare as follows in support of Plaintiff's Motion for Summary Judgment in the above-captioned action:

1. I am an associate with Latham & Watkins LLP and an attorney of record for Plaintiff in the above-captioned matter. I have personal knowledge of the matters set forth herein. If called and sworn as a witness, I could and would competently testify thereto.

2. Attached hereto as **Exhibit A** is a true and correct copy of Aaron Vandervelde et al., BRG, *For-Profit Pharmacy Participation in the 340B Program* (Oct. 2020), available at https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf.

3. Attached hereto as **Exhibit B** is a true and correct copy of Adam J. Fein, *Drug Channels, New HRSA Data: 340B Program Reached $29.9 billion in 2019; Now Over 8% of Drug*

*Sales* (June 9, 2020), available at https://www.drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html.

4. Attached hereto as **Exhibit C** is a true and correct copy of excerpts of Walgreens Boots Alliance, Inc.'s Form 10-K (Oct. 15, 2020), available at https://www.sec.gov/ix?doc=/Archives/edgar/data/1618921/000161892120000082/wba-20200831.htm.

5. Attached hereto as **Exhibit D** is a true and correct copy of Letter from Senator Charles Grassley to Gregory Wasson, President and CEO, Walgreens (July 31, 2013), available at http://www.pembrokeconsulting.com/pdfs/Grassley_340B_Letter_to_Walgreens_31July2013.pdf.

6. Attached hereto as **Exhibit E** is a true and correct copy of Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020), available at https://340breport.com/hrsa-says-its-340b-contract-pharmacy/.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on July 16, 2021.

Washington, DC

/s/*Ryan S. Baasch*_____.
Ryan S. Baasch

# EXHIBIT A

# For-Profit Pharmacy Participation in the 340B Program

OCTOBER 2020

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INTELLIGENCE THAT WORKS

BRG

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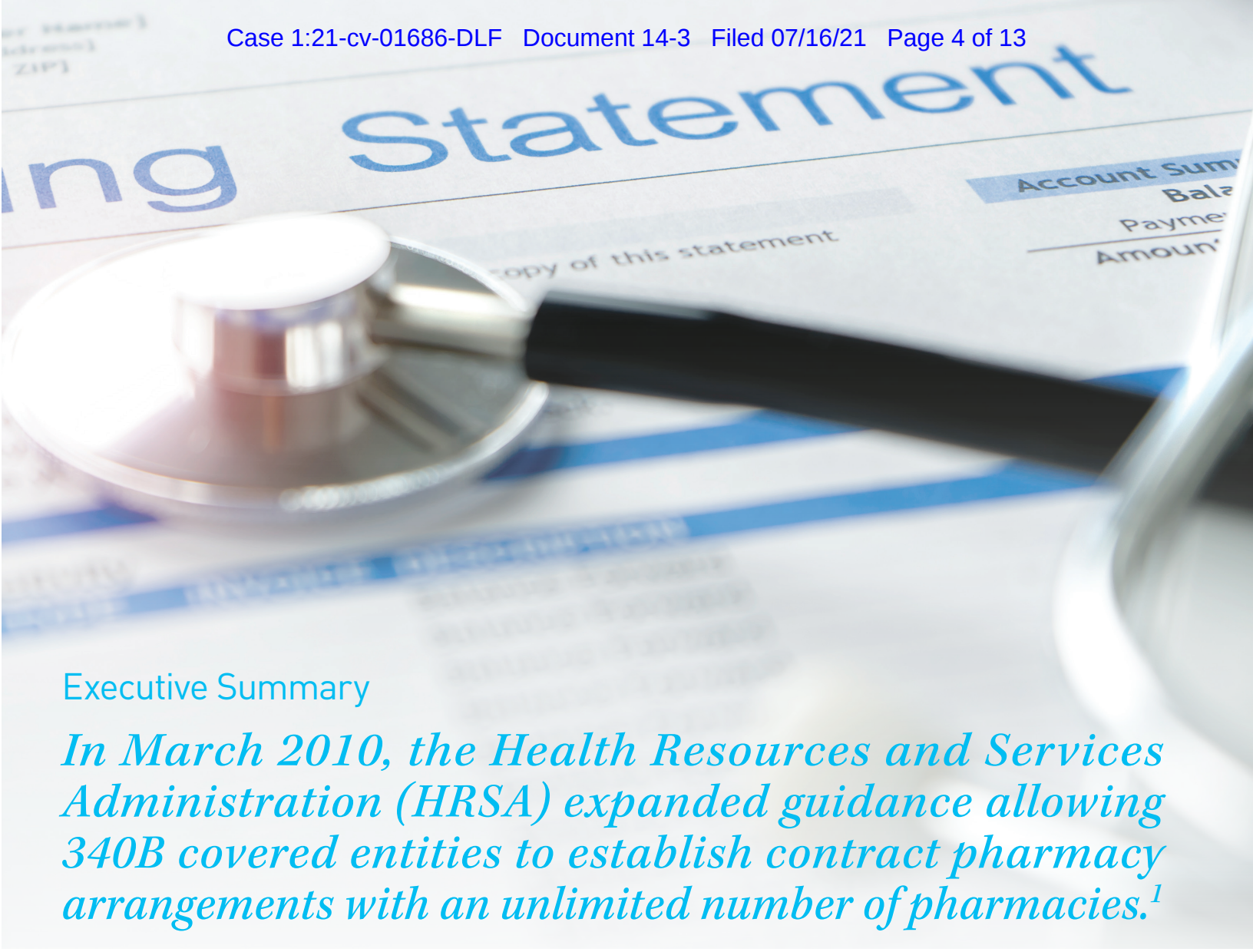


## Executive Summary

*In March 2010, the Health Resources and Services Administration (HRSA) expanded guidance allowing 340B covered entities to establish contract pharmacy arrangements with an unlimited number of pharmacies.*[1]

What started as a well-intentioned effort to provide safety-net providers free or discounted drugs to treat uninsured and vulnerable patients appears to have evolved into a profit-centric corporate initiative that has fundamentally altered the 340B program. Today, half of the twenty largest for-profit corporations in the United States—including Walgreens, Cigna, CVS Health, and Walmart—are active participants in the 340B program through contract pharmacy arrangements.[2] Using vertically integrated supply chains consisting of pharmacies, pharmaceutical benefit managers (PBMs), and health plans, these corporations can leverage their market power to drive growth in the 340B program and capture profits related to 340B sales.

In light of this evolution in the 340B program, BRG professionals conducted this analysis to better understand historical trends in 340B contract pharmacy arrangements, the increased participation of for-profit corporations in the 340B program, average profit margins on 340B purchased medicines dispensed through contract pharmacies, and the potential impact of growth in 340B contract pharmacy participation. Key findings include:

1. Following HRSA's expansion of the contract pharmacy program in March 2010, contract pharmacy participation grew 4,228 percent between April 2010 and April 2020.
2. While over 27,000 distinct pharmacies participate in the 340B program today, we estimate over half of the 340B profits retained by contract pharmacies are concentrated in just three pharmacy chains (Walgreens, Walmart, CVS Health) and Cigna's Accredo specialty pharmacy.
3. The average profit margin on 340B medicines commonly dispensed through contract pharmacies is an estimated 72 percent, compared with just 22 percent for non-340B medicines dispensed through independent pharmacies.
4. 340B covered entities and their contract pharmacies generated an estimated $13 billion in gross profits on 340B purchased medicines in 2018, which represents over 25 percent of the total gross profits on brand medicines realized by all providers that dispense or administer medicines.

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1 Federal Register, "Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services," Vol. 75, No. 43 (March 5, 2010), available at: https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf

2 Based on BRG analysis of the 340B contract pharmacy database.

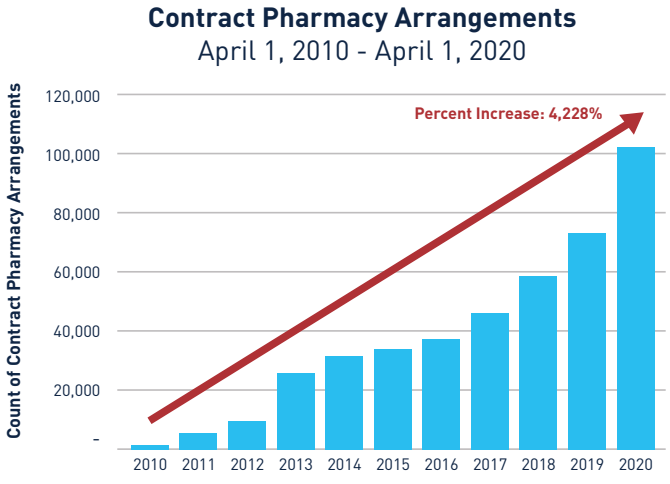
## History of 340B Contract Pharmacies

Congress created the 340B program in 1992 to provide recipients of HRSA grants (known as "grantees") and safety-net hospitals access to the voluntary discounts pharmaceutical manufacturers had provided before the enactment of the Medicaid rebate statute. These voluntary discounts had declined due to the Best Price provision in the Medicaid rebate statute for these covered entities. To assist the covered entities, Congress made qualifying hospitals and safety-net clinics eligible for steep discounts on medicines under the 340B program.

340B contract pharmacies were first permitted through guidance issued by HRSA in 1996.[3] At the time, grantees (e.g., community health centers, Ryan White clinics, black lung clinics) that did not have a pharmacy license were unable to dispense 340B purchased medicines to the indigent populations they served on site. Through the 1996 guidance, HRSA enabled any 340B covered entity that did not operate its own pharmacy to contract with a single third-party pharmacy to dispense 340B purchased medicines to eligible patients on its behalf. These are referred to as contract pharmacy arrangements and were predominantly established with independently owned community pharmacies located near the 340B covered entity. In 2000, 98 percent of all contract pharmacy arrangements were with independent pharmacies, and 80 percent of these pharmacies were within ten miles of the 340B covered entity. Of the forty-nine total contract pharmacy arrangements, 98 percent were established by grantees as opposed to safety net hospitals.[4]

In 2001, in response to requests by 340B covered entities to expand the 340B contract pharmacy program, HRSA initiated a demonstration project that allowed a small number of 340B covered entities to contract with multiple third-party pharmacies. This demonstration project enabled 340B covered entities that served patients in a geographically broad area to provide 340B purchased medicines in the communities where their patients lived.[5] The profile of these multiple contract pharmacy networks looked different from the original program in that there was greater participation by national pharmacy chains (54 percent overall) and less than half of the contract pharmacies were within ten miles of the 340B covered entity.[6]

*Figure 1*




*"The average gross margin on 340B purchased medicines dispensed through contract pharmacies is an estimated 72%... For some products, 340B contract pharmacies dispense a medicine that was purchased by the 340B covered entity for a penny, but still receive full reimbursement for the medicine from private insurance and Medicare Part D plans."*

In March 2010, HRSA issued additional guidance allowing all 340B covered entities, even those with their own outpatient pharmacies, to contract with an unlimited number of third-party pharmacies. This guidance fundamentally opened the doors for all covered entities to generate additional profits on 340B purchased drugs. Subsequently, for-profit pharmacies rushed to capitalize on the outsized profit margins available on 340B purchased medicines. Between April 1, 2010, and April 1, 2020, the number of contract pharmacy arrangements increased from 2,321 to 100,451—a 4,228 percent increase (see Figure 1).

Today, more than 27,000 individual pharmacies (almost one out of every three pharmacies) participate in the 340B program as contract pharmacies, including virtually all the major national and regional chains, such as Walgreens, Walmart, CVS, Rite-Aid, Kroger, Albertsons, Costco, and many more. Hospitals enrolled in the 340B program contract on average with twenty-two distinct pharmacies, and the largest contract pharmacy networks include over 250 pharmacies, some of which are thousands of miles away from the 340B covered entity (see Case Study 1). Hospitals now account for over 44 percent of all contract pharmacy arrangements, up from 2 percent in 2000.

The enormous growth in 340B contract pharmacy arrangements seems to boil down to a single factor: outsized profit margins. The National Community Pharmacists Association (NCPA) issues an annual report on independent pharmacy financials. Between 2013 and 2018, NCPA reported that the average gross margin on all prescription medicines ranged between 22 percent and 23 percent. As we will discuss in more detail later in this report, the average gross margin on 340B purchased medicines dispensed through contract pharmacies is an estimated 72 percent. For some products, 340B contract pharmacies dispense a medicine that was purchased by the 340B covered entity for a penny but still receive full reimbursement for the medicine from private insurance and Medicare Part D plans. That reimbursement can exceed $1,000 for many specialty medicines. The profit potential inherent in the 340B program appears to have attracted the largest for-profit corporations in the world and altered the hierarchy of 340B program stakeholders.

3 Federal Register, *Vol. 61, No. 165 / Friday, August 23, 1996 / Notices* (August 23, 1996), available at: https://www.govinfo.gov/content/pkg/FR-1996-08-23/pdf/96-21485.pdf

4 Based on BRG analysis of 340B covered entity and contract pharmacy data published by HRSA.

5 Federal Register, "Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services," notice by HRSA (January 12, 2007), accessed at: https://www.federalregister.gov/documents/2007/01/12/E7-334/notice-regarding-340b-drug-pricing-program-contract-pharmacy-services

6 Based on BRG analysis of the 340B covered entity and contract pharmacy data published by HRSA.

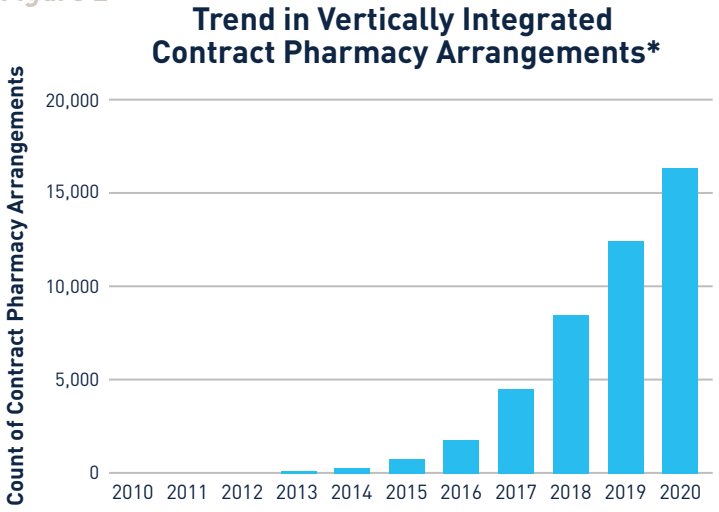
# Evolution of For-Profit Pharmacy Participation

The 340B program was originally created for non-profit healthcare providers viewed as the backbone of the "safety net" of the US healthcare system.[7] The first participants in the 340B program included not-for-profit hospitals that served large indigent populations and small healthcare clinics that relied on federal grants, because many of their patients were uninsured and could not afford basic healthcare services. Between 2004 and 2010, the 340B program grew substantially driven primarily by new enrollments of disproportionate share hospitals. By 2010, 16 percent of covered entities had established contract pharmacy arrangements, and over 85 percent of those contract pharmacy arrangements were with independent community pharmacies.

That changed following the March 2010 expansion of the contract pharmacy program and the lack of oversight over how for-profit entities can benefit from the 340B program. The 2010 guidance created an opportunity for sophisticated, for-profit pharmacy chains to realize larger margins than they otherwise could. Between 2010 and 2015, large national and regional pharmacy chains established tens of thousands of contract pharmacy arrangements. By 2015, these chain pharmacies represented over 66 percent of all contract pharmacy arrangements, up from just 15 percent at the beginning of 2010. Instead of maintaining close relationships with covered entities, as had been the practice for independent pharmacies before 2010, large national and regional chains turned to sophisticated software algorithms to identify 340B prescriptions and maximize the revenue generated from these discounted fills.

Starting in 2016, a new pattern of vertically integrated specialty pharmacy enrollments emerged. Specialty pharmacies dispense expensive medications that may require special handling or patient support services. Operations for these pharmacies are typically concentrated in a small number of locations distributed throughout the US, and medicines are shipped directly to patients.

*Figure 2*




*Excludes certain Walgreens mail order pharmacies that disenrolled en masse in 2015/2016

Over the past two decades, PBMs, the organizations that establish pharmacy reimbursement rates, make formulary decisions, and set cost-sharing amounts, have built large national specialty pharmacies that primarily serve the beneficiaries of the PBM that owns the specialty pharmacy. In January 2016, there were 1,473 contract pharmacy arrangements between 340B covered entities and these vertically integrated specialty pharmacies. By April 2020, this count had grown to 16,293—a 1,006 percent increase in four years (see Figure 2).

