IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED THERAPEUTICS CORPORATION,

Plaintiff,

v.

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

Defendants.

Case No. 1:21-cv-1686

PLAINTIFF'S COMBINED OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AND REPLY BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Defendant Health Resources and Services Administration (HRSA) cannot reconcile its "contract pharmacy" requirements with 42 U.S.C. § 256b (commonly known as the "340B" statute). Likewise, HRSA's determination that Plaintiff United Therapeutics (UT) is violating that statute lacks *any* support in the record.

First, HRSA is trying to muscle an obligation on manufacturers into 42 U.S.C. § 256b that simply is not there. Congress instructed in § 256b(a)(1) that the Secretary must enter an "agreement" with each "manufacturer of covered outpatient drugs" requiring them to "offer" specified healthcare providers (defined as "covered entities") certain outpatient medications at highly discounted "ceiling prices." At the same time, Congress prohibited resale or "transfer" of those highly discounted drugs to any person or entity other than the patient of a "covered entity." 42 U.S.C. § 256b(a)(5)(B). Nothing in the statutory text empowers HRSA to compel manufacturers to sell or ship drugs to every "contract pharmacy" that a covered entity might choose to identify. And aside from the specified 340B "ceiling prices," nothing in the statute dictates any other commercial terms of manufacturers' sales of these drugs to covered entities. Those arrangements, including the place and method of delivery for drug shipments, are left to the relevant parties themselves to negotiate in commercial contracts. Indeed, even HRSA itself, in drafting the "agreement" Congress instructed it to enter into with manufacturers, explicitly recognized that "[d]isputes arising under a contract between a Manufacturer and a covered entity should be resolved according to the terms of *that* contract," not by HRSA. VLTR_000054 (emphasis added). Likewise, HRSA's attempt to assemble a broad "non-discrimination principle" from the last sentence of § 256b(a)(1) is not remotely supported by the words Congress actually employed; Congress knows how to write such provisions and it did *not* do so here. In short, the

new legal justification HRSA has recently proffered for its May 17, 2021 and May 28, 2021 letters (collectively, HRSA's "Violation Determination" regarding UT) has fallen apart. The Court can vacate HRSA's Violation Determination on those grounds alone.

Second, HRSA's administrative record contains, literally, *no* factual support for any conclusion that UT's policies have failed to provide appropriate 340B discounts for patients of covered entities. HRSA now purports to have conducted a "comprehensive review" of the record relevant to UT, to have reviewed over *8,000 pages* of relevant record material, and to have compiled a "legion of evidence" regarding UT. HRSA MSJ at 9-10, 15, ECF No. 16-1. But, as was true with its Violation Determination for UT, large portions of HRSA's brief are again simply *copied and pasted* from other briefs it filed in other cases about other manufacturers. For example, not one word of HRSA's factual assertions on pages 12-15 genuinely relates to UT at all—every word addresses other manufacturer plaintiffs in different cases. There is not a "legion of evidence" regarding UT (*id.* at 15); there are *four* documents, encompassing *not* "8,000+-page[s]" as HRSA claims (at 10), but instead only 12 total pages (not counting duplicates). And as explained in depth below, nothing in those 12 pages of record material demonstrates that UT has violated the law, or that any drug prescription written for a patient genuinely treated by a covered entity failed to receive a proper 340B discount. HRSA cannot conclude that UT is in violation of the law without *actual record evidence regarding UT*.

Third, an agency action is arbitrary and capricious when it fails to provide an adequate rationale, including by failing to explain changes in agency position or failing to address important aspects of the problem. *See infra* at 28-37. Here, nothing in the record explains or justifies why HRSA changed its 340B policy: The HRSA contract pharmacy policy was, in HRSA's own *prior* words, "guidance [that] is not legally enforceable," and not binding on manufacturers. *See infra*

at 30. HRSA unequivocally does not have the same view today. And UT's own current contract pharmacy policy runs parallel to HRSA's 1996 guidance. *See* VLTR_000094 (HRSA 1996 Guidance: "When a patient obtains a drug from a retail pharmacy other than" the covered entity's single "contract pharmacy, the manufacturer is not required to offer this drug at 340B pricing."). How can HRSA now say its contract pharmacy policy has not changed and at the same time fault UT for complying with HRSA's own 1996 policy? HRSA's recent brief denies that the agency's policy changed at all, despite unambiguous evidence in the record that it, in fact, did. Likewise, HRSA offers no genuine explanation for how it will deal with the potentially serious problems that the HHS Inspector General and GAO have identified in their audits. *See, e.g.*, GAO, GAO-18-840, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* at 45 (June 2018), https://www.gao.gov/assets/gao-18-480.pdf (2018 GAO Rep.) ("The expansion of contract pharmacies . . . increases potential risks to the 340B Program, such as risks related to diversion and duplicate discounts."). Again, these HRSA flaws justify vacating the Violation Determination. *See infra* at 31-37.

Fourth, HRSA has no statutory basis for concluding that UT's claims data portal would violate the law either. As noted, there is no general "non-discrimination" mandate in the statute. And UT's claims data policy requires only an exceptionally limited expenditure of time and effort to provide data on claims that will allow UT to determine whether the requests for 340B discounts are appropriate. These claims data requirements are not wholly different from data required every day on other types of drug purchase transactions. *See infra* at 37-38. Nothing about the claims data portal defeats the purposes of the 340B program; indeed, the policy reinforces Congress's purposes. UT's claims data portal policy is entirely legal and will now take effect on December 1, 2021.

Finally, HRSA's record fails to identify any evidence of anything that might be called an "overcharge" by UT. So there is no basis on which the agency could apply any of the threatened civil monetary penalties here.

For all these reasons and those set forth in UT's opening brief, the Violation Determination should be vacated, summary judgment should be entered in UT's favor, and Defendants' cross-motion for summary judgment should be denied.

ARGUMENT

I. THE VIOLATION DETERMINATION CONFLICTS WITH THE 340B STATUTE

As UT explained in its opening brief (at 26-28), the 340B statute contains three critical and unambiguous features that confirm manufacturers are under no obligation to provide discounted drugs to contract pharmacies. First, the statute says: "[T]he manufacturer shall . . . offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." 42 U.S.C. § 256b(a)(1) (emphasis added) (the "Shall Offer" provision). Second, it explicitly defines "covered entit[ies]" as fifteen specific types of facilities, and that list does not include contract pharmacies. *Id.* § 256b(a)(4). Third, covered entities are statutorily barred from reselling *or* "*transfer[ring]*" a drug purchased at the 340B price to a non-patient of the entity, *id.* § 256b(a)(5)(B) (emphasis added), and as a matter of basic logic and fundamental administrative law, covered entities may not end-run this prohibition by forcing manufacturers to do what the covered entities cannot do directly (*i.e.*, directing manufacturers to "transfer" a covered entity's 340B drugs to a contract pharmacy). The Court "must take [this] statutory language at its word," *Allegheny Def. Project v. FERC*, 964 F.3d 1, 18 (D.C. Cir. 2020), and that language plainly provides that manufacturers cannot be required to provide 340B drugs to contract pharmacies. HRSA's contrary arguments fail.

A. The 340B Statute Does Not Require Manufacturers to Deal with Contract Pharmacies

1. *The Plain Text of the "Purchased By" Provision Does Not Require Manufacturers to Honor Covered Entity Requests for 340B Drugs to Be Delivered To Contract Pharmacies*

HRSA claims there is a *fourth* operative clause in the statute that compels what the other three clauses foreclose. Specifically, HRSA notes that the statute "condition[s] Medicaid coverage on compliance with 'an agreement with each manufacturer of covered drugs under which the amount required to be paid . . . to the manufacturer for covered drugs . . . **purchased by** a covered entity . . . does not exceed' the statutory ceiling price." HRSA MSJ at 19 (emphasis added) (citation omitted). According to HRSA (at 19), it is *this* statutory provision—through the "purchased by" language—that "requires manufacturers" to deal with contract pharmacies. That is a surprising assertion because, for one, it is not the statutory provision HRSA invoked in the Violation Determination. *See* VLTR_000011 (invoking the Shall Offer provision only); *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947) ("[A] reviewing court . . . must judge the propriety of [agency] action solely by the grounds invoked by the agency."); *see also infra* at 24. And while HRSA now claims (at 19) that UT "completely ignores *this key statutory* language," just a few months ago the agency took the position in litigation against another manufacturer that the *Shall Offer* provision (not the "Purchased By" provision) is the "core requirement" that mandates manufacturers to deal with contract pharmacies. *See* Defs.' Mem. in Supp. of Mot. to Dismiss or for Summ. J. at 12, *Novo Nordisk Inc. v. DHHS*, No. 3:21-cv-806 (D.N.J. May 11, 2021), ECF No. 37-1. HRSA's inability to anchor its interpretation to the text of the statute should be telling.

The plain language of the "Purchased By" provision demonstrates that HRSA's new argument is wrong and that the Purchased By provision does nothing more than instruct the

Secretary to impose a price ceiling on certain transactions with covered entities. The "Purchased By" provision states:

> The Secretary [of HHS] shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) *purchased by* a covered entity on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2).

42 U.S.C. § 256b(a)(1) (emphasis added). As HRSA concedes, this provision's supposed requirement for manufacturers to deal with contract pharmacies is "not expressly delineated in the text." HRSA MSJ at 21. Indeed, this provision does not even obligate manufacturers to deal with *covered entities*. The only obligation this provision explicitly imposes is on ***the Secretary of HHS*** (to enter into contracts with manufacturers). 42 U.S.C. § 256b(a)(1) ("*The Secretary* shall . . . ." (emphasis added)); *see also Astrazeneca Pharms. LP v. Becerra*, No. 21-27-LPS, 2021 WL 2458063, at *9 (D. Del. June 16, 2021). And while the statute instructs HHS to impose an obligation through contract on manufacturers, that obligation is only to charge covered entities no more than the specified ceiling price. 42 U.S.C. § 256b(a)(1). This particular "Purchased By" provision does *not*, by its plain terms, obligate manufacturers *to* sell anything to covered entities, much less contract pharmacies. In other words, the Purchased By provision leaves manufacturers free to refuse to deal with covered entities entirely. *See Astrazeneca*, 2021 WL 2458063, at *9 (concluding that the Purchased By provision "simply cannot bear the weight that the government places on it").

HRSA recognized this at the beginning of the 340B program, which is why it attempted to impose an obligation on manufacturers to deal with covered entities through guidance. *See* HHS, Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines,

59 Fed. Reg. 25,110, 25,113 (May 13, 1994) (stating that "manufacturers *must offer* covered outpatient drugs at or below the section 340B discount prices" (emphasis added)). But HRSA has no authority to impose such a requirement, so in 2010 Congress was forced to step in and impose a statutory "Shall Offer" provision. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 827 (2010) (adding the text: "[T]he manufacturer shall . . . offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price."). The effect of that provision is that manufacturers must *offer* the ceiling price on covered outpatient drugs to covered entities. Thus, to the extent that a requirement for manufacturers to deal with contract pharmacies exists, it must be found in that provision. And, as UT has explained and HRSA now appears to concede, the Shall Offer provision imposes no such requirement.

HRSA's theory—that the Purchased By provision requires manufacturers to ship to contract pharmacies so long as a covered entity nominally "purchases" the 340B drug—is also at odds with the most natural reading of the words "purchased by." *See* HRSA MSJ at 19-22 (arguing that UT must process orders regardless of "delivery location" or "dispensing mechanism"). The words "purchased by" in the statutory text modify the term "covered outpatient drugs"—specifically, that part of the sentence explains that not *all* covered outpatient drugs are subject to the 340B program—only those covered outpatient drugs that a covered entity purchases. 42 U.S.C. § 256b(a)(1) (governing "the amount required to be paid . . . for covered outpatient drugs . . . purchased by a covered entity"). The sentence as a whole instructs the Secretary to enter into agreements with manufacturers that require certain pricing for certain drugs purchased by covered entities.[1] There is nothing here at all about shipping drugs to *anyone*—much less to

[1] Even when read in isolation, the terms "purchased by" do not help HRSA. The common usage of this phrase would indicate to the reader that the entity purchasing the item will be the one

contract pharmacies. Indeed, until inventing this new interpretation in litigation, not even HRSA understood the term "purchased by" to include other commercial terms, like delivery. When it authored the "agreement" with manufacturers required by the statute, HRSA took care to specify that the agreement did not cover other commercial terms not specified in the agreement. VLTR_000054 ("Disputes arising under a contract between a Manufacturer and a covered entity should be resolved according to the terms of ***that*** contract. Actions taken by the parties in such disputes are not grounds for termination of the Agreement with the [agency] . . . ." (emphasis added)). In short, both the statute and the agreement focus on the 340B ceiling price; neither can be read to impose the type of obligations HRSA seeks to impose here.

Defendants used to understand the limited nature of manufacturers' obligations under the statute. Indeed, in 2020 the General Counsel of HHS attempted in an Advisory Opinion to bring the HRSA contract pharmacy policy into compliance with the statute by explicitly limiting its application to situations where the pharmacy is an instrumentality of the covered entity itself, *i.e.*, the pharmacy is "an agent" of a covered entity (a fiduciary) and the drug purchases subject to 340B discounts remain at all times within the ownership and control of the covered entity. VLTR_006832-39. In that world, "the covered entity and contract pharmacy are *not distinct*," but rather the contract pharmacy is (as a legal fiction) a part of the covered entity. VLTR_006837

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to come into possession of it. *See Return Mail, Inc. v. USPS*, 139 S. Ct. 1853, 1862 (2019) (in the absence of express definition, courts look to "common usage" to interpret terms (citation omitted)). A "purchaser" ordinarily "*obtains*" what he has purchased. *See United States v. Christiansen*, 594 F.3d 571, 576 (7th Cir. 2010 ("To purchase means '**to obtain** by paying money or its equivalent'" (emphasis added) (quoting dictionary)); *Purchase*, Pocket Oxford Dictionary of Current English 600 (7th ed. 1991) ("buy; **obtain** or achieve" (emphasis added)). And an entity that "obtains" something is presumed to take possession of it. *See Obtain*, American Heritage Dictionary 575 (3d ed. 1994) ("To succeed in gaining **possession** of" (emphasis added)); *Honeycutt v. United States*, 137 S. Ct. 1626, 1632 (2017) (obtain is "defined as 'to come into possession of' or to 'get or acquire'" (citing dictionaries)).