The evolution in for-profit pharmacy participation in the 340B program encompasses both the types of pharmacies participating and the structure of the contracts themselves. Based on our primary research, we understand that most contract pharmacy arrangements established prior to 2010 provided for an enhanced dispensing fee paid to the contract pharmacy. This contracting structure reflected the more complex service the contract pharmacy provided (i.e., dispensing a 340B purchased medicine to a 340B patient, managing 340B eligibility, and potentially maintaining separate inventories) and the increased compensation for that service. Any profit associated with the reimbursement of the medicine (less the enhanced dispensing fee) went to the 340B covered entity as the primary stakeholder in the 340B program.

A 2018 Government Accountability Office (GAO) report based on data collected between 2014 and 2016 found that the types of contracting arrangements had evolved to include pharmacies retaining a percentage of 340B profits or overall reimbursement.[8] This shift toward 340B profit sharing by contract pharmacies suggests that for-profit pharmacies are also a primary stakeholder in the 340B program, despite this never having been conceived of nor explicitly included in the program by Congress when it passed the 340B statute. Current guidance makes no recommendations on how profit-sharing agreements between covered entities and contract pharmacies should be structured. As a result, covered entities freely negotiate the terms of agreements with contract pharmacies. Although large, sophisticated academic medical centers may have enough leverage to negotiate favorable terms with an organization wielding the combined market power of a national pharmacy, PBM, and health plan, small grantees carry little leverage when negotiating with these entities.[9]

# 340B Profit Margins for Retail and Specialty Medicines

Outsized profit margins on 340B purchased medicines dispensed through a retail or specialty pharmacy has attracted for-profit national pharmacies that are vertically integrated with PBMs and health plans. For nearly all contract pharmacy arrangements, the determination of whether a medicine is eligible for a 340B discount is made after the medicine is dispensed to and paid for by the patient and his or her health plan. For brand medicines, this reimbursement amount is roughly equivalent to the list price or wholesale acquisition cost (WAC) of the medicine. To determine the profit margin on a 340B purchased medicine dispensed through a 340B contract pharmacy, we must also estimate the 340B discounted price of the medicine.

7 HRSA, *Sec. 340B Public Health Service Act*, available at: https://www.hrsa.gov/sites/default/files/opa/programrequirements/phsactsection340b.pdf
8 Government Accountability Office, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* (June 2018).
9 *Cares Community Health v. Department of Health and Human Services*, No. 18-5319, slip. op. at 10 (D.C. Cir. Dec. 20, 2019).

The 340B price is calculated using a statutory formula derived from two pricing metrics incorporated in the Medicaid Drug Rebate Program. At a high level, these pricing metrics for brand medicines are:

**Basic Medicaid Rebate**: Equal to the greater of 1) 23.1 percent of average manufacturer's price (AMP) or 2) the largest discount available in the commercial market (referred to as "Best Price").

**Consumer Price Index (CPI) Penalty**: A price inflation penalty that grows as increases in AMP for a medicine exceed the rate of inflation.

Using these two primary components, the 340B price is equal to AMP less the Basic Medicaid rebate less the price inflation penalty (see Figure 3). Depending on the competitive dynamics that exist in any therapeutic category, the 340B price could fall below $0.00. In these instances, the price is reset to $0.01 and is referred to as "penny pricing."

### Table 1: 340B Price Calculation Examples

| | Pricing Component | Formula | Diabetes Example | Oncology Example |
|---|---|---|---|---|
| [A] | AMP | | **$500.00** | **$1,000.00** |
| [B] | Medicaid Rebate | Greater of [C] or [D] | 250.00 | 231.00 |
| [C] | Base Rebate | [A] * 23.1% | 115.00 | 231.00 |
| [D] | Best Price | Largest Discount | 250.00 | 100.00 |
| [E] | CPI Penalty | Price Increase Above CPI | 225.00 | 200.00 |
| [F] | 340B Discounted Price | [A] - [B] - [E] | **$25.00** | **$569.00** |

95 PERCENT DISCOUNT

43 PERCENT DISCOUNT

As discussed further in Appendix A, we developed a methodology for estimating the 340B price using publicly available data and applied this methodology to the eighty-six largest retail and specialty brand medicines that are commonly dispensed through a 340B contract pharmacy based on 2018 sales volume. Our methodology incorporates both concepts discussed above. Where public statements on 340B pricing are available, we have compared our results against actual 340B prices. Based on these comparisons and the structural design of our methodology, we believe that our 340B price estimates, and therefore the 340B profit margins these prices are used to calculate, are conservative.

When comparing our 340B price estimate to the WAC price for the same medicine, our analysis found the average 340B discount from WAC across the eighty-six retail and specialty brand medicines examined was 72 percent in 2018. By comparison, most non-340B pharmacies typically purchase a brand medicine at a 2 percent to 3 percent discount off of WAC.[10] For certain therapeutic categories with steep commercial discounts attributable to competition in the category, the average 340B discount exceeded 80 percent (see Figure 4). Twenty-seven of the medicines in our analysis had an average discount in 2018 of at least 90 percent, and we identified six medicines with a 340B price equal to $0.01.

### Table 2: Average 340B Discounts by Therapeutic Class

| Average 340B Discounts by Therapeutic Class | | | | | | |
|---|---|---|---|---|---|---|
| Therapeutic Class* | Avg. Discount | # Medicines in Class | Medicines with a Discount of at Least: | | | |
| | | | 72% | 80% | 90% | 95% |
| Anti-infective agent | 44% | 11 | | | | |
| Antineoplastic agent | 50% | 8 | 1 | | | |
| Blood modifier agent | 58% | 4 | | | | |
| Cardiovascular agent | 71% | 3 | 1 | 1 | | |
| Central nervous system agent | 58% | 13 | 2 | | | |
| Anti-diabetes agent | 90% | 23 | 18 | 17 | 10 | 10 |
| Gastrointestinal agent | 90% | 7 | 6 | 5 | 2 | 1 |
| Immunological agent | 47% | 4 | | | | |
| Respiratory agent | 67% | 11 | 5 | 3 | | |
| **Top 86 Products** | **72%** | **86** | **35** | **27** | **12** | **11** |

**Excludes Therapeutic Classes with one product*

10 Based on BRG analysis of National Average Drug Acquisition Cost (NADAC) data.

# *FAST FACTS:* Contract Pharmacy Growth

| | Hospitals | | Grantees | |
|---|---|---|---|---|
| **General Statistics** | **2010** | **2020** | **2010** | **2020** |
| Total Contract Pharmacy Arrangements | 193 | 43,217 | 2,128 | 58,252 |
| % of Total Contract Pharmacy Arrangements | 8% | 43% | 92% | 57% |
| Average Contract Pharmacies per Entity | 1 | 22 | 1 | 11 |
| Average Distance b/w Contract Pharmacy & Entity (miles) | 34 | 334 | 36 | 198 |
| **Penetration Rate** | | | | |
| Count of Entities w/ Contract Pharmacies | 116 | 1,999 | 1,803 | 5,195 |
| % of Entities w/ Contract Pharmacies | 13% | 78% | 16% | 27% |

Because reimbursement by Medicaid, commercial, and Medicare Part D insurance plans is approximately equal to WAC for brand medicines, 340B covered entities and their contract pharmacies realized an average 72 percent profit margin on 340B purchased brand medicines. This margin is more than three times greater than the average margin realized by independent pharmacies and contributes to the rapid growth of 340B contract pharmacy arrangements. We estimate that 340B covered entities and their contract pharmacies generated over $13 billion in profits from 340B purchased medicines in 2018, which represents over 25 percent of the total $48 billion in profits realized by all providers that dispensed or administered brand medicines in 2018.[11] These profits are highly concentrated in 340B hospitals and the pharmacies they contract with, which account for almost 90 percent of all 340B purchases.[12]

There is little information on how profits are shared between 340B covered entities and their contract pharmacies. A 2018 GAO report[13] found a variety of contracting designs, but the underlying data was collected between 2014 and 2016, and 340B contract pharmacy arrangements have evolved rapidly since then. Although we don't know what share of the $13 billion in profits generated through 340B contract pharmacies are retained by for-profit pharmacies, we can estimate their relative shares of profits. To do this, we considered the total number of contract pharmacy arrangements by chain, the type of pharmacy (retail versus specialty), and the size of the 340B covered entity contracted with each pharmacy. Our analysis found that more than half of all profits realized by the 27,000 340B contract pharmacies participating in the 340B program today are concentrated in just four companies: Walgreens, CVS, Walmart, and Cigna's Accredo specialty pharmacy.

*More than half of all profits realized by 340B contract pharmacies are concentrated in just four companies.*

## Implications of For-Profit Pharmacy Participation in the 340B Program

As the prevalence of contract pharmacy arrangements has grown and the contracting design between 340B covered entities and contract pharmacies has evolved, the implications of these arrangements are becoming clear. First, profits on 340B purchased medicines are now distributed across a vertically integrated supply chain that includes not just the covered entities but also pharmacies, contract pharmacy administrators, PBMs, health plans, and employer groups. The 340B program was originally intended to provide healthcare services to indigent populations but income from the program is now being captured by some of the largest corporations in the world.

Second, 340B covered entities are often in competition with the very pharmacies with which they contract. This occurs because the vertically integrated healthcare companies implement cost-sharing models that create incentives for 340B patients to fill their prescriptions in the contract pharmacy instead of the 340B covered entity's own pharmacy. Given the choice between a $35 copayment at the preferred contract pharmacy or a $250 coinsurance payment at the 340B covered entity's own hospital outpatient pharmacy, most patients will fill their prescriptions at the contract pharmacy. Based on our work with 340B purchase data, we estimate that almost two-thirds of all retail and specialty drugs purchased at a 340B price are dispensed by contract pharmacies. Separately, the covered entity also enters into contracts with the vertically integrated PBM, which establishes reimbursement rates for the pharmacies owned and operated by the covered entity. When PBMs reduce reimbursement rates to the covered entities' owned pharmacies, the margins at the vertically integrated contract pharmacies may exceed those at the covered entities' owned pharmacies. This creates further incentives for utilization through the vertically integrated contract pharmacy.

11 Aaron Vandervelde and Andrew Brownlee, *Revisiting the Pharmaceutical Supply Chain: 2013-2018*, BRG white paper (January 2020), available at: https://ecommunications.thinkbrg.com/44/1613/uploads/vandervelde-pharmaceutical-supply-chain-2020-final-cleaned.pdf

12 Hatwig, Christopher, *The 340B Prime Vendor Program; Supporting All 340B Stakeholders*, Apexus PPT presentation (2014).

13 Government Accountability Office, "DRUG DISCOUNT PROGRAM: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement" (June 21, 2018), available at: https://www.gao.gov/products/GAO-18-480

| Vertical Integration of National Pharmacies | | | | |
|---|---|---|---|---|
| Health Plan | Aetna | Cigna HealthSpring | | United Healthcare |
| PBM | CVS Caremark | Express Scripts | | OptumRX |
| Pharmacy *(retail, mail order and/or specialty pharmacy)* | CVS Caremark | Accredo | Walgreens | OptumSpecialty |
| Third Party 340B Services Firm | Wellpartner | Verity Solutions | 340B Complete<br>Shields Health Solutions | |

Third, the outsized profit margins on 340B purchased medicines may contribute to additional consolidation and vertical integration in the healthcare marketplace. Three of the largest pharmacy chains participating in the 340B program (Walgreens, CVS Health, and Accredo), have developed or acquired 340B contract pharmacy administrators (see Figure 5). Contract pharmacy administrators develop and operate the software algorithms that determine 340B eligibility and enable the for-profit pharmacies to influence which prescriptions are classified as 340B. Walgreens recently announced an equity investment in Shields Health Solutions,[14] which operates 340B hospital outpatient pharmacies on an outsourced basis; and Optum recently completed a series of 340B contract pharmacy acquisitions to create Optum Specialty (Optum acquired Diplomat[15] and Avella). As consolidation and vertical integration in the 340B contract pharmacy space continues, 340B covered entities will likely be forced to give up a growing share of 340B program income to these for-profit entities.

## Conclusion

The role of contract pharmacies has evolved extensively since HRSA allowed 340B covered entities to contract with an unlimited number of for-profit pharmacies in 2010. What began as a close alignment between 340B covered entities serving indigent populations and independent community pharmacies has morphed into a sophisticated network of vertically integrated for-profit national pharmacies with enormous power. This evolution has fundamentally altered the 340B program and resulted in for-profit entities earning substantial profits through complex profit-sharing agreements with the 340B covered entities. Fueled by margins that are three times greater than the average non-340B medicine, the 340B contract pharmacy channel has grown dramatically over the last ten years and now accounts for over 25 percent of all margins realized by pharmacies and providers in the United States. The growing prevalence of these arrangements is taking the 340B program farther away from its original intended goal of helping safety-net entities provide care to vulnerable patients.

14 Walgreens, "Shields Health Solutions Receives Equity Investments from Welsh, Carson, Anderson & Stowe and Walgreen Co.," press release (July 30, 2019), available at: https://news.walgreens.com/press-releases/general-news/shields-health-solutions-receives-equity-investments-from-welsh-carson-anderson-stowe-and-walgreen-co.htm

15 Tozzi, John, "UnitedHealth Bought Pharmacy Company Avella to Build Optum Unit," *Bloomberg* (October 16, 2018), available at: https://www.bloomberg.com/news/articles/2018-10-16/unitedhealth-bought-pharmacy-company-avella-to-build-optum-unit

## Case Study #1

**Description:** Academic medical center that is part of a Midwestern health system
**Covered Entity Type:** Disproportionate Share Hospital (DSH)
**Total Contract Pharmacy (CP) Arrangements:** 250+

| Category | Year of First Registration | Date of Most Recent Registration | Percent of Total Active CP Network | Average Distance from Parent Site (mi) |
|---|---|---|---|---|
| Independent Pharmacies | 2011 | 1/1/2020 | 22% | 80.868 |
| Chain Retail Pharmacies | 2012 | 4/1/2020 | 64% | 55.092 |
| Specialty Pharmacies | 2011 | 4/1/2020 | 14% | 611.212 |

## Case Study #2

**Description:** Grantee community health center located in the Northeast
**Covered Entity Type:** Community Health Center (CH)
**Total Contract Pharmacy (CP) Arrangements:** 9

| Category | Year of First Registration | Date of Most Recent Registration | Percent of Total Active CP Network | Average Distance from Parent Site (mi) |
|---|---|---|---|---|
| Independent Pharmacies | 2015 | 7/1/2019 | 100% | 8.394 |
| Chain Retail Pharmacies | N/A | N/A | 0% | N/A |
| Specialty Pharmacies | N/A | N/A | 0% | N/A |

*These are meant for illustrative examples. Actual contract pharmacy arrangements may vary*

# Appendix A: Methodology

The analysis in this paper encompasses all 340B covered entities and their respective contract pharmacies registered with Health Resources and Services Administrations (HRSA) since the inception of the program in 1992. Figures related to 340B discounts and contract pharmacy profit margins are estimates, as exact calculations would require data proprietary to the parties involved, such as detailed gross sales figures and rebate data. Therefore, these estimates rely primarily upon publicly available data or data that can be purchased through third-party vendors. In some instances, certain figures in the analysis have been estimated, conservatively, based on the authors' direct and extensive industry experience. These instances are noted below.

To understand the growing prevalence of contract pharmacies in the 340B channel as well as overall program growth, we rely upon information obtained directly from HRSA reports. Current and historical registrations for both covered entities and contract pharmacies can be obtained directly from HRSA's Office of Pharmacy Affairs (340B OPAIS) website. After acquiring data from HRSA, additional analysis and research was required for the following:

- Identification of pharmacy chains/ownership (parent corporate entities).
- Classification of pharmacy channel:
  - Most pharmacies can be classified as retail (brick and mortar) or specialty/mail pharmacies. Specialty/mail pharmacies generally focus on dispensing higher-cost medicines that may require special handling, such as cold storage. These medicines are frequently used in therapeutic areas such as immunology, oncology, or virology.
- Identification of exact geographical location (latitude and longitude) of covered entities and contract pharmacies.
- Association of demographic information based on geographic location.
- Association of Hospital Cost Report data (HCRIS).