(emphasis added). That Advisory Opinion, however, has since been vacated and withdrawn, *see* UT MSJ at 23, ECF No. 14-1, and HRSA no longer relies on the limitation set forth in the Advisory Opinion. But that Advisory Opinion was premised on the notion that an actual agency relationship between the covered entities and contract pharmacies was necessary under the statute to ensure compliance with the statute. HRSA now affirmatively disclaims that agency concept, probably because the contract pharmacies *are not* in fact agents of covered entities. *See* HRSA MSJ at 24 n.4 (conceding that the "principal-agency rationalization" is "found nowhere in HRSA's Violation Letter" and that "HRSA's determination that UT's contract-pharmacy restrictions violate the 340B statute does not rest on the assumption that a covered entity and its contract pharmacies are 'legally one and the same'"). But the underlying admission implicit in the Advisory Opinion remains relevant: HRSA cannot impose obligations on manufacturers to deal with parties who are not covered entities.

HRSA also argues (at 21-23) that the Supreme Court's ruling in *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), is relevant here, and provides an example of statutory interpretation similar to what HRSA is attempting to achieve by interpreting the term "purchased by." But *Bostock* is a dramatically different case: There, the question was whether Congress intended that the statutory phrase "discriminate . . . because of such individual's . . . sex" would include the concept of discrimination based on sexual orientation based on the term's "ordinary public meaning" at the time it was enacted. *Bostock*, 140 S. Ct. at 1738-39 (citation omitted). The Court concluded it did. *Id.* at 1754. But here, the question is whether a narrow instruction to the Secretary to enter into agreements with manufacturers to charge no more than the ceiling price was broad enough to also dictate that manufacturers follow the purchasers' demands to sell or ship drugs to thousands of pharmacies anywhere in the United States under whatever related conditions the purchasers may

require. Nothing in *Bostock* can be stretched to support HRSA's atextual reading here. The cases are not remotely the same. Here, there is no reading of "purchased by" that can bear the weight HRSA attaches to it. *Astrazeneca*, 2021 WL 2458063, at *9. No matter how broadly it is construed, the word "purchased" cannot be stretched to cover analytically and definitionally distinct concepts like delivery. *See, e.g.*, *In re Valley Media, Inc.*, 226 F. App'x 120, 122-23 (3d Cir. 2007) (explaining that the term "'Delivery' has a well-defined meaning and common usage within the context of sales transactions under the UCC" that is different from the term "sale").

2. *HRSA Has No Meaningful Answer to the Statutory Prohibition on Transfers*

To be sure, in ordinary business transactions, someone who "purchases" something can generally turn around and resell or transfer it to a third party. But even *if* the Purchased By provision in isolation could be read to authorize covered entities to use contract pharmacies (it cannot, as explained above), the more specific statutory prohibition in 42 U.S.C. § 256b(a)(5)(A) on *transfers* forecloses this reading. *See, e.g.*, *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012) (concluding that "a specific prohibition" supersedes text that could otherwise be construed to contain a "general permission"). The statutory transfer prohibition states that "[a] covered entity shall not resell or otherwise transfer the drug [it has purchased] to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). A contract pharmacy is a "person," *see* 1 U.S.C. § 1 (Dictionary Act providing that "the word[] 'person' . . . include[s] corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals"), that is obviously "not a patient of the [covered] entity," 42 U.S.C. § 256b(a)(5)(B). So if a covered entity gives its 340B drugs to a contract pharmacy, the covered entity is by definition "transferring" the drug in violation of the 340B statute. *See 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 that is true no matter what mechanism the covered entity uses to effectuate the transfer. *See Bostock*, 140 S. Ct. at 1747 ("[W]hen Congress chooses not to include any exceptions to a broad rule, courts apply the broad rule.").

HRSA contends (at 23-24) that "contract-pharmacy arrangements [do not] run afoul of Congress's prohibition on unlawful transfers of discounted drugs."[2] According to HRSA, "certainly [the transfer prohibition] would not encompass instances where a licensed pharmacist dispenses outpatient drugs to an eligible patient on behalf of an eligible covered entity." The agency's point is not clear, but it appears to be that if the statute does not prohibit this arrangement, then it should not be read to prohibit contract pharmacies. But HRSA's premise is only partially correct. If the licensed pharmacist works for the covered entity, it is true that the transfer prohibition does not prohibit the pharmacist from dispensing to the covered entities' patients. Indeed, that is how the statute is intended to operate.

There is a closer question where the licensed pharmacist works for a third party that is an agent or instrumentality of the covered entity and is handling covered entity inventory being dispensed exclusively to the covered entity patients. In that situation, there is at least an argument that the pharmacist is acting as an extension of the covered entity itself. As indicated *supra* at 8-9, this appears to explain in part why the HHS General Counsel initially promulgated his Advisory Opinion claiming that contract pharmacies must operate as "agents" of covered entities who

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[2] HRSA's only support (at 24) for this counter-textual assertion is its *own* 1994 guidance, which failed to grapple with the statutory text and just offered a handful of *non-comprehensive* "common situations" that *would* constitute unlawful transfer. *See* HHS, Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,112-13 (May 13, 1994). And even if HRSA's guidance said that this list of "common situations" was exhaustive, that pronouncement could not supersede the statutory text. *See U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 592 (D.C. Cir. 2004) ("[A]n agency cannot, absent strong structural or contextual evidence, exclude from coverage certain items that clearly fall within the plain meaning of a statutory term.").

dispense covered entity owned drugs to covered entity patients. VLTR_006837 ("[T]he covered entity and contract pharmacy are not distinct, but function as principal-agent."); *see also* HHS, Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996) ("[E]ntities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients."). But, as noted, HRSA has now abandoned that rationale. HRSA MSJ at 24 n.4 (conceding that the "principal-agency rationalization" is "found nowhere in HRSA's Violation Letter" and that "HRSA's determination that UT's contract-pharmacy restrictions violate the 340B statute does not rest on the assumption that a covered entity and its contract pharmacies are 'legally one and the same'").[3]

So where does that leave HRSA? HRSA's defense of the Violation Determination (at 21) is that a manufacturer must ship its 340B drugs to contract pharmacies whenever those drugs were nominally "purchased by" a covered entity that seeks to dispense those drugs at the contract pharmacy. That is *far* broader than an obligation to ship to an entity that is legally one and the same as a covered entity, and it therefore conflicts irreconcilably with the transfer prohibition. The factual particulars of the replenishment model (which HRSA concedes (at 37) is the "predominant" contract pharmacy arrangement) demonstrate the illegality vividly. In fact, that model is materially indistinguishable from an arrangement that even HRSA seems to agree would be statutorily prohibited. Specifically, HRSA does not seem to dispute that if a covered entity obtained possession of a 340B drug (say, at $15, instead of the ordinary commercial price of $20) and then

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[3] Even if HRSA had not abandoned that rationale, it could not carry the day here because, among other reasons, HRSA never did any of the work necessary to determine whether, on a case-by-case basis, the covered entities that UT does business with have *bona fide agency relationships* with any contract pharmacies to dispense 340B drugs only to the covered entity's patients. *See* UT MSJ at 29-30, 34 (explaining this shortcoming).

resold that drug to a pharmacy (say, at $19), that would constitute statutorily prohibited transfer, *see* 42 U.S.C. § 256b(a)(5)(B), *regardless* of what the pharmacy did with the drug afterwards, *see* 59 Fed. Reg. at 25,112 (HRSA recognizing that "[c]overed entities are required not to resell" 340B drugs to non-patients). But that is essentially what happens under the replenishment model: Instead of physically obtaining 340B drugs and then reselling them for a fee to contract pharmacies to dispense to their patients, covered entities instruct manufacturers to ship the drugs directly to contract pharmacies and then collect some form of fee or other compensation at some later date after the pharmacies sell those drugs to whoever walks in the door or otherwise presents a prescription. *See* UT MSJ at 12-17 (explaining at length how this arrangement works). The record, the publicly available reports, and even HRSA's own declarant show that covered entities using this model use contract pharmacies that intermingle 340B drugs with regular, non-340B inventory and then dispense those 340B drugs to 340B and non-340B patients alike at a profit. *See* Pedley Decl.[4] ¶¶ 9, 11, ECF No. 16-2 (HRSA declarant conceding that contract pharmacies use stock replenished at 340B prices as "neutral inventory" that "may be dispensed to any subsequent patient"); VLTR_008004 (GAO finding showing how contract pharmacies earn fees from dispensing covered entity drugs); Baasch Decl. Ex. C, Walgreens Boots Alliance, Inc., Annual Report (Form 10-K) at 23 (Oct. 15, 2020), ECF No. 14-5 (Walgreens stating that 340B profits are material to its business operations).[5] Congress did not authorize this gamesmanship. 42 U.S.C. § 256b(a)(5)(B) (prohibiting "resell[ing] or *otherwise transfer[ring]* the drug" (emphasis added));

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[4] UT's opening brief cited to a Declaration of Krista M. Pedley that HRSA submitted in litigation against another manufacturer. HRSA has now filed that identical declaration here. ECF No. 16-2.

[5] And even if HRSA were to claim that this scenario does not always occur with the replenishment model, it has no evidence in the record that this is not how the two contract pharmacies eligible to receive UT's drugs are in fact operating. Barton Decl. ¶¶ 5, 15-16, ECF No. 14-8.

see also 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").

UT's straightforward reading of the transfer prohibition would not, as HRSA contends (at 27), make "the statutory scheme . . . ineffective in many instances" or frustrate "preexisting supply chains." Indeed, on this record, it appears that UT's contract pharmacy policy *should not affect a single covered entity's ability to procure 340B drugs for its patients*. Specifically, HRSA's administrative record contains vanishingly few complaints about UT's contract pharmacy policy (and *zero* bona fide complaints, as discussed *infra* at 26-28). Two complaints were submitted by UCLA Ronald Reagan and UCLA Santa Monica Medical Centers. VLTR_005766-67; VLTR_005769-70. But nothing in the record shows that these facilities actually need to rely on contract pharmacies to serve their patients who are prescribed covered UT drugs. Instead, they are both serviced by UCLA's own UCLA Specialty Pharmacy, which advertises "fast and convenient medicine *delivery* to [the patient's] home, workplace or other location" (wherever that may be) and that it "deliver[s] all types of prescriptions."[6] *Cf.* Barton Decl. ¶ 5 (explaining that the two pharmacies that dispense UT's specialty drugs do so by mail or other forms of delivery). The third and final complaint in the record concerning UT is from UC Davis Medical Center. VLTR_005708. But that entity likewise has a specialty in-house pharmacy that advertises "fast and convenient delivery of [its patients'] prescriptions" at "no additional cost."[7] In sum, there is no evidence in HRSA's record that UT's policy has made the 340B statute ineffective, would

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[6] UCLA Health, Pharmaceutical Services, https://www.uclahealth.org/medical-services/pharmaceutical-services (last visited Aug. 30, 2021).

[7] UC Davis Health, Specialty Pharmacy, https://health.ucdavis.edu/pharmacy/specialty_pharm.html (last visited Aug. 30, 2021).

frustrate any supply chain, or has deprived (or would deprive) any patient of a 340B discounted drug no matter where that patient is physically located.

B. UT's Contract Pharmacy Policy Does Not Violate Any Non-Discrimination Rule

HRSA advances (at 20) an alternative statutory interpretation to defend the Violation Determination, but it is also fatally flawed: Specifically, HRSA says (at 20) that the statutory Shall Offer provision contains a silent "non-discrimination" requirement providing that "manufacturers cannot discriminate by treating commercial purchases more favorably than 340B purchases." And HRSA says (at 20) that UT violates this non-discrimination provision because "UT places no delivery-location or dispensing-mechanism restrictions on full-priced sales—only covered entities' purchases." HRSA has no information on what kind of restrictions UT may or may not impose on non-covered entity purchasers—the administrative record does not contain any evidence concerning those arrangements. *Nat. Res. Def. Council, Inc. v. SEC*, 606 F.2d 1031, 1053 (D.C. Cir. 1979) (agency factual conclusions are arbitrary and capricious if not supported by record evidence).[8] But in any event, like the purported requirement to deal with contract pharmacies, this purported "non-discrimination" requirement has no basis in the statutory text.

The Shall Offer provision states:

> Each such agreement [between HHS and a manufacturer] shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly

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[8] As a factual matter, UT's non-340B arrangements are distinguishable from 340B contract pharmacy arrangements in that, among other things, UT's commercial arrangements generally involve bulk purchases that are not uniquely connected or restricted to certain individual patient prescriptions. Moreover, UT's commercial arrangements are subject to their own distinct and varied contractual obligations, as determined through arm's length negotiation with various purchasers—as opposed to the rigid obligations of UT's agreement with the HHS Secretary for participation in the 340B program. UT's contract pharmacy policy therefore would not violate the non-discrimination requirement, if one were to exist.

> be required to pay for the drug (referred to in this section as the "ceiling price"), and **shall require that the manufacturer offer each covered entity covered outpatient drugs** for purchase at or below the applicable ceiling price **if such drug is made available to any other purchaser at any price.**

42 U.S.C. § 256b(a)(1) (emphases added).

The Shall Offer provision bears no resemblance to how Congress writes non-discrimination provisions; it does not mention "discrimination" at all, and it goes no further than to say that manufacturers "shall . . . offer" outpatient drugs to covered entities at a discounted ceiling price "if such drug is made available to any other purchaser." *Id.* When Congress seeks to create commercial non-discrimination requirements it does so explicitly. *See, e.g.*, 42 U.S.C. § 300gg-5(a) ("A group health plan and a health insurance issuer offering group or individual health insurance coverage ***shall not discriminate*** with respect to participation under the plan or coverage against any health care provider who is acting within the scope of that provider's license or certification under applicable State law." (emphasis added)); 15 U.S.C. § 13(a) ("***It shall be unlawful*** for any person engaged in commerce, in the course of such commerce, either directly or indirectly, ***to discriminate*** in price between different purchasers of commodities of like grade and quality . . . ." (emphases added)).[9] And other parts of the statute further confirm that the Shall Offer provision contains no non-discrimination requirement. Congress *explicitly* provided through the transfer prohibition that covered entities do not enjoy all the privileges that ordinary purchasers