To estimate the average 340B discount for contract pharmacy dispensed medicines, we identified a market basket of medicines representative of those medicines dispensed at contract pharmacies. First, we identified the top two hundred medicines by gross sales in the US, then limited our analysis to self-administered brand medicines with enough gross volume to be material to our calculations. Although generic medicines are included in the 340B program, margins associated with these medicines are often too small to support the fees associated with contract pharmacy utilization and were therefore excluded in our analysis. Physician-administered medicines are rarely dispensed through contract pharmacies and were also excluded from the analysis. Though our methodology does not include the full universe of 340B eligible products, our market basket is highly representative of the products that drive 340B contract pharmacy margins.

After identifying our market basket of eighty-six medicines, we estimated the two components of the 340B price for each medicine as outlined above—*2018 CPI Penalty* and *Basic Medicaid Rebate*—and calculated the 340B discount by comparing the estimated 340B price with the WAC for each medicine. Our final estimated 340B discount of 72 percent reflects the average of these discounts weighted by each medicine's gross sales.

**2018 CPI Penalty:** We relied on Elsevier Gold Standard pricing data to determine the WAC for each medicine at launch and in 2018. We assumed the average manufacturer's price (AMP) to be 98 percent of WAC both at launch and in 2018. Inflation data was collected from the Bureau of Labor and Statistics and used to establish the allowable increase in AMP for each product. The CPI penalty was calculated as the difference between the allowable AMP in 2018 versus the estimated 2018 AMP derived from the Gold Standard pricing data.

**Basic Medicaid Rebate:** As discussed in this study, this is the greater of the base Medicaid rebate (23.1 percent of AMP) or the Best Price, which represents the discount from AMP of the lowest available commercial price offered by the pharmaceutical manufacturer. The lowest available commercial price is typically the difference between the WAC and the largest rebate offered to commercial health plans. As rebate data is proprietary, we relied upon public disclosures and MACPAC estimates of Medicaid rebate amounts by therapeutic class as a proxy for the Best Price. Because the MACPAC data represents an average rebate amount for a therapeutic category (as opposed to the largest rebate), we believe the proxy rebate amount to be below the Best Price for each medicine, and therefore consider our discount estimate and the resulting profit margin calculations to be conservative.

To estimate contract pharmacies' share of 340B profit margins, we first calculate contract pharmacies' share of all 340B sales. We estimate that in 2018, 25 percent of all sales for medical-benefit medicines (physician-administered) and 6 percent of pharmaceutical-benefit medicines (self-administered) were dispensed in a 340B setting—whether at an outpatient or contract pharmacy. These estimates were informed by our experience working directly with a broad group of manufacturers participating in the 340B program and analysis of Medicare Part B and Part D claims data. Using this information in conjunction with IQVIA estimates[16] of the breakout between self-administered and physician-administered branded medicines and our estimate of the average branded discount in for 340B self-administered medicines in 2018 (72 percent), we approximate that 21 percent of all 340B sales are for self-administered medicines. Our final calculation is outlined in Table 3:

*Table 3: Methodology to Estimate 340B Profit Margin*

| Step | Calculation | Estimated Value |
|---|---|---|
| A | Total Indirect Sales at 340B Price | $24.3 B |
| B | % of 340B Sales for Retail Medicines | 21% |
| C = A x B | Total Retail Sales at 340B Price | $5.2 B |
| D | Avg. 340B Retail Discount | 72% |
| E = C / (1-D) x 1.1 | Gross 340B Retail Sales (Direct & Indirect) | $18.6B |
| **F = E–C** | **340B Profit Margin on Retail Sales** | **$13.2** |

16 IQVIA, "2018 Medicine Use and Spending in the US" (May 2019), available at: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us---a-review-of-2018-outlook-to-2023.pdf?_=1573048662823

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# EXHIBIT B

TUESDAY, JUNE 09, 2020

# New HRSA Data: 340B Program Reached $29.9 Billion in 2019; Now Over 8% of Drug Sales


The 340B Drug Pricing Program has logged another year of incredible growth.

According to data provided to *Drug Channels* by the Health Resources and Services Administration (HRSA), discounted 340B purchases were at least $29.9 billion in 2019. That figure is an astonishing 23% higher than its 2018 counterpart.

Since 2014, purchases under the 340B program have tripled. Over the same period, manufacturers' net drug revenues have grown at an average rate that's below 5%. Consequently, the 340B program has grown to account for more than 8% of the total U.S. drug market and about 16% of the total rebates and discounts that manufacturers provide.

What's more, the 340B program is now almost as large as the Medicaid program's outpatient drug sales. However, 340B lacks Medicaid's regulatory infrastructure and controls. Medicaid rebates directly and transparently lower drug costs for the government, while 340B discounts disappear into providers' financial statements. It's troubling and hard to defend.

Read on for our latest details on the 340B program's ongoing and startling growth.

**340BACKGROUND**

The 340B program mandates that pharmaceutical manufacturers provide outpatient drugs to certain healthcare entities—known as eligible covered entities—at significant discounts. In 2019, more than 2,500 hospitals participated in the program. Since 2010, 340B covered entities have also been able to access 340B pricing through multiple external pharmacies. More than 25,000 pharmacies contracted with 340B covered entities in 2019.

Hospitals and other 340B covered entities profit from the difference between a drug's third-party reimbursement and the covered entity's 340B acquisition cost, a.k.a., the 340B ceiling price.

The 340B ceiling price is equivalent to the Medicaid net price. More technically, the 340B discount as a percentage of the average manufacturer price (AMP) equals the Medicaid rebate as a percentage of AMP. Click here to read my explanation of how to compute the 340B ceiling price.

Consequently, hospitals and other 340B covered entities can acquire many brand-name specialty pharmaceuticals for as little as $0.01, a practice known as **penny pricing**. This can occur when the calculation for a 340B price yields zero, which means that a drug has hit its 100% Medicaid rebate cap. For instance, AbbVie disclosed that Humira, the top-selling drug in the U.S., hit the rebate cap starting in early 2016. (source) Since then, both 340B hospitals and the Medicaid program have been able to buy Humira for $0.01.

For broader background on 340B's role in the pharmacy and PBM industries, see section 11.5 of our *2020 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*.

I have been covering the 340B program on *Drug Channels* for eight years now. Click here to read my more than 80 articles about the program.

**340BOOM**

In recent years, the Health Resources and Services Administration (HRSA) has provided *Drug Channels* with data measuring the 340B program. Apexus, the HRSA-designated Prime Vendor, reports these data to HRSA. A little-known fact: Apexus is owned by Vizient, one the largest hospital group purchasing organizations.

The following chart summarizes the ongoing surge in covered entities' purchases made under the 340B Drug Pricing Program. It also includes our estimates of the value of those purchases at undiscounted, non-340B prices.

[Click to Enlarge]

Drug Channels is written by Adam J. Fein, Ph.D. Dr. Fein is CEO of Drug Channels Institute, a subsidiary of Pembroke Consulting, Inc. Read More...

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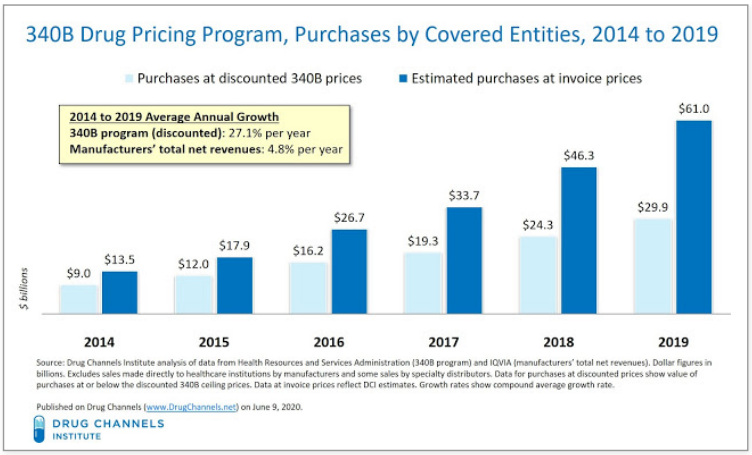


Here's a summary of our latest findings:

- Discounted purchases made under the program totaled $29.9 billion in 2019—an increase of 23% from the $24.3 billion in 2018.
- The compound average growth rate (CAGR) of 340B purchases was an incredible 27.1% from 2014 through 2019.
- Manufacturers' net revenues (per IQVIA) grew at a CAGR of only 4.7% from 2014 to 2019.

Two important comments on these data:

- The chart above includes DCI's estimated invoice value of these purchases. The undiscounted invoice figure is based on average Medicaid drug rebate rates, as reported by MACSTATS. For 2018, MACSATS reported that rebates reduced Medicaid's gross spending on outpatients prescriptions by 59%. We have adjusted these rebate figures to account for pharmacy dispensing and PBM administration costs included in the Medicaid gross spending data. The figures above therefore differ slightly from our previous estimates. The actual undiscounted figures are unknown.
- The data from Apexus include only indirect sales made via wholesalers. The $29.9 billion figure is therefore less than the actual total of 340B purchases at discounted prices. That's because the Apexus data exclude an unknown amount of manufacturer sales made directly to healthcare institutions and some sales by specialty distributors.

**340BIG**

Many partisan supporters try to minimize 340B's share of the total U.S. market. In reality, the 340B program is a significant and growing part of the industry.

Here are three computation approaches that portray the size of today's 340B program:

**1) 340B as a share of net drug sales = 8.3%**

The discounted HRSA figures above include purchases at or below the deeply discounted 340B ceiling prices. An appropriate comparison must therefore also be discounted sales, i.e., manufacturers' net revenues after rebates and discounts.

According to IQVIA, manufacturers' net revenues were projected to be $360 billion in 2019.

Using net revenues, 340B's share in 2019 was **8.3%**, or $29.9 billion ÷ $360 billion.

This overall average also hides wide variation. Specialty drugs have a higher-than-average share of sales made at 340B discount prices. For example, Merck recently disclosed that one-third of Keytruda's sales come from 340B covered entities.

FYI, 340B's 2019 share is 120 basis points higher than our 7.1% computation for 2018.

**2) 340B as a share of gross-to-net discounts for brand-name drugs = 16%**

The 340B program has become a significant and growing part of the total discounts that manufacturers provide.

For 2019, the total value of gross-to-net reductions for brand-name drugs was $175 billion. (See Section 9.2.2. of our 2020 pharmacy/PBM report.) This figure measures the gap between: (1) manufacturers' gross revenues of brand-name drugs at the wholesale acquisition cost (WAC) list price, minus (2) manufacturers' actual revenues at drugs' net prices after rebates, off-invoice discounts, copay assistance, price concessions, and such other reductions as distribution fees, product returns, the 340B Drug Pricing Program, and more. Rebates constitute about two-thirds of gross-to-net reductions.

Based on the chart above, the total value of gross-to-net reductions from the 340B

program was $31.1 billion (= $61.0 - $29.9). We estimate that brand-name drugs account for 90% of 340B discounts, or $28 billion.

Therefore, 340B's share of total gross-to-net discounts for brand-name drugs in 2019 was **16%**, or $28 billion ÷ $175 billion.

**3) Drug sales under the 340B program now almost equal drug sales under the Medicaid program.**

For a final comparison, consider the Medicaid Drug Rebate Program (MDRP). Pharmaceutical manufacturers that participate in the MDRP must also agree to offer a 340B ceiling price to covered entities.

The Centers for Medicare & Medicaid Services (CMS) projects that net sales of outpatient drugs paid by Medicaid were $34.9 billion in 2019. See The Latest CMS Outlook for Drug Spending—And How COVID-19 Will Change It.

Therefore, the 340B program is now **85%** (= $29.9 ÷ $34.9) as large as the Medicaid program.

For an alternative estimate, I recommend Measuring the Relative Size of the 340B Program: 2018 Update. Using different assumptions about 340B discounts, Berkeley Research Group concluded that 340B accounted for 14.0% of brand-name drug sales.

**340BETTER**

340B Health, which lobbies for hospitals that participate in the 340B program, continues to claim falsely that 340B is "just 1% of the total U.S. drug market." LOL. (As of this morning, this figure appeared on the 340B Infographics page of 340B Health's website.)

BTW, 340B Health always launches an annual *ad hominem* attack on me to distract us from the uncomfortable facts about the program's true size. Can't wait.

Longtime readers know that I believe that the 340B program is long overdue for reform, especially in light of the many abuses and problems that have been uncovered by the U.S. Government Accountability Office (GAO) and the Office of the Inspector General (OIG). Substantial evidence suggests that 340B savings are not always shared with patients and their insurance providers, including Medicare.

Unlike the highly regulated Medicaid program, the 340B program is managed via a tangle of sub-regulatory guidance, private letters, and "Frequently Asked Questions" posted to the HRSA website.

There is also no transparency into how 340B discounts are spent, because hospitals and their lobbyists fight any call for them to disclose or account for how they use their 340B profits. There is compelling evidence that hospitals are double-counting 340B savings against their fundamental legal and statutory community benefit obligations as non-profit organizations.

By contrast, detailed Medicaid data are available from nonpartisan government agencies. Meanwhile, the 340B program's advocates and regulators consistently misrepresent the program's size and growth.

In our current environment, there's little chance for reform. Consider this year's update to be my annual reminder that the 340B program is not fine.



Print Posted by Adam J. Fein, Ph.D. on Tuesday, June 09, 2020 3 Comments
Labels: 340B, Gross-to-Net Bubble, Health Care Policy, Hospitals

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**DRUG CHANNELS IN THE NEWS**

Rules block patients from counting thousands in drug discounts toward health insurance deductible *Columbus Dispatch*

Pharmacy Economist Describes Fork in the Road for Generics and Biosimilars *AJMC Center for Biosimilars*

A reality check on Amazon's rumored pharmacy stores *Axios*

Amazon reportedly planning physical pharmacies, diagnostic tests *Freight Waves*

Drug manufacturers and middlemen both responsible for rising consumer costs *Ohio Capital Journal*

GoodRx helps people afford drugs. But is it improving health care or profiting off a broken system? *Fortune*

Americans paid two to four times as much for some drugs as in three other countries *STAT*

Costco Brings Its Low-Price Magic to Employer-Paid Drug Plans *Bloomberg BusinessWeek*

Overworked, understaffed: Pharmacists say industry in crisis puts patient safety at risk *NBC News*

Walker exaggerates effect of Trump drug order, Biden freeze *Politifact*

Insulin's Out-Of-Pocket Cost Burden To Diabetic Patients Continues To Rise Despite Reduced Net Costs To PBMs *Forbes*

Comments and reactions for this thread are now closed.

3 Comments Drug Channels Disqus' Privacy Policy Login

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**Scott Brown** • a year ago

Mr Fein, Let me start by saying that most of your commentary on this and other topics is spot-on, and I enjoy reading your columns as they are released.

Also, I agree with you that the 340b program as a whole needs more oversight and structure. However, you consistently miss some of the most salient points regarding 340b: (1) the overwhelming majority of covered entities (CE) operate their respective programs by the book and as Congress intended in 1992; (2) most, if not all, of the confusing guidance and conflicting information is a DIRECT result of manufacturer influence and input on the 340b program; (3) CE hospitals, do, in fact, generate extra revenue by obtaining OUTPATIENT drugs at 340b pricing, but they also LOSE revenue on those patients who are not eligible to receive 340b-priced drugs due to the rock-bottom reimbursement rates of the cut-throat PBMs; and (4) there are countless numbers of people who, because of the high cost, would have foregone critical, life-saving and life-sustaining medications if 340b didn't exist (see insulins and chemo for a couple of examples).

The big box pharmacies (Walgreens and CVS, et al) have also taken advantage of vulnerable patients and CE with their draconian and arbitrary requirements placed on CE's for the use of contract pharmacies. They have stiff-armed the CE into contracts that benefit them more than patients or CE.

I do have a question for you: do the 340b prices supplied by HRSA include the enormous upcharge that Apexus puts on 340b drugs they supply to CE?

As a 25-year practicing pharmacist with 21+ years of 340b experience, I would welcome the opportunity to have a frank, open discussion with you regarding the merits and shortfalls of the 340b program.

Respectfully, Scott Brown

^ | v • Share ›

**Melissa Jenkins** ➚ Scott Brown • a year ago

Thank you for raising these important points.