[9] *See also, e.g.*, 12 U.S.C. § 265 ("Notwithstanding any other provision of law, no department . . . or agent of the United States shall issue or permit to continue in effect any regulations, rulings, or instructions or enter into or approve any contracts or perform any other acts having to do with the deposit, disbursement, or expenditure of public funds, or the deposit, custody, or advance of funds subject to the control of the United States as trustee or otherwise which shall discriminate against or prefer national banking associations, State banks members of the Federal Reserve System, or insured banks not members of the Federal Reserve System, by class, or which shall require those enjoying the benefits, directly or indirectly, of disbursed public funds so to discriminate.").

do (that is, they cannot resell or transfer property that they have purchased). 42 U.S.C. § 256b(a)(5)(B). Had Congress wished to create a "non-discrimination" provision here, it could have written something like: HRSA "shall require that manufactures offer each covered entity for purchase at or below the applicable ceiling price covered outpatient drugs, and shall prohibit manufacturers from discriminating against covered entities by imposing different commercial terms regarding delivery, payment and other arrangements than the manufacturer imposes on other commercial purchasers of those drugs." Of course, the statute does not say anything like that.

HRSA nonetheless argues that, through the Shall Offer provision, Congress intended to silently codify a non-discrimination policy that HRSA had set out in a guidance document in 1994. HRSA MSJ at 20 (citing VLTR_000108-09, a HRSA "policy release"). But the historical chronology shows that, if anything, the opposite is true—Congress *declined* to ratify HRSA's non-discrimination policy. As noted *supra* at 6-7, originally, the 340B statute contained only the Purchased By provision—not the Shall Offer provision. As a textual matter, this meant that although a manufacturer could not set a price for drugs "purchased by" covered entities above the ceiling price, the manufacturer had no obligation to deal with covered entities in the first instance—it had the option to forego their business. HRSA attempted to rectify that issue in 1994 by imposing a regulatory "shall offer" requirement in a set of agency guidelines. *See* 59 Fed. Reg. at 25,113 (stating that "manufacturers *must offer* covered outpatient drugs at or below the section 340B discount prices"). At the same time, HRSA *also* imposed a separate non-discrimination requirement: "Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective." *Id.* But in 2010, Congress codified ***only a Shall Offer requirement***. *See* Pub. L. No. 111-148, § 7102(b)(1), 124 Stat. 119, 827. Congress's decision to codify a "shall offer" requirement but *not HRSA's* non-discrimination

policy is decisive. *See, e.g.*, *Glob. Crossing Telecomms., Inc. v. Metrophones Telecomms., Inc.*, 550 U.S. 45, 48 (2007) (using "regulatory history [to] help[] . . . illuminate the proper interpretation and application" of provisions of statute).

C. HRSA's Other Arguments Fail

All of HRSA's remaining arguments fail.

1. *HRSA's slippery slope arguments are meritless*

HRSA (at 22-23) claims supposed "untenable results that would accrue should UT's interpretation be credited." Specifically, HRSA contends (at 22) that Congress's silence on various aspects of the 340B scheme cannot be taken to mean that manufacturers possess unrestricted freedom in those areas (*i.e.*, such as where a 340B drug is delivered) because if that were true then the 340B program could collapse in practice. HRSA's bottom line is that it must be able to create limitations on manufacturers in order to save the practical workings of the program. And HRSA posits two examples of what it believes could happen if it loses this ability.

As a threshold matter, HRSA is wrong about Congressional "silence" and about how administrative law works. The 340B statute is meticulously crafted. Among other things, "Congress enumerated 15 types of covered entities with a high degree of precision." *Astrazeneca*, 2021 WL 2458063, at *10. It articulated how to treat covered entities that are "a distinct part of a hospital" that is itself "not" a covered entity. 42 U.S.C. § 256b(a)(6). It authorized HHS to create a program for how covered entities can physically obtain possession of drugs from manufacturers. *Id.* § 256b(a)(8). It carved out a highly specific category of outpatient drugs (orphan drugs) from the 340B program. *Id.* § 256b(e). Granted, Congress did not explicitly articulate rules for the dispensing of drugs. But this is not "silence" in any relevant administrative law sense. As demonstrated *supra* at 10-15, the plain text of the transfer provision provides that the prevalent contract pharmacy models are unlawful. "[T]he mere fact that it does so implicitly rather than

expressly" does not give HRSA license to re-write the statute as it sees fit. *See Engine Mfrs. Ass'n v. EPA*, 88 F.3d 1075, 1088 (D.C. Cir. 1996) (explaining this administrative law point).

HRSA's two slippery slope examples are in any event highly flawed:

(1) HRSA posits (at 22-23) that if UT's interpretation is correct, then "UT could entirely refuse to deliver 340B-discounted drugs and require each covered entity . . . to physically pick up their purchased drugs from UT's warehouses." That is incorrect. The statute explicitly speaks to this issue and provides that "covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs" from manufacturers to covered entities, and that, if a "covered entity obtains drugs directly from a manufacturer" (*i.e.*, without the help of a vendor/wholesaler), then "the manufacturer shall be responsible for the costs of distribution." 42 U.S.C. § 256b(a)(8). The plain text of this provision gives covered entities multiple avenues to procure 340B drugs without having to physically go to a manufacturer's warehouse.

(2) HRSA also says (at 23) that if UT's interpretation is right, then "UT could require covered entities to pay only in pennies." But that would never happen because it would be highly commercially impractical ***for UT***, and arguably ***not*** for the covered entity. A covered entity could, in theory, just direct a bank to send UT a pallet of pennies as payment for 340B drugs. UT, on the other hand, would have to count those pennies, and then physically transport them to a bank for deposit. It is not realistic to expect that any manufacturer would employ such a tactic.

In any event, there is a limiting principle. At some point, conditions imposed by manufacturers may become so onerous that a manufacturer cannot truly be said to be "offering" a 340B drug to a covered entity. For example, if a manufacturer imposed the penny requirement, and that requirement did, in fact, effectively stop covered entities from purchasing 340B covered drugs, HRSA may be able to take an enforcement action in that context based on a factual record

with evidentiary support. But UT's policy does not prevent any covered entity from purchasing covered outpatient drugs, and HRSA has no record evidence to establish that it does. *See infra* at 26-28.

2. *The legislative history does not support HRSA's position*

HRSA's resort (at 27-28) to legislative history fares no better. HRSA notes that in a draft version of the 340B statute, Congress proposed to restrict 340B discounts to drugs "purchased and dispensed by, or under a contract entered into for on-site pharmacy services" with a covered entity. S. Rep. No. 102-259 at 1-2 (1992). The relevant proposed text provided as follows:

> (a) Requirement.—An entity that receives funds under this Act may not purchase any drug or biological described in this section that is produced by a manufacturer unless the manufacturer enters into a written agreement with the Secretary that requires the manufacturer to provide a discount price, as determined under subsection (c)(1)(A), to the covered entity for the purchase of drugs described in subsection (b) or the manufacturer enters into a negotiated agreement under subsection (c)(1)(B) or (d).
>
> (b) Covered Entities.—A drug of the type described in subsection (a) shall be a drug as defined in section 1927(k)(2) of the Social Security Act, and any over the counter drug, birth control device, or vaccine that is purchased and dispensed by, or under a contract entered into for on-site pharmacy services with—[a list of covered entities].

Id. (emphases added). Congress omitted the "dispensed by" language in the final bill, and HRSA believes this means that covered entities should be permitted to engage anyone to dispense 340B drugs, including off-site contract pharmacies. But this bill was dramatically different, in multiple respects, than the bill that Congress ultimately enacted, and cannot be taken as a reasonable guide to what Congress intended. For example, the draft bill was a bar on what *covered entities* could do (underlined text above). And the legislative history is fatal for HRSA, because Congress also omitted the draft language contemplating that covered entities could enter into a "contract" for "pharmacy services" (which would have authorized *on-site* third-party pharmacies). *See*

Astrazeneca, 2021 WL 2458063, at *10 ("Congress chose not to include pharmacy services in the version of the bill that it ultimately passed.").

3. *Applying the plain text does not contravene Congressional purpose*

HRSA next argues (at 25) that its contract pharmacy requirement "furthers congressional purpose" because, without it, at least some covered entities would not be able to participate effectively in the 340B program because they lack an in-house pharmacy. In other words, HRSA thinks this is good policy. But "[n]either courts nor federal agencies can rewrite a statute's plain text to correspond to its supposed purposes." *Eagle Pharms., Inc. v. Azar*, 952 F.3d 323, 335 (D.C. Cir. 2020) (quoting *Landstar Express Am., Inc. v. Fed. Mar. Comm'n*, 569 F.3d 493, 498 (D.C. Cir. 2009)); *see also Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 328 (2014) (reiterating that "an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate").

In any event, HRSA has not established that applying the text would contravene Congressional purpose. HRSA relies (at 25) on its assertion that approximately 5% of covered entities had in-house pharmacies at the time of passage of the 340B statute. But, even if true, that does not establish that covered entities could not or would not create their own in-house pharmacies in the absence of HRSA's illegal contract pharmacy policy, or perhaps enlist a specific single pharmacy as an agent or instrumentality of the covered entity to perform this specific role (as was contemplated by HRSA's own 1996 guidance). Indeed, the statute operated in precisely that way (which HRSA thought was reasonable) for 14 years. And covered entities that establish in-house pharmacies would enjoy all of the fruits of the 340B discounts, as opposed to the existing system that siphons off some of those savings to for-profit pharmacies and intermediaries.

In addition, even if Congress would have wanted to maximize the number of covered entities that can participate in the 340B program, Congress never "pursues its purposes at all costs."

Rodriguez v. United States, 480 U.S. 522, 525-26 (1987). Here, it takes no great leap of logic to conclude that Congress would not have wanted to expose manufacturers to opportunistic, for-profit pharmacies seeking to pad their bottom line with unearned discounts on the manufacturers' drugs. *See, e.g.*, Baasch Decl. Ex. D, Letter from Senator Charles Grassley to Gregory Wasson, President and CEO, Walgreens (July 31, 2013), ECF No. 14-6 (explaining the 340B program "is not intended to subsidize pharmacies that team up with covered entities to turn a profit"). Indeed, there is no other good explanation for why the transfer prohibition exists: Congress clearly recognized the opportunity for price arbitrage, and prophylactically sought to shut it down from the outset. 42 U.S.C. § 256b(a)(5)(B).

4. *The* Astrazeneca *case does not help HRSA*

HRSA also argues that the *Astrazeneca* case supports its interpretation, even though it concluded that the HHS General Counsel's Advisory Opinion was arbitrary and capricious. *See* 2021 WL 2458063, at *11. That is not the case. HRSA (at 31) makes much of the fact that although the *Astrazeneca* Court vacated the Advisory Opinion, it also noted that the Opinion's statutory interpretation was "permissible." *At most, that means that the former* ***Advisory Opinion itself*** *was permissible*, which expressly relied on the concept that the "covered entity and contract pharmacy [would not be] distinct, but function as principal-agent." VLTR_006837. So the *Astrazeneca* court's *dicta* about the permissibility of the Advisory Opinion has no bearing on whether HRSA's current, and far broader, interpretation is permissible. Moreover, that *dicta* is inconsistent with governing D.C. Circuit law. The *dicta* was premised on the notion that, because Congress did not explicitly address covered entity agents in the 340B statute, the statute was "silent" and "ambiguous" on this issue. 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.*, 88 F.3d at 1088.

5. Skidmore *deference is not appropriate*

Finally, HRSA's appeal (at 32) for deference under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), is unavailing. That minimal degree of deference turns on the "thoroughness evident in [the agency's] consideration, [and] the validity of its reasoning." *Id.* at 140. HRSA's Violation Determination was plainly not "thorough"—it was a boilerplate, largely cut-and-pasted two-page letter that recycled inapt language sent to UT's peers. *See* VLTR_000001-12; *see also infra* at 26-28. And the reasoning in the Violation Determination was hardly "valid," as HRSA now essentially recognizes. HRSA has abandoned the premise of its Violation Determination—the Shall Offer provision, VLTR_000011—in favor of yet another statutory hook, the Purchased By provision, *see Fox v. Clinton*, 684 F.3d 67, 80 (D.C. Cir. 2012) (refusing to apply *Skidmore* deference in a similar scenario). No deference of any sort is due an interpretation invented by the agency's lawyers during litigation that conflicts with the reasoning of the agency itself. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212 (1988) ("[W]e have declined to give deference to an agency counsel's interpretation of a statute.").

II. THE VIOLATION DETERMINATION IS ARBITRARY AND CAPRICIOUS

Even if HRSA's lawyers have somehow now gotten the interpretation of the statute right (they have not), the Violation Determination is still invalid because it contains no valid legal or factual basis. *See* UT MSJ at 31-35. It is also arbitrary and capricious for multiple additional reasons.

A. HRSA Effectively Concedes That the Violation Determination Failed to Articulate a Valid Legal Basis

HRSA concedes (at 16) that the question of "whether UT is, in fact, in violation of its statutory obligation . . . must be decided on the basis of HRSA's reasoning contained" in the Violation Determination. But the Violation Determination does not advance the same legal reasoning that the agency now invokes. Specifically, as noted *supra* (at 5), HRSA now contends that UT's obligation to deal with contract pharmacies flows from the statutory Purchased By provision. But the Violation Determination *did not cite that provision*; it cited only the Shall Offer provision. VLTR_000011. That discrepancy is fatal for HRSA. *See Council for Urological Ints. v. Burwell*, 790 F.3d 212, 222 (D.C. Cir. 2015) (courts must "look to what the agency said at the time of the [decision]—not to its lawyers' post-hoc rationalizations"); *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947) ("[A] reviewing court . . . must judge the propriety of [agency] action solely by the grounds invoked by the agency."); *Prill v. NLRB*, 755 F.2d 941, 947 (D.C. Cir. 1985) ("An agency decision cannot be sustained . . . where it is based . . . on an erroneous view of the law.").