The program includes a wide range of participants, not just hospitals. Community health centers, one of the eligible covered entities, rely on 340B drugs for savings (on drug purchases for which they receive no reimbursement), and many - - if not most - - do pass on the discounted pricing. They should not be summarily lumped together with hospitals in discussions of the program, its benefits, and its potential abuses.

^ | v • Share ›

**Derek Pihl** ➚ Melissa Jenkins • a year ago

I want to second what Melissa says about not lumping community health centers and other non-hospital 340B covered entities into broad statements about 340B abuse. I work for one and we are very transparent with how we use the money we save by purchasing medication at 340B prices for patient services. We have a board-approved "340B Program Impact Statement" that specifies the patient programs that are directly supported by this.

^ | v • Share ›

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Amazon's drugs unlikely to prove fatal to pharmacies, say experts *Financial Times*

Amazon Pharmacy Profits From Rebates, Instead Of Replacing Them *Inside Health Policy*

Is Amazon's pharmacy foray disruptive? Experts disagree. *Healthcare Dive*

Amazon's Drugstore Isn't Revolutionizing Anything—for Now *Bloomberg*

## INDUSTRY NEWS AND BLOGS

**Chain Drug Review**
Budweiser teams with actor Bill Pullman to recreate presidential speech from Independence Day

**Fierce Pharma**
Amid rush of scandals, Eli Lilly settles sex discrimination, harassment suit with former lobbyist

**Endpoints**
ICER finds Biogen's new exorbitantly priced Alzheimer's drug doesn't match even an optimistic view of potential clinical benefits

**STAT**
STAT+: Pharmalittle: Most doctors disagree with FDA approval of the new Alzheimer's drug; women underrepresented in life sciences C-suites

**Drug Store News - Pharmacy**
Schick Intuition, Molly Burke partner on inclusive content initiative

**Healthcare Economist**
Links

**The Catalyst (PhRMA)**
3 things that support robust biopharmaceutical research and development

**Biosimilars Review & Report**
Enticing Patients to Switch to Infliximab Biosimilars

**Health Business Group**
Interview with Glympse Bio CEO Caroline Loew

**PCMA**
The Pharmacy Benefit Brief | June 2021

**RxTrace**
FDA's Food Safety Modernization Act (FSMA), Explained

**Eye on FDA**
Virtual Reality – FDA and AdComms

**Pharmaceutical Commerce**
HKSTP, AstraZeneca introduce biotech incubator program

**Pharmaceutical Executive**
Central Focus: Targeting Unmet Need in CNS

# EXHIBIT C

**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

# FORM 10-K

☑ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

**For the fiscal year ended August 31, 2020**

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Transition Period From _____ to _____
Commission file number 001-36759

# WALGREENS BOOTS ALLIANCE, INC.

(Exact name of registrant as specified in its charter)

| **Delaware** | **47-1758322** |
|---|---|
| (State of incorporation) | (I.R.S. Employer Identification No.) |
| 108 Wilmot Road, Deerfield, Illinois | 60015 |
| (Address of principal executive offices) | (Zip Code) |

Registrant's telephone number, including area code: (847) 315-3700

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, $0.01 par value | WBA | The Nasdaq Stock Market LLC |
| 2.875% Walgreens Boots Alliance, Inc. notes due 2020 | WBA20 | The Nasdaq Stock Market LLC |
| 3.600% Walgreens Boots Alliance, Inc. notes due 2025 | WBA25 | The Nasdaq Stock Market LLC |
| 2.125% Walgreens Boots Alliance, Inc. notes due 2026 | WBA26 | The Nasdaq Stock Market LLC |

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

| | |
|---|---|
| Large accelerated filer ☑ | Accelerated filer ☐ |
| Non-accelerated filer ☐ | Smaller reporting company ☐ |
| | Emerging growth company ☐ |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☑

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

As of February 29, 2020, the aggregate market value of Walgreens Boots Alliance, Inc. common stock held by non-affiliates (based on the closing transaction price on Friday, February 28, 2020) was approximately $33.5 billion.

As of September 30, 2020, there were 865,915,666 shares of Walgreens Boots Alliance, Inc. common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the definitive proxy statement for our Annual Meeting of Stockholders planned to be held on January 28, 2021 are incorporated by reference into Part III of this Form 10-K as indicated herein.

developing and maintaining customer loyalty. The expansion of our private brand offerings also subjects us to additional risks, such as potential product liability risks and mandatory or voluntary product recalls; our ability to successfully protect our proprietary rights and successfully navigate and avoid claims related to the proprietary rights of third parties; our ability to successfully administer and comply with applicable contractual obligations and regulatory requirements; and other risks generally encountered by entities that source, sell and market exclusive branded offerings for retail. An increase in sales of our private brands may also adversely affect sales of our vendors' products, which, in turn, could adversely affect our relationship with certain of our vendors. Any failure to adequately address some or all of these risks could have a material adverse effect on our reputation, business operations, results of operations and financial condition.

**We are subject to payment-related and other financial services risks that could increase our operating costs, expose us to fraud or theft, subject us to potential liability and potentially disrupt our business operations.**

We accept payments using a variety of methods, including cash, checks, credit and debit cards, gift cards and mobile payment technologies such as Apple Pay™, and we may offer new payment options over time. Acceptance of these payment options subjects us to rules, regulations, contractual obligations and compliance requirements, including payment network rules and operating guidelines, data security standards and certification requirements, and rules governing electronic funds transfers. These requirements and related interpretations may change over time, which has made and could continue to make compliance more difficult or costly. For certain payment methods, including credit and debit cards, we pay interchange and other fees, which could increase over time and raise our operating costs. We rely on third parties to provide payment processing services, including the processing of credit cards, debit cards, and other forms of electronic payment. If these companies become unable to provide these services to us, or if their systems are compromised, it could disrupt our business. The payment methods that we offer also subject us to potential fraud and theft by persons who seek to obtain unauthorized access to or exploit any weaknesses that may exist in the payment systems. If we fail to comply with applicable rules or requirements, or if data is compromised due to a breach or misuse of data relating to our payment systems, we may be liable for costs incurred by payment card issuing banks and other third parties or subject to fines and higher transaction fees, or our ability to accept or facilitate certain types of payments could be impaired. In addition, our reputation could suffer and our customers could lose confidence in certain payment types, which could result in higher costs and/or reduced sales and materially and adversely affect our results of operations.

Additionally, we offer money (wire) transfer services and sell prepaid debit, credit and gift cards at certain business units. These products and services require us to comply with global anti-money laundering laws and regulations. Failure to comply with these laws and regulations could result in fines, sanctions, penalties and damage to our reputation.

**Changes in the healthcare industry and regulatory environments may adversely affect our businesses.**

Political, economic and regulatory influences are subjecting the healthcare industry to significant changes that could adversely affect our results of operations. In recent years, the healthcare industry has undergone significant changes in an effort to reduce costs and government spending. These changes include an increased reliance on managed care; cuts in certain Medicare and Medicaid funding in the United States and the funding of governmental payers in foreign jurisdictions; consolidation of competitors, suppliers and other market participants; and the development of large, sophisticated purchasing groups. We expect the healthcare industry to continue to change significantly in the future. Some of these potential changes, such as a reduction in governmental funding for certain healthcare services or adverse changes in legislation or regulations governing prescription drug pricing, healthcare services or mandated benefits, may cause customers to reduce the amount of our products and services they purchase or the price they are willing to pay for our products and services. We expect continued governmental and private payer pressure to reduce pharmaceutical pricing, and these pressures could be further exacerbated if payer deficits or shortfalls increase due to COVID-19 or otherwise. Changes in pharmaceutical manufacturers' pricing or distribution policies and practices as well as applicable government regulations, including, for example, in connection with the federal 340B drug pricing program, could also significantly reduce our profitability.

In the United States, electoral results and changes in political leadership often generate uncertainty with respect to, and could result in, significant changes in legislation, regulation and government policy that could significantly impact our businesses and the healthcare and retail industries. We cannot predict whether current or future efforts to modify healthcare laws or regulations and/or adopt new healthcare legislation or regulations will be successful, nor can we predict the impact that such a development would have on our business and operating results. Future legislation or rulemaking or other regulatory actions or developments could impact the number of Americans with health insurance and, consequently, prescription drug coverage, increase regulation of pharmacy services, result in changes to pharmacy reimbursement rates, and otherwise change the way we do business. We cannot predict the timing or impact of any future legislative, rulemaking or other regulatory actions, but any such actions could have a material adverse impact on our results of operations.

# EXHIBIT D

July 31, 2013

Mr. Gregory Wasson
President and CEO
Walgreens
200 Wilmot Road
Deerfield, Illinois, 60015

Dear Mr. Wasson:

The 340B program, as established in the Public Health Service Act (PHSA), is a voluntary program that ensures that certain providers within our nation's health care safety net (covered entities) have access to outpatient drugs at or below statutorily defined ceiling prices.[1] The original intent of the program was to extend the Medicaid drug discount to the most vulnerable of patients at PHS Clinics, those who are mostly, "medically uninsured, on marginal incomes, and have no other source to turn to for preventive and primary care services."[2]

In its September 2011 report on the 340B program, the Government Accountability Office (GAO) notes an inadequate level of oversight by the Health Resources and Service Administration (HRSA) and a lack of necessary direction on program requirements.[3] The greatest concern of the GAO finding is that, "Increased use of the 340B program by contract pharmacies and hospitals may result in a greater risk of drug diversion, further heightening concerns about HRSA's reliance on participants' self-policing to oversee the program."[4] Moreover, GAO found that, "Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies."[5]

The growth of contract pharmacies has exploded in recent years with HRSA's new multiple contract pharmacy guidance issued on March 5, 2010. According to GAO, as of July 2011, there were over 7,000 contract pharmacy arrangements in the program.[6]

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[1] 42 U.S.C. 256(b).
[2] Public Health Clinic Prudent Pharmaceutical Purchasing Act, Comm. Report to Accompany S. 1729, 102-259, Senate Comm. On Labor and Human Resources, Mar. 3, 1992.
[3] U.S. Government Accountability Office, GAO-11-836, Drug Pricing: Manufacturing Discounts In The 340B Program Offer Benefits, But Federal Oversight Needs Improvements (2011).
[4] *Id.*
[5] *Id.*
[6] *Id.*

As more discounted drugs intended for indigent patients under the 340B program are resold at a markup to those insured through Medicare, the financial liability to the federal government increases. The intent and design of the program is to help lower outpatient drug prices for the uninsured. It is not intended to subsidize pharmacies that team up with covered entities to turn a profit. Of the 7,000 contract pharmacies, 5,400 are Walgreens. In a February 28, 2012, slide presentation entitled, "Innovation Care Delivery Models: Pharmacy and Health Systems Collaborations," Walgreens discusses ways to, "generate revenue from [its] 340B patients."[7] Additionally, the presentation describes ways in which Walgreens can help manage inventory and information, such as, "daily patient detail reports – date, medication, quantity filled and copay."[8]

Furthermore, Walgreens Senior 340B Inventory and Reconciliation Analyst, Timothy Hong, states on his LinkedIn page that 340B is "…a relatively new area within Walgreens and is projected to add a minimum of $250 million in incremental revenue over the next 5 years."[9] Mr. Hong goes on to say that Walgreens "…optimizes client's 340B program, so they can be more profitable while lowering Walgreens liability."[10]

To help better understand Walgreen's participation as a contract pharmacy, please provide the following documents and response to the below inquires by August 14, 2013:

1) Please provide a list of all 340B covered entities with which Walgreens has an active contract pharmacy agreement, either indirectly or directly. When providing this information, please provide the distance between each participating Walgreens and the 340B covered entity and the type of covered entity (i.e. Critical Access Hospitals, Disproportionate Share Hospitals).

2) Please provide a summary of all profits generated as a result of participating in the 340B program as a contract pharmacy. When providing this information, please break down the revenue by location and participating covered entity.

3) Please provide the different types of 340B services that Walgreens provides to covered entities, and the fees associated with each type of service.

4) For the top 100 340B drugs dispensed, please provide a breakdown of the financial arrangement, including: how much money goes to (1) the participating covered entity; (2) Walgreens; and (3) any supplemental vendor or contractor that assists in managing the relationship between Walgreens and the covered entity (i.e. split billing software vendor).

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[7] February 28, 2012, PowerPoint presentation entitled "Innovative Care Delivery Models: Pharmacy & Health Systems Collaborations."
[8] *Id.*
[9] *See* http://www.linkedin.com/pub/timothy-hong/28/651/511
[10] *Id.*

5) What protections does Walgreens have in place to ensure low-income, uninsured eligible 340B patients are receiving the 340B discounted drug as close to acquisition cost as possible?

6) Covered entities have long argued that the 340B program was intended to assist non-profit safety-net providers to, "stretch scarce Federal resources," in serving the underserved populations in their communities. Under this interpretation, why should Walgreens, as a for-profit corporation, financially benefit from such a program?

7) Does Walgreens have a transparent process for reinvesting money back into underserved communities generated by being a contract pharmacy in the 340B program? If not, why not?

8) The February presentation mentions that Walgreens is able to assist with 340B related auditing requirements. Please provide additional information regarding such abilities and a breakdown of any assistance provided to covered entities to date.

Maintaining the integrity of the 340B program is of the utmost importance, and we trust that you share our concerns. If you have any questions regarding this request, please contact Erika Long of the Senate Committee on the Judiciary at (202) 224-5225.

Sincerely,

Charles E. Grassley
Ranking Member
Committee on the Judiciary

# EXHIBIT E

# HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable

## Your 340B Report for Thursday July 9, 2020

Tom Mirga
Jul 9



***A note from Publisher and CEO Ted Slafsky:*** Attention 340B covered entities! I am honored and excited to be speaking on a virtual panel July 15 hosted by 340B Report sponsor PSG on the latest 340B developments. I am speaking with a great group of experts including my long-time colleague Bill von Oehsen of Powers Law (also a 340B Report sponsor) and Dustin Ottemiller, Vice President of Finance and Population Health at Jefferson Health. I hope you can join us

for this timely and candid conversation. More details about the event and how to register can be found in PSG's sponsored content article, which is immediately after our lead story below.



**HRSA says that although its 2010 contract pharmacy guidelines remain in effect, "guidance is not legally enforceable." The agency says it "strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements." | Source: Shutterstock**

## HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable

In what some perceive as a break with a position dating back to 1996, the U.S. Health Resources and Services Administration (HRSA) said late yesterday that although its 2010 contract pharmacy guidance remains in effect, it is not legally enforceable. HRSA was responding to questions from 340B Report about drug manufacturer Eli Lilly's July 1 decision

to stop providing 340B discounts on its erectile dysfunction drug Cialis when it is dispensed by contract pharmacies.

Asked if Lilly is obligated to provide 340B-priced product to contract pharmacies, HRSA told us:

> Contract pharmacies are a mode for dispensing 340B drugs and serve a vital function in covered entities' ability to serve underserved and vulnerable populations. Manufacturers that refuse to honor contract pharmacy orders would have the effect of significantly limiting access to 340B discounted drugs for many underserved and vulnerable populations who may reside in geographically isolated areas and rely on a contract pharmacy as a critical point of access for obtaining their prescriptions. HRSA strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements.

We asked HRSA if it would take action against Lilly for not providing 340B-priced drugs to contract pharmacies. It said:

> As previously stated, HRSA strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements.

We also asked HRSA if it still stands by its 2010 contract pharmacy guidelines. HRSA answered:

> The 2010 guidance is still in effect. However, 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. Without comprehensive regulatory authority, HRSA is unable to develop enforceable policy that ensures clarity in program requirements across all the interdependent aspects of the 340B Program.

When 340B Report broke the news two days ago of Lilly's decision to stop providing 340B discounts on Cialis shipped to contract pharmacies, attorneys for health care providers interpreted the company's move as an invitation to the U.S. Health and Human Services (HHS) Department either to sue Lilly or initiate administrative proceedings against it in defense of HRSA's 340B contract pharmacy guidelines. It appears now that HHS and HRSA have concluded that Lilly cannot be compelled to provide 340B discounts on drugs dispensed by contract pharmacies. One attorney for providers said HRSA appears to be breaking with the position it has held on that subject for 24 years.