UT also explained in its opening brief (at 31-33) that the Violation Determination almost certainly rested on the vacated and now-withdrawn Advisory Opinion, which would render the Violation Determination arbitrary for yet another reason. *See AstraZeneca*, 2021 WL 2458063, at *8. HRSA admits (at 10) that it "considered" the defective Advisory Opinion but contends that the Violation Determination "does not rest upon" it. How can that be? HHS's General Counsel (who issued the Advisory Opinion) has final, legal decision-making authority over every division of the agency (except for the Inspector General). *See* HHS, Statement of Organizations, Functions, and Delegations of Authority, 86 Fed. Reg. 6,349, 6,351 (Jan. 21, 2021). And HRSA offers no explanation for how it could have advanced a legal rationale that conflicted with the then-operative Advisory Opinion—which contained a key caveat limiting the contract pharmacy policy to

situations where a principal-agent relationship exists. HRSA's only answer (at 9-10) is that the Violation Determination was the "culminat[ion] [of an] evaluative process . . . [that began] months before the Advisory Opinion was issued." But that "evaluative process" consisted of nothing more than telling certain manufacturers (and notably *not* UT) that the agency was "considering whether" the manufacturers were violating the 340B statute, *see* HRSA MSJ at 9 (citing warning letters to Eli Lilly and AstraZeneca), and the gathering of complaints about those manufacturers, *see id.* at 10 (referring to "proof of the real-world implications" of manufacturer policies that HRSA gathered). The Advisory Opinion was plainly the upshot of this "process," as the opinion itself recognizes: It was promulgated because "[r]ecently, certain drug manufacturers participating in the 340B Program are declining to distribute covered outpatient drugs through contract pharmacies at the ceiling price." *See* VLTR_006832. No surprise, then, that one Judge already concluded that the Advisory Opinion was the "'consummation' of HHS's decisionmaking process" and "offered" the agency's "unequivocal answer to a legal question." *Astrazeneca*, 2021 WL 2458063, at *7. That unequivocal answer cannot be separated from HRSA's subsequent decision to issue a Violation Determination to UT based on the same issue addressed in the Advisory Opinion.

B. HRSA Fails to Articulate Any Valid Factual Basis for the Violation Determination

UT also explained in its opening brief (UT MSJ at 34-35) that the factual record is devoid of support for HRSA's Violation Determination. As UT explained in its opening brief (at 18-19), UT is uniquely situated as a drug manufacturer. UT's outpatient drugs (by virtue of their unique features) are dispensed either through in-house pharmacies within the covered entity or at two outside specialty pharmacies that deliver drugs by mail. (In practice, only one outside specialty pharmacy has been dispensing 340B drugs in recent years.) Accordingly, patients do not have a need for multiple physical pharmacies in various locations to obtain these drugs. Those features

set UT on a different playing field than the other manufacturers, yet HRSA has inexplicably failed to grapple with the atypical features of UT's distribution system or the contours of its policies. There is no evidence in the administrative record that UT has failed to offer covered entities 340B drugs. *See infra* at 26-28. Nor is there any evidence in the record that covered entities were unable to purchase 340B drugs at or below the ceiling price as a result of UT's policies. *See id.* An agency's conclusions "must be rationally justified," *Ethyl Corp. v. EPA*, 541 F.2d 1, 28 (D.C. Cir. 1976) (citation omitted), and the facts undergirding those conclusions must "have some basis in the record," *Nat. Res. Def. Council, Inc. v. SEC*, 606 F.2d 1031, 1053 (D.C. Cir. 1979). Nothing in the Violation Determination or HRSA's administrative record identifies even a single instance where UT's policy has deprived any patient of a covered entity of 340B discounted drugs. That requisite factual support is absent here.

At bottom, there are no *bona fide* complaints in the administrative record that corroborate HRSA's boilerplate assertion that the agency "analy[zed]" "complaints" about UT "from covered entities." VLTR_000011. And HRSA's brief confirms this is true. Specifically, HRSA's brief focuses on a host of material that (1) involves *other* manufacturers, (2) is irrelevant to UT's specific contract pharmacy policy, *see* Barton Decl. ¶¶ 17-33 (explaining UT's unique policies), UT MSJ at 18-22 (same), and (3) underscores that the Violation Determination was just a copy-paste job of determinations HRSA prepared and sent to other manufacturers who are not similarly situated to UT.

For example, HRSA asserts that its "evidence" was gathered following events that started "[f]our months before the Advisory Opinion was issued." HRSA MSJ at 9. The Advisory Opinion was issued on December 30, 2020. VLTR_006832. But UT did not adopt its contract pharmacy policy *until November 2020*. Barton Decl. ¶ 20. That is obviously far less than "four months

before the Advisory Opinion." And, underscoring the lack of any record evidence *with respect to UT*, HRSA devotes four pages of its brief to discussing complaints directed at *other* manufacturers. *See* HRSA MSJ at 11-15; *e.g.*, VLTR_007255-57 (complaining about "Eli Lilly, Sanofi, and AstraZeneca" only); VLTR_007263 (complaining that "Eli Lilly, Sanofi, and AstraZeneca would cease providing outpatient prescription drugs at 340B prices to [the entity's] contract pharmacies"); VLTR_007297 (complaining that "Eli Lilly and Sanofi[] had unilaterally decided, without government approval, to cease providing outpatient prescription drugs at 340B prices to most or all of [the entity's] contract pharmacies").

In the entirety of its brief, HRSA identifies just three complaints (at 11) about UT. HRSA says these three complaints are "representative," but in reality they are the only complaints about UT in the record, as UT noted in its opening brief (at 34-35). And UT explained why these three complaints do not corroborate the Violation Determination. To recap: One of them (from UC Davis Medical Center) was generic and identified multiple "manufacturers" without specifying anything about *UT*. VLTR_005708. It did not identify any drugs that the entity could not purchase from UT, nor did it mention any contract pharmacy that it uses to which UT would not ship drugs. Indeed, the only indication that this entity was even complaining about UT seems to be an appended copy of UT's November 2020 notice about its contract pharmacy policy. *See* VLTR_005713; *see also supra* at 14 (explaining that this entity has the ability to dispense UT's drugs by mail). And the other two covered entities (UCLA Santa Monica and UCLA Ronald Reagan Medical Centers) filed complaints that appear directed to UT's claims data portal policy *only*, even though that policy had not—and *still has not*—gone into effect. *See* VLTR_005765-70; *see also* UT MSJ at 25 (explaining why these complaints logically could only have been

directed to UT's still-dormant claims data portal policy); *supra* at 14 (explaining how these entities can dispense UT's drugs by mail). HRSA (at 11) does not dispute any of this.

Unable to present evidence and facts to substantiate *UT*'s purported violations, HRSA spends five pages (10-15) discussing general evidence about covered entities. But none of that material (other than the three complaints just discussed) mentions UT. And though HRSA proclaims that it used this material to "analyze the legality of UT's contract-pharmacy restriction," the agency conspicuously fails to explain *how* it used any of that material to scrutinize UT's specific policies. *Cf.* UT MSJ at 13 n.3 (explaining that the number of 340B discount claims UT has received grew substantially between 2018 and 2020). Again, that is particularly important in this case where UT's distribution model for its 340B drugs is unique. Rather than addressing UT's specific facts and its specific policies, HRSA has thrown 8,000 pages of inapplicable spaghetti against the wall attempting to parlay allegations regarding *other* manufacturers into a violation determination for UT. That is arbitrary and capricious.