An attorney for drug manufacturers, however, agreed with Lilly's position that the 340B statute imposes no obligation on manufacturers to sell to contract pharmacies at the 340B price. The government would likely fail if it tried to enforce HRSA's non-binding contract pharmacy guidance, the attorney said.

Attorneys for providers also say HRSA's statement to 340B Report that program guidelines are legally unenforceable could encourage other drug manufacturers to follow Lilly's lead and declare that they, too, will stop providing 340B discounts on drugs dispensed by contract pharmacies. Depending on how many manufacturers did so, that could significantly reduce provider revenues on 340B drugs—with harmful effects, providers say, on patient care. It also could boost drug manufacturer profits.

More broadly, HRSA's statement that 340B guidance in general cannot be enforced raises questions about the viability of many 340B program requirements—not just those for manufacturers, but for covered entities, too.

According to Stephen Kuperberg, Counsel with Powers Law, a 340B Report sponsor, when HRSA issued guidance in 1996 setting parameters for covered entities to contract with a single outside pharmacy, it "did not believe that its guidance established any new right or obligation. Rather, it interpreted the obligations established by the 340B statute in light of existing common law contract and agency law."

"Congress certainly intended for the 340B statute to be enforceable," Kuperberg continued. "That the agency has now decided it cannot act to enforce what it has maintained for over two decades was a clear and enforceable right under the statute is puzzling and disquieting, and certainly could be seen among other manufacturers as an invitation to follow suit."

Richard Church, Partner at K&L Gates, noted that when a South Carolina community health center sued HRSA in federal court in 2018 over its termination from 340B over an adverse audit finding, HRSA similarly backed down.

"Their options were similar here to either challenge Eli Lilly and risk litigation or simply encourage compliance with their guidance," Church said. "It appears they have chosen the latter path. Each of these incidents suggests that much of their guidance may not be enforceable, particularly if HRSA is unwilling to risk another litigation loss on this front."

Andrew Ruskin, also Partner at K&L Gates, added that "covered entities may opt to explore where they believe they have similar flexibilities in interpreting HRSA's guidance. That is, unless and until HRSA does get rulemaking authority from Congress."

Todd Nova, a Shareholder in Hall Render, said, "Much like with the 340B mega-guidance that was withdrawn, it seems HRSA OPA [Office of Pharmacy Affairs] is acknowledging that they do not have direct statutory guidance conferring authority to establish regulations governing contract pharmacy arrangements. Still, it is common for agencies across the HHS spectrum including OPA to publish sub-regulatory guidance that provides insight into their interpretation of existing statutory authority. Though it's somewhat subjective, at some point that guidance becomes 'longstanding' and can be afforded the force of law by a court. The 2010 contract pharmacy guidance has been in place for quite some time now, so I do not think HRSA OPA is suggesting it is unenforceable but rather is acknowledging it is sub-regulatory rather than an authorized regulation."

Jason Reddish, Partner at Feldesman Tucker, said, "HRSA clearly continues to believe in the contract pharmacy model and rightly supports that covered entities have the well-settled ability to contract with a pharmacy to dispense the 340B drugs that they have a right to purchase. The contract pharmacy guidance is simply that—guidance for entities that choose to use a contract pharmacy so they can do so in a manner that prevents diversion and fee-for-service Medicaid duplicate discounts."

John Shakow, a Partner at King & Spalding who represents drug manufacturers, said, "The law doesn't impose any obligation on manufacturers to sell to contract pharmacies at the 340B price, so in that respect Lilly is well within its rights. Manufacturers also aren't obliged to cause product purchased by a covered entity to be shipped to anyone other than the covered entity itself (with certain exceptions). Because there is no legal obligation on manufacturers to honor contract pharmacy arrangements in this way, any attempt by the government to enforce HRSA's non-binding guidance would likely fail."


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- Dustin Ottemiller, Vice President, Finance, Thomas Jefferson University Hospital
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# Providers Worry About Impact if Other Drug Companies Follow Lilly's Lead on Contract Pharmacy

Corporate and pharmacy executives at 340B covered entities are concerned about the potential long-term implications for patient care and their finances of Eli Lilly and Co.'s position that there is no statutory obligation to provide 340B-priced drugs to contract pharmacies.

Hudson Headwaters Health Network, a system of 19 health centers in upstate New York, pioneered 340B multiple contract pharmacy starting in 2001 under a U.S. Health Resources and Services Administration (HRSA) demonstration project. It has since launched a consulting firm, Hudson Headwaters 340B, a 340B Report sponsor.

According to Hudson Headwaters 340B President Jim Donnelly:

> Without the network of contract pharmacies allowed by the current 340B contract pharmacy model, Hudson Headwaters would not be able to participate in this vital program. The 340B program has allowed Hudson Headwaters to improve medication affordability for patients with financial need through increasing discounts and coordinating assistance programs and has also contributed stability which has allowed for more comprehensive services to be accessible to all patients within its diverse and sprawling geographic footprint. Reverting to the original 340B limitations on contract pharmacies would be an extraordinary step backwards for the nation's healthcare safety-net. This would be devastating to most covered entities, their communities and patients who now rely on the access to pharmacy services and the healthcare services 340B has been instrumental in supporting.

Michael Bonck, System Director of Clinical Pharmacy Services at CommonSpirit Health, said:

> 340B entities may not be able to provide prescriptions to the poor and underserved patient populations in our communities, our true mission to help build healthy communities. Contract pharmacies have allowed covered entities to stretch their scare resources to be able to afford taking care of the poor and underserved within our communities long term prescription needs. It could lead to sicker populations, increased ER visits and hospitalizations, a vicious cycle. Removing contract pharmacy benefits could lead to closure not only of services, but closure of system pharmacies and in some poorer communities, even hospitals.

A 340B program manager for a major U.S. health system who requested anonymity said:

Our biggest concern is with our at-risk diabetic patients who depend on insulin products produced by Lilly. A number of these patients have little to no financial means and depend on the 340B pricing to help make the insulin affordable on their limited incomes. Losing 340B pricing on those products, in particular, will shift the cost of care back to the hospital to help support these patients, causing additional financial strain onto our hospitals and health system.



## New Drug Manufacturer Notices on HRSA Website

The U.S. Health Resources and Services Administration (HRSA) has posted a new drug manufacturer notice on its website about refunds for 340B overcharges and two new manufacturer notices about limits on distribution of certain drugs.

- Spectrum Pharmaceuticals has restated its 340B ceiling price on Zevalin injection, which is used to treat non-Hodgkin's lymphoma, from Q3 2009 through Q2 2020. The notice includes instruction on how covered entities may request refunds.

- Kyowa Kirin says in a notice that it has arranged for its Parkinson's disease drug Nourianz to be available for purchase at its 340B price from Cardinal Health. Covered entities also can obtain Nourianz from Caremark and Walgreens specialty pharmacies if they have a contract pharmacy relationship with such pharmacies.

- Johnson & Johnson subsidiary Actelion published a limited distribution notice for six products: for Opsumit, Tracleer, Uptravi, Veletri, and Ventavis (all treatments for pulmonary arterial hypertension) and for Zavesca (for Gaucher disease). 340B covered entities can access 340B ceiling prices for these products through contract pharmacy arrangements with Accredo Specialty Pharmacy. Orders must be placed with CuraScript Specialty Distribution. CuraScript will facilitate bill to/ship to replenishment orders for the products at the 340B ceiling price. Covered entities will be charged the 340B ceiling price, and product will be shipped to Accredo Specialty Pharmacy.



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**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

| | |
|---|---|
| UNITED THERAPEUTICS CORPORATION,<br><br>Plaintiff,<br><br>v.<br><br>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,<br><br>Defendants. | Case No. 1:21-cv-01686 |

**DECLARATION OF DAVID BARTON IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT**

I, David Barton, declare as follows:

1. I am Associate Vice President of Managed Markets and Reimbursement at Plaintiff United Therapeutics Corporation (UT). I have held this role for two years and been employed at UT since February 22nd, 2010.

2. As Associate Vice President of Managed Markets and Reimbursement, I am responsible for, among other things, oversight of payor contracts with pharmacy benefit managers (PBMs) and health plans, and government price reporting and compliance obligations under Medicaid, Medicare Part B, and the 340B program. I have substantial experience in managing UT's participation in the 340B Drug Pricing Program (known as the "340B program").

3. I have personal knowledge of the matters stated in this declaration and would testify truthfully to them if called upon to do so.

4. UT is a biotechnology company focused on the development and commercialization of innovative products to address the unmet medical needs of patients with chronic and life-threatening cardiovascular diseases and cancer.

5. UT was founded in 1996 as a mission-driven company to develop a treatment for our founder's youngest daughter who had been diagnosed with a rare, life-threatening disease. That year, UT began funding early academic research. In the years since, UT has successfully commercialized multiple therapies that help treat vulnerable patient populations, including children. UT products mostly are "specialty" drugs, which generally require additional patient education and support beyond mere dispensing activities. Such patient support is typically available only from specialty pharmacies, and as a result, UT makes such drugs available only through in-house pharmacies of the facilities who treat these patients, or through two qualified specialty pharmacies in what is known as limited distribution arrangements. When dispensed by the particular qualified specialty pharmacies, the drugs are dispensed by mail or other forms of delivery. Two specialty pharmacies—"Accredo Health Inc." (Accredo) and "CVS Caremark" (Caremark)—fill these prescriptions.

6. UT's mission defines our culture and drives everything the company does. UT continually strives to make life better for patients and their families, and it is UT's belief that even the smallest patient populations deserve access to the best treatment options.

**UT's Participation in the 340B Program**

7. Since 2002, UT has participated in the 340B program. As required under the 340B statute, 42 U.S.C. § 256b, and the Pharmaceutical Pricing Agreement and Addendum (PPA), UT offers its covered outpatient drugs for purchase at a discounted price (known as the "ceiling price") by statutorily enumerated 340B "covered entities."

8. As a company uniquely dedicated to supporting vulnerable patient populations, UT proudly supports the goals of the 340B program and continues to fulfill the program's requirement of offering its covered outpatient drugs for purchase by covered entities at the 340B ceiling price. For this same reason, UT also seeks to promote 340B program integrity and ensure that the 340B program continues to support covered entities' patients.

9. In recent years, UT has grown increasingly concerned that the Health Resources and Services Administration's (HRSA) contract pharmacy policy has allowed commercial actors to inappropriately share in and absorb the benefits provided under the 340B program. Our concern relates to the increases in requests for 340B pricing since 2018. UT data demonstrate that the number of 340B discount claims in total for UT's drugs Remodulin® (treprostinil) Injection, Tyvaso® (treprostinil) Inhalation Solution, and Orenitram® (treprostinil) Extended-Release Tablets more than doubled from 2018 to 2020.

10. We are not aware of a substantial increase in patient population that could be driving these increased requests for 340B pricing. Instead, it appears that Accredo's recent positioning as a "contract pharmacy" for UT's outpatient drugs is the cause of the increased number of requests.

11. The increased use of contract pharmacy arrangements in turn increases the risk of "diversion" and "duplicate discounts," both of which are expressly prohibited by the 340B statute. I am aware that government auditors have examined and identified these problems. *See* GAO, *Federal Oversight of Compliance at 340 Contract Pharmacies Needs Improvement* at 45 (June 2018) ("The expansion of contract pharmacies . . . increases potential risks to the 340B Program, such as risks related to diversion and duplicate discounts.").

12. Diversion occurs when UT's 340B drugs are resold or transferred to entities or individuals who are not patients who were treated by the facilities entitled to receive 340B discounts. This is harmful to UT because it results in improperly selling a product at the 340B discounted price, which is generally significantly less than the price UT would otherwise charge.

13. Duplicate discounting occurs when UT 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. In other words, under this scenario, a covered entity that has acquired a covered outpatient drug from UT at the 340B ceiling price bills a state Medicaid program for a given unit of UT drug it has acquired at the 340B ceiling price and dispensed to a Medicaid-eligible patient. If the state Medicaid program is not itself aware that the unit has already been acquired under the 340B program, and if the covered entity has not informed the state Medicaid program of this fact, the state Medicaid program will submit an invoice to UT for payment of a rebate on the same unit of drug. This is particularly harmful because it results in UT providing *two* significant discounts on a single unit of product. The risk of diversion and duplicate discounting, which is already increased in the contract pharmacy context, is exacerbated by the "replenishment" model that contract pharmacies use for 340B drug orders.

14. As noted, in recent years the 340B sales of UT's specialty outpatient drugs (Remodulin®, Tyvaso®, and Orenitram®) have been dispensed by the specialty pharmacy Accredo. For the vast majority of those sales, the orders are placed by a "third-party administrator" that is a corporate affiliate of Accredo, known as "Verity Solutions" (Verity). (Sometimes, a different third-party administrator makes purchase orders.)

15. Our understanding is that Accredo and Verity operate under what is known as a "replenishment model" through the 340B program. Specifically, to our understanding, that means

that Accredo will dispense a drug from its general inventory to a patient irrespective of whether that patient is a patient from a 340B covered entity. Then, at some future date, Verity will use an "algorithm" to determine which of Accredo's patients for a designated preceding timeframe were likely patients associated in some manner with a 340B covered entity. We do not have insight into how that algorithm functions. Using the estimate generated by the algorithm, Verity will then place a "replenishment" order for UT's drugs. Our understanding is that that order will replenish Accredo's general inventory with drugs at the 340B price that will then, again, be dispensed by Accredo indiscriminately to patients from 340B covered entities as well as other patients.

16. The replenishment model described here with Accredo and Verity occurs one step removed from UT itself. Specifically, UT sells these drugs in bulk—all at commercial pricing—to a single specialty distributor, and that specialty distributor receives and fills orders across markets, including to covered entities and Accredo. When the specialty distributor receives a "replenishment" order from Verity it fills the order at 340B pricing and then requests a "chargeback" from UT to make up the difference between the commercial pricing that the specialty distributor initially purchased the drug at, and the 340B ceiling price that it was sold for. Although UT is aware of these "chargeback" requests, it lacks information demonstrating that these chargebacks actually correspond to actual drugs sold and dispensed to patients of covered entities, or that the covered entities have actually ordered or paid for these drugs.

**UT's Policies**

17. To confront what it perceived to be an inexplicable and unjustifiable growth in requests for 340B discounts (see *supra* ¶¶ 9-10), UT decided to implement two contract pharmacy policies designed to ensure 340B program integrity and support covered entities' patients. UT's

policies, as described below, apply to three UT outpatient drugs: Remodulin®, Tyvaso®, Orenitram® (as well as UT's inpatient drug Unituxin® (dinutuximab) for the reasons described *infra* at ¶ 19).

18. UT also distributes another drug under the trade name Adcirca® (tadalafil). Adcirca® is not a specialty drug and is not subject to UT's contract pharmacy policies.

19. Unituxin® is not dispensed by contract pharmacies and is not labeled or prescribed for use in any outpatient setting. It is only administered in hospitals, and then only in a carefully supervised setting. Because the 340B program is an outpatient drug program, Unituxin® cannot genuinely be subject to any 340B discount. Yet the distributor of Unituxin® (not a contract pharmacy) still regularly seeks 340B discount chargebacks related to Unituxin® based on 340B sales from hospital covered entities. This is one of many examples of misuse of the 340B program. Because UT receives 340B chargebacks for Unituxin®, UT has previously listed that drug as one of the drugs subject to its 340B policy, but again no contract pharmacies dispense Unituxin® to patients because it is administered only by medical professionals in an inpatient hospital setting.

20. UT notified HRSA by letter of its contract pharmacy policies on November 13, 2020, a true and correct copy of which is attached as **Exhibit A**. UT also issued letters to covered entities detailing these policies and the program integrity concerns they are intended to redress.

***UT's First Policy – The "Contract Pharmacies Policy"***

21. UT's first policy, the "Contract Pharmacies Policy," is directed at stemming the further growth in contract pharmacies. Under this policy, for orders placed by a contract pharmacy on or after November 20, 2020, UT will accept the order only if the particular contract pharmacy (which has in practice been one of two specialty pharmacies) was used by the related

covered entity to make 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).

22. This first policy is subject to an important exception: If a covered entity does not have a contract pharmacy that meets this requirement *and* the covered entity does not have its own on-site pharmacy, then that covered entity may contact UT to designate a single 340B contract pharmacy; UT will then accept 340B orders from that designated contract pharmacy.

23. UT's Contract Pharmacies Policy is intended to mitigate the risks of diversion and duplicate discounting inherent in the growth of ordering 340B drugs through contract pharmacies.

24. UT implemented its Contract Pharmacies Policy on November 20, 2020, and informed HRSA and covered entities that the policy applies to UT's drugs as discussed *supra* at ¶¶ 17-19.

25. The drugs subject to UT's Contract Pharmacies Policy are specialty drugs and, as noted, they are subject to a limited distribution arrangement with Accredo and Caremark. In recent years, the covered entities that purchase UT's drugs for dispensing by an outside pharmacy have all had patient prescriptions filled by Accredo. This means covered entities that utilized this contract pharmacy for UT's subject drugs during the first three quarters of 2020 can continue using the same contract pharmacy. We believe the vast majority of covered entities treating patients who may require the UT drugs at issue were already dealing with Accredo and/or its corporate affiliates during this time period.

26. Under UT's Contract Pharmacies Policy, if a covered entity does not have its own in-house pharmacy and has not used a contract pharmacy during the relevant calendar quarters, the covered entity may seek an exception from UT, as noted above. Additionally, any covered entity that has its own in-house pharmacy may order any of the UT drugs at the 340B ceiling price

directly from the specialty distributor for shipment to the covered entity for dispensing through the in-house pharmacy. In other words, UT's Contract Pharmacies Policy has no impact whatsoever on the covered entity's ability to itself purchase UT drugs at the 340B ceiling price when such orders take place without the involvement of a contract pharmacy. (Nor does UT's "Claims Data Portal Policy," discussed below.)

27. Since UT's implementation of the Contract Pharmacies Policy, there has been no decrease in the number of 340B discounts provided by UT for the covered outpatient drugs at issue. Specifically, UT's 340B chargebacks from November 2020, to May 2021 were approximately 8% larger than UT's 340B chargebacks in that same period from November 2019, to May 2020.

***UT's Second Policy – The "Claims Data Portal Policy"***

28. UT's second policy—the "Claims Data Portal Policy"—is directed at ensuring the integrity of the 340B program, that 340B orders are *bona fide*, and that unlawful duplicate discounts are detected. Under this policy, covered entities using a contract pharmacy will be required 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 Medicaid rebate invoice for the same unit, *i.e.*, a duplicate discount.

29. Specifically, each covered entity that uses a contract pharmacy and that wishes to order a UT drug at the 340B discounted price will create an online account with this third-party platform and for each 340B claim submit the following basic information: prescription number, prescribed date, fill date, National Drug Code (NDC), quantity, pharmacy ID, prescriber ID, wholesaler invoice number, and 340B covered entity ID.

30. A covered entity's submission of such limited claims data—which does not include any protected health information (PHI) and cannot be used to identify a patient—will achieve the goal of preventing unlawful duplicate discounts by giving UT a ledger that it can compare against rebate requests by state Medicaid programs. For instance, if contract pharmacy claims data reveals a sale at the 340B ceiling price, and the sold units are the subject of a Medicaid rebate invoice, UT will work to resolve the identified duplicate discount.

31. This claims data will also help UT to determine if 340B discounts are being sought for prescriptions not actually written by prescribers of a covered entity.

32. As with its Contract Pharmacies Policy, UT informed HRSA and covered entities that UT's Claims Data Portal Policy applies to 340B purchases excerpt for Adcirca®.

33. UT's Claims Data Portal Policy has not yet been implemented. It was originally scheduled to take effect in May 2021, but it has been delayed and is currently not scheduled to take effect until September 1, 2021.

34. By letters to UT dated May 17, 2021, and May 28, 2021, HRSA issued a determination that UT's policies violated Section 340B (the Violation Determination), true and correct copies of which are attached as **Exhibits B and C**. UT responded to these letters on May 26 and June 10, 2021, true and correct copies of which are attached as **Exhibits D and E**.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 16th day of July 2021, in the State of Texas.

David Barton

David Barton

# EXHIBIT A

United Therapeutics
CORPORATION
Medicines for Life®

P.O. Box 14186
55 T.W. Alexander Drive
Research Triangle Park, NC 27709
tel 919.485.8350
fax 919.485.8352

To: 340B Covered Entity

From: Kevin Gray, Senior Vice President, Strategic Operations, United Therapeutics Corporation

Date: November 18, 2020

Subject: United Therapeutics Corporation 340B Contract Pharmacy Policy Effective November 20, 2020

Dear 340B Covered Entity:

We are writing to inform you of United Therapeutics Corporation's new 340B contract pharmacy policy. The policy will be implemented in two steps.

*Orders placed on or after November 20, 2020*:

- United Therapeutics Corporation will accept 340B contract pharmacy orders placed on or after November 20, 2020 only if the contract pharmacy was utilized by the covered entity for a valid 340B purchase of a United Therapeutics Corporation covered outpatient drug during the first three full quarters of the 2020 calendar year (i.e., January 1 through September 30, 2020).
- United Therapeutics Corporation will deny any 340B contract pharmacy orders where the contract pharmacy does not meet this requirement.
- To identify your contract pharmacies that are eligible under this policy, please visit UTAssist.com, select "Our Services" followed by "Product Distribution"
- If a covered entity does not have its own on-site pharmacy, United Therapeutics Corporation will provide the covered entity the opportunity to designate a single contract pharmacy for which United Therapeutics Corporation will accept 340B orders. To apply for this exception, please contact United Therapeutics Corporation at 340b@unither.com.

*Orders placed on or after May 13, 2021*:

- United Therapeutics Corporation will accept 340B contract pharmacy orders placed on or after May 13, 2021 only if the covered entity also has agreed to provide to United Therapeutics Corporation, and is providing on an ongoing basis, claims data associated with all 340B contract pharmacy orders of United Therapeutics Corporation's covered outpatient drugs placed after May 13, 2021 via a platform hosted by a third party with appropriate security and patient privacy safeguards.
- We will provide additional information to you with respect to the platform and this process in advance of May 13, 2021.

This policy will apply to all of United Therapeutics Corporation's covered outpatient drugs, except for ADCIRCA (tadalifil). United Therapeutics Corporation may revise this policy at its sole discretion at any time and without prior notice.

Please be advised that we have notified the Office of Pharmacy Affairs, Health Resources and Services Administration, of this policy.

For questions regarding this policy, please contact United Therapeutics Corporation at 340b@unither.com.

# EXHIBIT B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

May 17, 2021

Ms. Lynn Robson
Vice President, Associate General Counsel, Market Access
United Therapeutics Corporation
55 TW Alexander Drive
Research Triangle Park, NC 27709

Dear Ms. Robson:

The Health Resources and Services Administration (HRSA) has completed its review of United Therapeutics Corporation's (United Therapeutics) policy that places restrictions on 340B pricing to covered entities that dispense medication through pharmacies, unless the covered entities provide claims data to a third-party platform. After review of this policy and an analysis of the complaints HRSA has received from covered entities, HRSA has determined that United Therapeutics' actions have resulted in overcharges and are in direct violation of the 340B statute.

Section 340B(a)(1) of the Public Health Service (PHS) Act requires that manufacturers "shall…offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." This requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. Nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities. Furthermore, the 340B statute does not permit manufacturers to impose conditions on covered entities' access to 340B pricing, including the production of claims data. Section 340B(a)(1) of the PHS Act also requires manufacturers that have signed a Pharmaceutical Pricing Agreement (PPA) and PPA addendum to comply with these requirements. United Therapeutics is bound by the terms of the PPA and must ensure that the 340B ceiling price is available to all covered entities.

Also consistent with section 340B(a)(1) of the PHS Act, manufacturers are expected to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs. This extends to the manner in which 340B drugs are made available to covered entities (e.g., access to 340B ceiling prices through wholesalers that make products available at non-340B ceiling prices).[1] The 340B Program Ceiling Price and Civil Monetary Penalties Final Rule (CMP final rule)[2] further specifies that a manufacturer's failure to provide 340B ceiling prices through the manufacturer's distribution agreements with wholesalers may violate a manufacturer's obligation under the 340B statute. HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor such purchases regardless of the dispensing mechanism.

[1] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017); 42 C.F.R. §10.11(b)(2)
[2] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017)

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

For the reasons set forth above, United Therapeutics must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy. United Therapeutics must comply with its 340B statutory obligations and the 340B Program's CMP final rule and credit or refund all covered entities for overcharges that have resulted from United Therapeutics' policy. United Therapeutics must work with all of its distribution/wholesale partners to ensure all impacted covered entities are contacted and efforts are made to pursue mutually agreed upon refund arrangements.

Continued failure to provide the 340B price to covered entities utilizing contract pharmacies, and the resultant charges to covered entities of more than the 340B ceiling price, may result in CMPs as described in the CMP final rule. The CMP final rule states that any manufacturer with a PPA that knowingly and intentionally charges a covered entity more than the ceiling price for a covered outpatient drug may be subject to a CMP not to exceed $5,000 for each instance of overcharging.[3] Assessed CMPs would be in addition to repayment for an instance of overcharging as required by section 340B(d)(1)(B)(ii) of the PHS Act. The Department of Health and Human Services will determine whether CMPs are warranted based on United Therapeutics' willingness to comply with its obligations under section 340B(a)(1) of the PHS Act.

HRSA requests that United Therapeutics 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**, to 340Bpricing@hrsa.gov.

Thank you for your commitment to the 340B Program.

Sincerely,

Diana Espinosa

Diana Espinosa
Acting Administrator

[3] Note, the Department of Health and Human Services publishes inflation-adjusted increases for various CMPs annually. The 2020 inflation adjusted penalty for 340B overcharging violations is $5,883. 85 Fed. Reg. 2,869, 2,873 (Jan. 17, 2020).

# EXHIBIT C

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Resources and Services Administration
Rockville, MD 20857

May 28, 2021

Ms. Lynn Robson
Vice President, Associate General Counsel, Market Access
United Therapeutics Corporation
55 TW Alexander Drive
Research Triangle Park, North Carolina 27709

Dear Ms. Robson:

Thank you for your May 26, 2021, letter regarding United Therapeutics Corporation's (United Therapeutics) request for an extension on the submission of your plan to restart selling, without restriction, 340B covered outpatient drugs at the 340B price to covered entities with contract pharmacy arrangements.

The Health Resources and Services Administration (HRSA) appreciates your letter and will provide an extension until June 10, 2021. In addition, HRSA would like to ensure United Therapeutics responds to all aspects of the restrictions that have been put into place. Your May 26, 2021, letter states that HRSA appears to only object to one element of United Therapeutics policy as described in a November 13, 2020, letter to HRSA, which relates to a requirement that covered entities provide claims data to a third-party platform. That in fact is not the case.

It is HRSA's understanding from United Therapeutics' November 13, 2020, letter that the company has also implemented a policy that only allows 340B contract pharmacy orders for contract pharmacies that participated in the Program and were utilized by the 340B Program for the first three quarters of 2020 (i.e., January 1 through September 30, 2020). Further, it is HRSA's understanding that United Therapeutics will deny any 340B contract pharmacy orders where the contract pharmacy does not meet this requirement. You also state that if a covered entity does not have its own on-site pharmacy, the company will allow one contract pharmacy per covered entity. HRSA also considers these restrictions in direct violation of the statute and HRSA has received 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.

As outlined in the May 17, 2021, letter, HRSA requests that United Therapeutics 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 10, 2021**, to 340Bpricing@hrsa.gov. Please also include in your response the restrictions outlined above.

Sincerely,

Krista M. Pedley

Krista M. Pedley, PharmD, MS
RADM, USPHS
Assistant Surgeon General
Director, Office of Pharmacy Affairs
Health Resources and Services Administration

# EXHIBIT D

**Christopher H. Schott**
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LATHAM & WATKINS LLP



**FOIA-EXEMPT CONFIDENTIAL COMMERCIAL INFORMATION**

May 26, 2021

***BY ELECTRONIC MAIL (krista.pedley@hrsa.hhs.gov)***
***AND FEDERAL EXPRESS***

Rear Admiral Krista M. Pedley, PharmD, MS, USPHS
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, Mail Stop 08W05A
Rockville, MD 20857

**Re: United Therapeutics Corporation 340B Contract Pharmacy Policy**

Dear Rear Admiral Pedley:

I am writing on behalf of my client, United Therapeutics Corporation ("UT"), in response to your letter dated May 17, 2021. In that letter, you request an "update" on UT's plans regarding its 340B contract pharmacy policy by June 1, 2021. We are pleased to respond to your letter, but are hereby requesting an extension until June 18, 2021 to do so.

Your May 17, 2021 letter responds to a letter from UT to the Health Resources and Services Administration ("HRSA") of November 13, 2020, and appears to object to at least one element of UT's 340B policy described therein. In particular, you object to a UT policy that would require that "covered entities provide claims data to a third-party platform," asserting in your letter that "the 340B statute does not permit manufacturers to impose conditions on covered entities' access to 340B pricing, including the production of claims data." We note that this particular element of UT's policies has now been delayed: while the policy would have taken effect on May 13, 2021, UT informed covered entities on May 11, 2021 that the policy would *not take effect for multiple additional months*—until September 1, 2021. A copy of that notice is attached hereto as Appendix A. UT's decision to delay implementation of that portion of its plan should give HRSA and UT sufficient time to address those specific issues.

We also note multiple ongoing litigation matters raising issues potentially similar to those addressed by your letter to UT, including in Federal District Courts in Indiana, Delaware, and New Jersey. In those cases, plaintiffs have now asked the Court for immediate injunctive relief (Indiana) and an immediate Administrative Stay (Delaware and New Jersey), and have referred specifically to other apparently similar May 17 letters from HSRA to other drug manufacturers. *See Eli Lilly & Co. v. Cochran*, No. 1:21-cv-81-SEB-MJD, Dkt No. 95 (S.D. Ind. May 20, 2021) (seeking temporary restraining order ("TRO") and preliminary injunction); *AstraZeneca Pharm. v. Becerra*, No. 1:21-cv-27-LPS, Dkt No. 66 (D. Del. May 19, 2021) (seeking administrative stay); *Sanofi-Aventis v. HHS*, No. 3:21-cv-634-FLW-LHG, Dkt No. 72 (D.N.J. May 20, 2021) (seeking administrative stay); *Novo Nordisk Inc. v. HHS*, 3:21-cv-806-FLW-LHG, Dkt No. 38 (D.N.J. May 21, 2021) (seeking administrative stay). Indeed, Judge Barker in Federal District Court for the Southern District of Indiana matter has scheduled a TRO hearing for this coming Thursday, May 27, and a full preliminary injunction hearing for June 16, 2021. *See Eli Lilly*, Dkt No. 97. And in Federal District Court in the District of Delaware, Judge Stark expedited a summary judgment hearing from June 9, 2021 to May 27, 2021. *See AstraZeneca*, Dkt No. 71. We anticipate that the agency will be watching those matters carefully, and that its approach to 340B issues will take into account the rulings of those courts.

Thank you very much for considering our request for an extension to respond to your letter until June 18, 2021.

* * * * *

We request that HRSA maintain the confidentiality of this letter and all UT-related information herein to the greatest degree and extent permitted by law. We specifically request, in accordance with the Freedom of Information Act ("FOIA"), HRAS's FOIA regulations, and Executive Order 12600, that HRSA protect all of the information provided in this letter from public disclosure. We believe all of this information constitutes financial and/or confidential commercial information not subject to disclosure under FOIA. UT hereby designates the information in this letter as exempt from disclosure under Exemption 4 of FOIA. Without limiting the foregoing, such FOIA-exempt designation pertains to any subsequent use by HRSA of the information provided herein, including, for example only, where such information is incorporated into any HRSA response to UT. We respectfully request that, should HRSA incorporate information from this letter into any secondary materials, it designate such materials as exempt from disclosure under FOIA. When any of this designated information is requested under FOIA or otherwise, we request that HRSA notify UT of the request and afford UT the opportunity to submit objections to disclosure.

LATHAM & WATKINS LLP

Please contact me at (202) 637-2208 or chris.schott@lw.com if you have any questions.

Sincerely,

Christopher H. Schott
Partner
Latham & Watkins LLP

cc: Kevin T. Gray, Senior Vice President, Strategic Operations, United Therapeutics Corporation
Lynn Robson, Vice President, Associate General Counsel, Market Access, United Therapeutics Corporation

May 26, 2021

LATHAM & WATKINS LLP

Attachment A

**Notice from United Therapeutics Corporation to Covered Entities dated May 11, 2021**

* * * * *

United Therapeutics CORPORATION

P.O. Box 14186
55 T.W. Alexander Drive
Research Triangle Park, NC 27709
tel 919.485.8350
fax 919.485.8352

To: 340B Covered Entity

From: Kevin Gray, Senior Vice President, Strategic Operations, United Therapeutics Corporation

Date: May 11, 2021

Subject: Update to United Therapeutics Corporation 340B Contract Pharmacy Policy Effective November 20, 2020

Dear 340B Covered Entity:

We are writing to inform you of an update to United Therapeutics Corporation's 340B contract pharmacy policy for orders placed on or after May 13, 2021, which has now been changed to September 1, 2021. The policy will be implemented in two steps.

*Orders placed on or after November 20, 2020*:

- United Therapeutics Corporation will accept 340B contract pharmacy orders placed on or after November 20, 2020 only if the contract pharmacy was utilized by the covered entity for a valid 340B purchase of a United Therapeutics Corporation covered outpatient drug during the first three full quarters of the 2020 calendar year (i.e., January 1 through September 30, 2020).
- United Therapeutics Corporation will deny any 340B contract pharmacy orders where the contract pharmacy does not meet this requirement.
- To identify your contract pharmacies that are eligible under this policy, please visit UTAssist.com, select "Our Services" followed by "Product Distribution"
- If a covered entity does not have its own on-site pharmacy, United Therapeutics Corporation will provide the covered entity the opportunity to designate a single contract pharmacy for which United Therapeutics Corporation will accept 340B orders. To apply for this exception, please contact United Therapeutics Corporation at 340b@unither.com.

*Orders placed on or after September 1, 2021 (previously May 13, 2021)*:

- United Therapeutics Corporation will accept 340B contract pharmacy orders placed on or after September 1, 2021 only if the covered entity also has agreed to provide to United Therapeutics Corporation, and is providing on an ongoing basis, claims data associated with all 340B contract pharmacy orders of United Therapeutics Corporation's covered outpatient drugs placed after September 1, 2021 via a platform hosted by a third party with appropriate security and patient privacy safeguards.
- United Therapeutics provided additional information to you with respect to the platform and this process in a letter dated April 12, 2021.

This policy will apply to all of United Therapeutics Corporation's covered outpatient drugs, except for ADCIRCA (tadalifil). United Therapeutics Corporation may revise this policy at its sole discretion at any time and without prior notice.

For questions regarding this policy, please contact United Therapeutics Corporation at 340b@unither.com.

# EXHIBIT E

**Christopher H. Schott**
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**FOIA-EXEMPT CONFIDENTIAL COMMERCIAL INFORMATION**

June 10, 2021

***BY ELECTRONIC MAIL (***krista.pedley@hrsa.hhs.gov***)***
***AND FEDERAL EXPRESS***

Rear Admiral Krista M. Pedley, PharmD, MS, USPHS
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, Mail Stop 08W05A
Rockville, MD 20857

**Re: United Therapeutics Corporation 340B Contract Pharmacy Policies**

Dear Rear Admiral Pedley:

I am writing on behalf of United Therapeutics Corporation (UT) in response to your letters dated May 17 and 28, 2021. Both letters assert that the Health Resources and Services Administration (HRSA) requires drug manufacturers enrolled in the 340B program, such as UT, to provide the 340B discount on "contract pharmacy" orders of covered outpatient drugs. Both letters also direct UT to "provide an update on its plan to start reselling [to contract pharmacies], without restriction." And both letters threaten civil monetary penalties (CMPs) unless UT acquiesces to HRSA's view of the facts and law.

We initially addressed this topic in correspondence to HRSA on November 13, 2020. There, we explained our significant legal concerns with HRSA's 340B contract pharmacy guidance and identified multiple government studies raising profound concerns about program integrity. In short, since HRSA's 2010 publication of its current "contract pharmacy" policy, the number of contract pharmacies utilized by covered entities has grown by over 4,000%, and the quantity of drugs ordered claiming 340B pricing has also grown astronomically—such that the number of requests for 340B pricing appears in certain cases to exceed any realistic estimate of the number of covered entity patients who might genuinely give rise to orders at the 340B price. Indeed, UT has calculated that the number of units ordered at the 340B price of several of its drugs nearly doubled between 2019 and 2020—an increase that cannot possibly be explained by a growth in the number of patients treated by covered entities. *See also infra* at 3-5. Despite troubling

analyses by the Department of Health and Human Services Inspector General[1] and the Office of Government Accountability,[2] as well as HRSA's own results from its audits of covered entities, HRSA still appears to have taken no sufficient action to confront the substantial 340B program compliance problems, many of which center on or are exacerbated by the use of contract pharmacies.

Notwithstanding these significant legal and programmatic concerns with HRSA's contract pharmacy policy, UT adopted company policies in November 2020 that *continued* to provide 340B pricing for *every order by every contract pharmacy* that was utilized by a covered entity for a valid 340B purchase of a UT-covered outpatient drug from January 1 through September 30, 2020.[3] In other words, UT has not *stopped* selling at 340B prices to contract pharmacies. Indeed, it continues to fill a very large number of contract pharmacy orders every day. In the unlikely event that the UT policies result in a covered entity without an on-site pharmacy not having any contract pharmacy relationship, UT will nevertheless accept 340B orders from one contract pharmacy for each such covered entity, which is the same approach suggested by HRSA in its original 1996 contract pharmacy guidance. This does not mean that all covered entities are limited under UT's policies to using a single contract pharmacy. Rather, UT assesses those few covered entities without an on-site pharmacy and no contract pharmacy on a case-by-case basis with the goal to support patient access to UT's covered outpatient drugs. Although UT also announced in its November 18, 2020 letter to covered entities that UT would require covered entities to provide 340B data needed to verify that contract pharmacy orders are validly originating from covered entities (which is strictly compliant with the relevant statutory text), UT has now deferred that specific requirement until September 1, 2021.[4] It appears from HRSA's recent correspondence that the agency may not fully understand UT's current policies on these issues.

UT also believes that HRSA is incorrect about what is required by the statute, and that the policy HRSA is implementing through its May 17 and May 28 letters is not legal. (*See infra* at 8-11.) Indeed, litigation by other manufacturers is proceeding in multiple courts at present, and it appears likely that the agency's current statutory interpretation supporting its contract pharmacy policy may be vacated. *AstraZeneca Pharms. v. Becerra*, Case No. 21-27-LPS, H'rg Tr. at 40:19-23, 79:5-11 (May 27, 2021) (AZ Tr.) (questioning government about why a remand with vacatur is not the required remedy for flawed agency analysis).

Given that UT has continued to provide 340B discounts to all contract pharmacies who were already placing 340B orders as of September 30, 2020, and has deferred the date for its new portal for covered entity claims data, we would anticipate that the number of existing "complaints"

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[1] OIG, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, No. OEI-05-13-00431 (Feb. 2014) (2014 OIG Report).

[2] *See* Government Accountability Office, *Federal Oversight of Compliance at 340 Contract Pharmacies Needs Improvement* (June 2018) (GAO Report).

[3] Letter from UT to Rear Admiral Krista M. Pedley at 1 (Nov. 13, 2020).

[4] Letter from Christopher H. Schott to Rear Admiral Krista M. Pedley at 1 (May 26, 2021).

by covered entities relating to UT (as referenced in your May 17 letter) would be *exceptionally* limited. Such complaints may be frivolous or perhaps even unrelated to our products. We are also concerned that certain covered entities are sending "form letter" complaints in certain contexts that do not correspond with our actual drugs or our business model, and so do not accurately implicate UT in any respect. Although HRSA's letter suggests it has analyzed some number of complaints, we have neither been given notice of nor an opportunity to respond to them. It is extremely difficult to see, therefore, how the agency could take the position that these complaints form the basis of a "knowing" or "intentional" violation of the statute by UT, when the company continues to sell its drugs to covered entities at the 340B ceiling price and also continues to honor contract pharmacy orders in accordance with the UT policy. UT should be given an opportunity to review these complaints. In any event, the statute does not otherwise permit the imposition of CMPs in these circumstances.

UT's policies related to the 340B program are lawful, entirely consistent with the statute, and a measured attempt to curb abuses that HRSA has ignored. Although your May 17th letter demands that we "start reselling" to contract pharmacies under the threat of CMPs, this demand appears to be based on a misunderstanding. UT never stopped providing 340B prices to contract pharmacies. For the reasons set forth in more detail below, we hereby request that HRSA immediately withdraw its threat of enforcement in the May 17 and 28 letters. UT is significantly aggrieved and may seek legal redress, as appropriate.

## DISCUSSION

### A. The Significant Program Integrity Concerns That Led To UT's New Contract Pharmacy Policies

UT's policies did not evolve in a vacuum—rather, UT is attempting to address significant uncorrected problems in HRSA's 340B program and their impacts on UT, patients and the costs of healthcare. As you are aware, the HHS Inspector General, the Government Accountability Office and others have made multiple credible findings that HRSA's contract pharmacy policy has put the program at risk of substantial abuse. Those same entities have also concluded that HRSA's policy has reduced the effectiveness of the program in meeting Congress's goals and effectuated a de facto transfer of hundreds of millions of dollars in benefits intended for covered entities and their patients to for-profit third parties like national pharmacy corporations and commercial middlemen, like third party administrators. Available evidence indicates that contract pharmacies foster and exacerbate diversion and duplicate discounting under the 340B program, and that low-income, uninsured patients frequently do not enjoy *any* benefits of the 340B program when they fill their prescriptions with contract pharmacies. A recent study by Berkeley Research Group found that "contract pharmacy participation grew 4,228 percent between April 2010 and April 2020," with now "more than 27,000 individual pharmacies" participating in the 340B program.[5]

[5] Aaron Vandervelde et al., BRG, *For-Profit Pharmacy Participation in the 340B Program*, at 4 (Oct. 2020), https://media.thinkbrg.com/wpcontent/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf (Vandervelde et al.).

And since 2014, purchases under the 340B program have *tripled*.[6] UT has experienced a similar increase in 340B activity; the amount of 340B chargebacks it paid for three of its products (Remodulin, Tyvaso, Orenitram) nearly doubled in the space of one year, from Q4 2019 to Q4 2020. Other than diversion, no other potential cause of such an immense increase is apparent. The amount of charity care provided by many covered entities appears to be *declining*; no growth in the population of covered entities' patients can possibly explain these massive increases in 340B purchases.[7]

This explosive growth is directly linked to fundamental problems with HRSA's contract pharmacy policy. As HRSA has instructed, covered entities should have multiple audit and other programs in place to police their contract pharmacy arrangements and halt diversion and duplicate discounts, but as the HHS IG reported: "most covered entities in our study do not conduct all the oversight activities" HRSA recommends.[8] Indeed, "[f]ew covered entities reported retaining independent auditors for their contract pharmacy arrangements as recommended in HRSA guidance."[9] As GAO explained in 2018, its evaluation "found weaknesses in HRSA's oversight that impeded its ability to ensure compliance with 340B requirements at contract pharmacies."[10] Specifically:

- "HRSA audits do not fully assess compliance with the 340B Program prohibition on duplicate discounts";
- While HRSA requires covered entities to assess and address contract pharmacy issues, HRSA "does not know the scope of the assessments [conducted by covered entities] and whether they are effective at identifying the full extent of non-compliance";
- "HRSA does not require all covered entities to provide evidence that they have taken corrective action and are in compliance with program requirements . . . . Instead, HRSA generally relies on each covered entity to self-attest"; and
- "Given these weaknesses, HRSA does not have a reasonable assurance that covered entities adequately identified and addressed non-compliance and 340B Program requirements."[11]

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[6] *See* Adam J. Fein, *New HRSA Data: 340B Program Reached $29.9 billion in 2019; Now Over 8% of Drug Sales* (June 9, 2020), https://www.drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html.

[7] *See* Adam J. Fein, *Exclusive: 340B Program Purchases Reach $24.3 Billion—7% of the Pharma Market—As Hospitals' Charity Care Flatlines* (June 9, 2020), https://www.drugchannels.net/2019/08/340b-program-purchases-reach-243.html.

[8] 2014 OIG Report at 2.

[9] *Id.*

[10] GAO Report Summary of Findings.

[11] *Id.*

While HRSA may have multiple authorities that allow it to identify and correct each of these significant problems with the covered entities, contract pharmacies, and third-party administrators involved in the 340B program, it does not share any of this information with manufacturers and appears to have taken no action to remedy these problems. Instead, as its May 17 and 28 letters demonstrate, it threatens to penalize manufacturers for attempting to obtain necessary information to understand the full extent of these problems. Indeed, under HRSA's current so-called "pay-and-chase" policy, a manufacturer must supply the 340B discount no questions asked, no matter how compelling the indications may be that contract pharmacies are engaged in diversion. And unless HRSA can and does compel contract pharmacies and third-party administrators (along with covered entities) to open their books and fully justify 340B pricing on these transactions, there is no genuine hope for an accurate reconciliation of past claims. Although significant information exists indicating that the program has run into profound problems, HRSA's recent initiatives appear only to be worsening those issues.

HRSA's policy has also enabled arbitrage opportunities that did not previously exist, allowing contract pharmacies and other third-party entities to make substantial profits under a program that Congress intended to ultimately benefit patients. In fact, in 2013 in a letter to Walgreens' CEO, Senator Grassley wrote the 340B program "is not intended to subsidize pharmacies that team up with covered entities to turn a profit."[12] Furthermore, in a recent report the U.S. Government Accountability Office found that in nearly ***half*** of the contract pharmacy arrangements it reviewed, discounts were not being passed to low-income, uninsured patients.[13] Many covered entities have specifically admitted to HHS's Office of Inspector General "that they do not offer the 340B price to uninsured patients in any of their contract pharmacy arrangements."[14] And indeed, it is now well-established that the savings from the 340B Program are "distributed across a vertically integrated supply chain that includes . . . pharmacies, contract pharmacy administrators, [pharmacy benefit managers], health plans, and employer groups."[15] This is the inevitable consequence of the replenishment model that is in widespread use in contract pharmacy arrangements, because contract pharmacies using such a model do not "determine 340B eligibility [until] *after* drugs are dispensed," which means that, at the time of dispensing, they could "not know to charge the discounted 340B price."[16] That model appears to be nothing more than an elaborate system for certain entities to collect economic rents without providing any genuine value to patients. It is difficult to see what public interest could be served by this arrangement. We hope the agency and the HHS IG have put an immediate priority on addressing these practices. Information on the enterprising efforts of pharmacies, consultants, and third party administrators to market the opportunity for arbitrage profits through the 340B program is readily

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[12] Letter from Senator Charles Grassley to Gregory Wasson, President and CEO, Walgreens (July 31, 2013).

[13] *See* GAO Report at 30.

[14] 2014 OIG Report at 14

[15] Vandervelde et al. at 7.

[16] *Id.*

available, including at https://www.mckesson.com/Pharmacy-Management/340B-Consulting/ (marketing "340B program consulting" to "capture revenue").[17]

In short, the 340B regulatory program is badly broken. And although HRSA has been aware of these serious problems for many years, it has taken few if any steps to correct course or otherwise limit abuses of the program.

**B. UT's Policies**

To combat these abuses, UT's November 13, 2020 letter to HRSA explained that UT would be adopting two new policies regarding contract pharmacies. UT's policies permit any covered entity to purchase its drugs at 340B prices and also permit the use of contract pharmacies despite the rampant abuses in the system. At this time, UT has two specific policies, as explained below.

*1. Policy on Multiple Contract Pharmacies*

First, UT indicated that it would begin fulfilling 340B contract pharmacy orders under two scenarios.

- Scenario 1: UT would fill the order "if the contract pharmacy was utilized by [a] covered entity for a valid 340B purchase of a United Therapeutics covered outpatient drug during the first three full quarters of the 2020 calendar year."

- Scenario 2: Consistent with HRSA's 1996 contract pharmacy policy, if a covered entity *did not* have any contract pharmacy eligible under Scenario 1, and if it did "not have its own on-site pharmacy," UT would "provide the covered entity the opportunity to designate a single contract pharmacy" for 340B orders.

This policy amounts to a very measured correction of covered entity use of contract pharmacies. It grandfathers in contract pharmacy arrangements from the first three quarters of the 2020 calendar year, and even allows covered entities who did *not* make a UT-covered outpatient drug purchase during those quarters to designate a contract pharmacy going forward (provided they do not already have their own in-house pharmacy). Your May 28 letter appears to misconstrue this policy by assuming that *all* covered entities are limited to only "one contract pharmacy." That is not the case: Only covered entities in Scenario 2—those that do not already have qualifying contract pharmacies under Scenario 1—are limited to designating a single, new contract pharmacy.[18] In this way, UT's policy is tailored to address the company's concerns with the continued exponential growth of contract pharmacy abuses, without disrupting patient access to

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[17] *See also* Adam J. Fein, *Senator Grassley Grills Walgreens About Its 340B Profits*, DrugChannels (Aug. 1, 2013), https://www.drugchannels.net/2013/08/senator-grassley-grills-walgreens-about.html.

[18] The choice of contract pharmacy will have to conform to limited distribution models that are in effect with respect to certain United Therapeutic covered outpatient drugs.

drugs or imposing hardships on covered entities. Importantly, UT has continued to offer the 340B ceiling price on all orders from covered entities.

Because UT's policy does not prohibit any covered entity from participating in the 340B program and UT continues to offer the 340B ceiling price to covered entities, it was surprising to see HRSA's letters reference covered entity complaints. Specifically, your May 17 letter referred to "an analysis of the complaints HRSA has received from covered entities," and your May 28 Letter referred to "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." UT was not previously privy to these complaints and has substantial doubts about them—as explained herein. We request the opportunity to review the complaints and any related analysis by the agency.

*2. Policy Requiring Covered Entities to Submit Claims Data*

UT's second policy will require covered entities to provide claims data to United Therapeutics via a third-party platform so that UT can determine whether a contract pharmacy is acting as a genuine agent of a covered entity, as described in General Counsel Charrow's December 30, 2020 Advisory Opinion (discussed in greater detail below). As I explained in my May 26 letter, this policy has been delayed and will not take effect before September 1, 2021.

UT understands from your May 17 letter that it is HRSA's position that manufacturers may only conduct after-the-fact audits of covered entities and are not allowed to request any data on those claims upfront, *i.e.* "pay and chase." Such an audit could only be effective, however, if the audit right extended to data held by the contract pharmacies and third-party administrators associated with each covered entity participating in the 340B program. We note that HRSA already "expect[s]" covered entities to use an independent auditor to perform annual audits of contract pharmacies and that covered entities are required to take immediate remedial action and notify the agency when these audits detect compliance issues.[19] It is therefore entirely sensible for a manufacturer's audit right to likewise extend to data held by third parties participating in the program. Indeed, since HRSA interprets contract pharmacies and other third parties to be agents of covered entities, the statute requires that they be subject to a manufacturer audit. Despite issuing multiple guidance documents about contract pharmacies and about the right of manufacturers to conduct audits under the 340B program, however, HRSA has never indicated that such an audit mechanism would be allowed by the agency. If HRSA intends to allow such an audit, it should immediately clarify that through guidance to manufacturers.

[19] Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,278 (Mar. 5, 2010).

### C. Contrary to the Conclusions in the May 17 and 28 Letters, UT's Policies Are Compliant with Section 340B

#### *1. UT is Not Required to Deal with an Unlimited Number of Contract Pharmacies*

Your May 17 letter concluded that "HRSA has determined that United Therapeutics' actions have resulted in overcharges and are in direct violation of the 340B statute." As described above, that conclusion appears to be premised on mistaken understandings of fact concerning the operation of UT's contract pharmacy policies, which do not preclude any covered entity from purchasing drugs at 340B prices. The conclusion is also, however, premised on mistaken understandings of law, because the statute does not require UT to accommodate *any* contract pharmacies, much less the unlimited number your letters demand.

Although your letters do not expressly invoke General Counsel Charrow's December 30, 2020 Advisory Opinion concerning Section 340B,[20] it is clear that they implement the interpretation contained in that Opinion, and the agency's administrative record will likely so demonstrate. That Opinion has not been withdrawn, and as the General Counsel is the "chief legal officer" of HHS there is no apparent way that HRSA could apply an interpretation of Section 340B that conflicts with the General Counsel's.[21] The Advisory Opinion purports to require manufacturers to deliver covered outpatient drugs to an unlimited number of contract pharmacies "to the extent [they] are acting as agents of a covered entity."[22] That purported requirement, however, is clearly unlawful.

First, there is no textual basis in Section 340B to require manufacturers to supply contract pharmacies with any 340B drugs whatsoever. Section 340B requires manufacturers to "offer each *covered entity* covered outpatient drugs." The statute sets out a comprehensive list of facilities that qualify as "covered entities" and are therefore eligible to acquire 340B discounted drugs.[23] Under well-settled principles of statutory interpretation, that statutory list must be considered exhaustive.[24] And that list does not identify contract pharmacies. *See* AZ Tr. at 65:2-5 (Court:

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[20] Advisory Opinion 20-06 On Contract Pharmacies Under The 340B Program (Dec. 30, 2020) ("Advisory Opinion").

[21] *See, e.g.*, Statement of Organizations, Functions, and Delegations of Authority, 86 Fed. Reg. 6349, 6351 (Jan. 21, 2021) (General Counsel "[f]urnishes all legal services" at HHS, "[s]upervises all legal activities," and "[r]eviews and approves all administrative complaints and enforcement actions . . . to ensure that [they are] legally sound").

[22] Advisory Opinion at 1.

[23] 42 U.S.C. § 256b(a)(4).

[24] *See Colautti v. Franklin*, 439 U.S. 379, 392 (1979) ("As a rule, a definition which declares what a term means excludes any meaning that is not stated." (cleaned up)); *United States v. Philip Morris USA*, 566 F.3d 1095, 1115 (D.C. Cir. 2009) (same).

"[C]ouldn't Congress have said something about contract pharmacies and said, you know, unlimited contract pharmacies can be used by covered entities? That would be clearer.").[25]

HRSA cannot sidestep Congress's decision to limit 340B participation to enumerated covered entities simply by declaring contract pharmacies to be "agents" of covered entities. Nothing in the statute suggests that Congress intended to extend the 340B program to agents of covered entities. To the contrary, when Congress contemplated involving representative arrangements in the 340B program, it said so expressly. The statute, for example, refers separately to "associations or organizations representing the interests of [] covered entities," who are allowed to represent covered entities in administrative dispute resolution proceedings.[26] Congress did not, however, require manufacturers to supply drugs at 340B prices to these associations or organizations. And Congress elsewhere made clear it did not intend for covered entities to transfer drugs to any person or entity other than a covered entity's patients, because it included an *express statutory prohibition* stating as much without making any allowance for "agents" or other entities associated with a covered entity.[27] Whereas Congress clearly distinguished between covered entities and entities acting on behalf of covered entities, the agency's interpretation conflates these separate entities as all being the same "covered entity." That violates cardinal principles of statutory interpretation.[28]

Tellingly, neither the agency's prior 1996 Guidance nor its 2010 Guidance claimed that manufacturers were *required* to recognize an unlimited number of "agent" contract pharmacies for each covered entity. By pursuing that interpretation now, the agency is admitting that the 1996 Guidance (which allowed a covered entity to contract with "*only one* pharmacy")[29] incorrectly interpreted the statute.[30] *See* AZ Tr. at 67:6-8 (Court stating that if HRSA's current interpretation

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[25] *See* AZ Tr. at 74:23 – 75:2 (Court observing that government's statutory interpretation presented "odd location" as the foundation for "Congress to purportedly write a clear and unambiguous requirement that a manufacturer has to satisfy all of the covered entities' demands for drugs and do so no matter how or when or where the covered entity wants").

[26] *See* 42 U.S.C. § 256b(d)(3)(B)(vi).

[27] *Id.* § 256b(a)(5)(B) (emphasis added).

[28] *See Digital Realty Trust v. Somers*, 138 S. Ct. 767, 776 (2018) ("When a statute includes an explicit definition, we must follow that definition, even if varies from a term's ordinary meaning.").

[29] *See* HRSA, Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549 (Aug. 23, 1996); HRSA, Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 72 Fed. Reg. 1540, 1540 (Jan. 12, 2007) (summarizing state of play as: "[A] covered entity could contract with only one pharmacy to provide all pharmacy services for any particular site of the covered entity.").

[30] Notably, the Advisory Opinion fails to acknowledge or explain its departure from these past interpretations—providing yet another reason why the interpretation contained in the Opinion is unlawful. *See Ramaprakash v. FAA*, 346 F.3d 1121, 1124-25 (D.C. Cir. 2003)

is right, then "the 1996 guidance, limiting it to one contract pharmacy was a wrong interpretation of the statute; correct?").

Second, even assuming that Section 340B can be read to require manufacturers to supply 340B drugs to an unlimited number of "agents" of covered entities, HRSA is demanding that manufacturers implement this concept in an impermissible way. "Agency" is a well-defined legal concept.[31] The Advisory Opinion provides no factual findings or supporting evidence for its conclusions that contract pharmacies operate as true agents of covered entities, such that they should effectively be considered the covered entity themselves.[32] Nor do your recent letters. Indeed, the Advisory Opinion seems to fundamentally misconstrue relevant agency principles. It relies heavily, for example, on the concept that "title" to the actual 340B drugs always remains with the covered entities and conceptualizes an arrangement where contract pharmacies are merely dispensing drugs owned by the covered entity to the covered entity's patients on behalf of the covered entity. As HRSA knows, however, that is not how the vast majority of contract pharmacy arrangements work.

Instead, contract pharmacy arrangements are almost always based on a "replenishment" model, a fact that the Advisory Opinion acknowledges only in a footnote. Under that model, title to the 340B drugs actually dispensed to patients does *not* remain with the covered entities. Rather, contract pharmacies dispense medications from a general inventory to all patients, and only later attempt through some undisclosed means to reconcile (or possibly estimate) how many of the drugs were actually dispensed to 340B patients; the pharmacies then "replenish" their general inventory with 340B discounted drugs. These concepts—"title" and "replenishment"—are incompatible and cannot be reconciled. But the Advisory Opinion nonetheless blesses the "replenishment" model and mandates that manufacturers deal with contract pharmacies that use that model. That renders the Advisory Opinion internally inconsistent and in direct conflict with the statute's prohibition on diversion, which bars "res[ale] *or other[] transfer*" of a drug from a covered entity to *anyone* other than "a patient of the [covered] entity."[33] Diversion is *exactly* what the replenishment model facilitates—340B drugs are being distributed to contract pharmacies for use as general inventory that can be dispensed to *any patient* of the pharmacy. This not only violates the 340B statute, but conflicts with HRSA's own contract pharmacy guidance.[34]

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("Agencies . . . . must provide a reasonable analysis indicating that prior policies and standards are being deliberately changed, not casually ignored."); AZ Tr. at 73:16-17 (Court: "I don't see how that could be true" that agency adopted this reading of the statute before 2020).

[31] Restatement (Third) of Agency § 1.01.

[32] *See Int'l Ladies' Garment Workers' Union v. Donovan*, 722 F.2d 795, 825 & n. 69 (D.C. Cir. 1983) (agency fails to engage in reasoned decisionmaking if it reaches conclusion without any supporting evidence).

[33] 42 U.S.C. § 256(a)(5)(B).

[34] For example, the 2010 guidance suggests that contracts between covered entities and contract pharmacies should provide, among other things, that the pharmacy "will dispense covered drugs only …[u]pon presentation of a prescription bearing … a designation that the patient is an eligible

*2. UT is Permitted to Collect Sufficient Data to Establish That Contract Pharmacies Are Operating as Actual Agents of Covered Entities*

Even if Section 340B can reasonably be read to require manufacturers to provide 340B drugs to "agents" of covered entities (it cannot, as explained above), Section 340B does not prohibit manufacturers from taking reasonable steps to verify that a purported agency relationship is *bona fide*. That is one of the goals that UT's policy requiring claims data is meant to advance. Far from violating the statute, UT's policy is completely consistent with the statute (if it can be reasonably read to accommodate HRSA's "agency" theory). That is because the statute gives manufacturers the right to access a list of "identities" of all qualifying Section 340B covered entities.[35] If contract pharmacies are treated as "agents" of covered entities, then logically manufacturers have a right to confirm their identities and whether they are properly entitled to "agency" status as well. This is especially important because HRSA has simply assumed—without conducting *any* fact finding or analysis on its own—that contract pharmacies operate as agents of covered entities. UT's policy addressing this issue—which again, is not yet in effect—will fill that void and will not in any way prevent a single covered entity from exercising its own right to "purchase" covered drugs under the 340B ceiling price.

**D. UT Has Not Overcharged Anyone**

Your May 17 letter also concluded that "[c]ontinued failure to provide the 340B price to covered entities using contract pharmacies, and the resultant charges to covered entities of more than the 340B ceiling price, may result in CMPs." But, under the plain statutory text, CMPs may be imposed only upon a manufacturer who "knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price."[36] And, under its policies, UT has not overcharged *anyone*—much less done so "knowingly and intentionally." Instead, UT has simply placed limited and very measured conditions on the types of contract pharmacies it will deal with. When UT denies a 340B contract pharmacy order under its policies, UT ***does not*** convert the order to a commercial order (*i.e.*, a non-340B order, at a price that is different than the 340B ceiling price). Because of that, there is *no plausible interpretation* that UT has charged a price that "exceeds the maximum applicable price" as HRSA appears to allege, in part because UT has charged no price at all.[37]

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patient of the covered entity." Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,279 (Mar. 5, 2010).

[35] *Id.* § 256(a)(9).

[36] 42 U.S.C. § 256b(d)(1)(B)(vi)(III).

[37] In addition, CMPs are a quasi-criminal penalty. *See Consol Buchanan Mining Co. v. Sec. of Labor*, 841 F.3d 642, 648-49 (4th Cir. 2016) (statutory monetary penalties are "quasi-criminal"). That means that HRSA was obligated to be acutely specific about the type of contract pharmacy arrangements that it believed manufacturers must honor. *See Ford Motor Co. v. Texas Dep't of Transp.*, 264 F.3d 493, 507-08 (5th Cir. 2001). But if, as appears likely, the Advisory Opinion is vacated, then there will be *no* legally relevant notice informing manufacturers that they are bound

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UT is confident that its 340B contract pharmacy policies fully comply with Section 340B and all other applicable laws and regulations. I am seeking assurance as soon as possible that you will withdraw your threat of enforcement in your May 17 and 28 letters. If there are complaints about UT's 340B practices, those complaints and any related HRSA analyses should be provided to UT as soon as possible so that it may evaluate that information and explain in greater detail why those complaints do not raise genuine concerns. UT is significantly aggrieved and continues to face substantial damage from the HRSA contract pharmacy policy and may seek legal redress, as appropriate.

This letter contains confidential commercial information protected from disclosure under Exemption 4 of FOIA and we request that HRSA maintain the confidentiality of this letter to the greatest degree and extent permitted by law. If any of this information is requested under FOIA or otherwise, we request that HRSA notify UT of the request and afford it the opportunity to submit objections to disclosure.

Please contact me at (202) 637-2208 or chris.schott@lw.com if you have any questions.

Sincerely,

Christopher H. Schott
Partner
Latham & Watkins LLP

cc: Kevin T. Gray, Senior Vice President, Strategic Operations, United Therapeutics Corporation
Lynn Robson, Vice President, Associate General Counsel, Market Access, United Therapeutics Corporation

to ship 340B drugs to any and all contract pharmacies. Thus, the agency could impose no CMPs at all until it takes legally appropriate steps to define precisely manufacturer obligations in this area.

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

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| UNITED THERAPEUTICS CORPORATION,<br><br>Plaintiff,<br><br>v.<br><br>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,<br><br>Defendants. | Case No. 1:21-cv-01686 |

**[PROPOSED] ORDER**

Upon consideration of the parties' cross-motions for summary judgment and the briefs in support and opposition, it is hereby ORDERED that Plaintiff's Motion for Summary Judgment is GRANTED, and Defendants' Motion for Summary Judgment is DENIED.

ORDERED that HRSA's May 17 and 28, 2021 letter determination concerning Plaintiff was unlawful, and is hereby vacated and set aside. 5 U.S.C. § 706.

ORDERED that Plaintiff's contract pharmacies policy and claims data portal policy are declared to be legally compliant with 42 U.S.C. § 256b.

IT IS SO ORDERED

Date:

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HON. DABNEY L. FRIEDRICH
United States District Judge