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

UT also explained in its opening brief (at 36-37) that HRSA's Violation Determination is arbitrary and capricious because it flouts "core principles of administrative law," which "dictate that 'an agency changing its course must supply a reasoned *analysis* indicating that prior policies and standards are being deliberately changed, not casually ignored.'" *Physicians for Soc. Resp. v. Wheeler*, 956 F.3d 634, 647 (D.C. Cir. 2020) (quoting *Lone Mountain Processing, Inc. v. Sec'y of Lab.*, 709 F.3d 1161, 1164 (D.C. Cir. 2013)). The Violation Determination fails to acknowledge HRSA's prior view that the agency's contract pharmacy guidance has never imposed binding obligations on manufacturers. HRSA's 1996 guidance stated that it was "creat[ing] no new law and . . . no new rights or duties," VLTR_000089, and the agency's 2010 guidance reaffirmed that

central point: "This guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law." VLTR_000101.[10]

HRSA ignores these previous statements and instead argues that the "relevant inquiry" is actually the agency's position on "the obligation to provide discounts to covered entities without non-statutory restrictions." HRSA MSJ at 36-37. According to the agency, "its view of manufacturers' obligations has not changed in more than twenty-five years." *Id.* at 36. But these assertions conflict with the HRSA guidance documents themselves as well as with other repeated pronouncements by HRSA. *Astrazeneca*, 2021 WL 2458063, at *7 ("[T]he government's position on drug manufacturers' obligations with respect to participation in the 340B Program has ***not*** remained constant but has, instead, materially shifted."). And HRSA's changes have had material consequences. The 1996 guidance, for example, expressly acknowledged that manufacturers are not obligated to deal with more than one contract pharmacy. *See* VLTR_000094 ("When a patient obtains a drug from a retail pharmacy other than" the covered entity's single "contract pharmacy, the manufacturer is not required to offer this drug at 340B pricing."). That is exactly the approach that UT's contract pharmacy policy takes. Barton Decl. ¶ 22 (covered entities who do not have a contract pharmacy grandfathered into UT's policy may "contact UT to designate a single 340B contract pharmacy"). The 1996 guidance also provided that the use of that single contract

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[10] UT's opening brief explained (at 33 n.12) that even if the 1996 and 2010 guidance documents purported to contain binding directives, the Department of Justice could not—consistent with the Justice Manual—take the position that an agency enforcement action can be predicated on a violation of agency guidance. DOJ indicated on July 16, 2021, that it will "revise" this portion of the Manual "at a later date." DOJ, Processes and Procedures for Issuance and Use of Guidance Documents, 86 Fed. Reg. 37,674, 37,676 (July 16, 2021). The Attorney General's recent statements, however, confirm that whatever revisions may occur, it will remain the case that "guidance documents do not bind the public and are not treated as binding by the courts." Mem. from Office of Att'y Gen., DOJ, to Heads of All Dept. Components, *Issuance and Use of Guidance Documents by the Department of Justice* at 1 (July 1, 2021), https://www.justice.gov/opa/page/file/1408606/download.

pharmacy was meant for entities "that do not have access to an appropriate 'in-house' pharmacy." VLTR_000090. And UT's contract pharmacy policy adopts that as one of its limitations. Barton Decl. ¶ 22 (covered entity who seeks to designate one new contract pharmacy must not have its own in-house pharmacy). HRSA used to believe that UT's approach to contract pharmacies was reasonable; now it doesn't.

HRSA's past statements about its authority in this area cannot be squared with its current position either. In 2020, HRSA told a 340B-focused publication that "[t]he 2010 guidance . . . is not legally enforceable" and that the agency could not "compel[]" manufacturers "to provide 340B discounts on drugs dispensed by contract pharmacies." Tom Mirga, HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable, 340B Report (July 9, 2020).[11] HRSA thus merely "strongly encourage[d]"—*because it could not compel*—"all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements." *Am. Hosp. Ass'n*, 2021 WL 616323, at *3; *see also, e.g.*, VLTR_003272, VLTR_003285, VLTR_004194 (also using "encouragement" language). And contrary to their arguments before this Court, HRSA's counsel has elsewhere acknowledged that the agency's "considered decision on what the *340B statute* requires," HRSA MSJ at 37, has not been consistent since 1994, *see* Hr'g Tr. at 83:10-14, *Astrazeneca Pharms. v. Becerra*, No. 21-cv-27 (D. Del. May 27, 2021), ECF No. 76 (Government counsel arguing that "HRSA, you know, *in the 2010 guidance*, *reconsidered* the issue of whether contract covered entities should be allowed to cho[o]se one or multiple contract pharmacies and

[11] *See* Baasch Decl. Ex. E, ECF No. 14-7; *see also Am. Hosp. Ass'n v. HHS*, 2021 WL 616323, at *3 (N.D. Cal. Feb. 17, 2021) (quoting HRSA email).

found [that] the statute directed manufacturers to provide the discounted drugs in sort of either circumstance" (emphasis added)).[12]

HRSA's failure to explain its drastic shifts is fatal to the Violation Determination. *Wheeler*, 956 F.3d at 647 ("An agency's wholesale failure to address past practice and formal policies regarding an issue, let alone to explain its reversal of course is arbitrary and capricious." (cleaned up)).

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

The Violation Determination also fails to adequately account for the potential for illegal transfers and duplicate discounting that could be caused by its contract pharmacy requirement—two issues that we know were of critical importance to Congress given the explicit prohibitions in the statute. 42 U.S.C. § 256b(a)(5)(A), (B). Under the APA, agencies are required to consider how their decisions will affect such "important aspect[s] of the [regulatory] problem." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *see 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). And, as UT detailed in its opening brief (at 37-40), extensive public evidence—including from HHS's own Inspector General, HRSA's own audits, and the U.S. Government Accountability Office—confirms that the contract pharmacy model facilitates transfer and

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[12] HRSA also asserts in passing (at 36) that the 1996 guidance interpreted the *statute* and that there was accordingly "nothing voluntary," or, ostensibly, non-binding about the guidance. But that is also untrue. In that guidance, HRSA said it was "clear that there were many gaps" in the 340B statute and that "[t]he statute is silent as to permissible drug distribution systems." VLTR_000088-89. In other words, HRSA was engaged in "programmatic gap-filling" in that guidance—not pure statutory interpretation. *Astrazeneca*, 2021 WL 2458063, at *6.

undermines the integrity of the 340B program. Indeed, in 2015, HRSA stressed in a (since-withdrawn) proposed omnibus guidance document that "not all covered entities have sufficient mechanisms in place to ensure their contract pharmacies' compliance with all 340B Program requirements," and that "[r]isk of duplicate discounts can increase with certain drug purchasing and distribution systems, including covered entity contract pharmacy arrangements." HRSA, 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52,300, 52,309, 52,311 (Aug. 28, 2015). But the copy-and-paste Violation Determination all but ignores these problems.

The agency's principal response (at 37) is that UT's argument is "rooted in a misunderstanding of the predominant replenishment model . . . which, in any event, is not at issue in the Violation Letter." As a threshold matter, it is not clear what *is* at issue in the Violation Letter—as explained *supra* at 26-28, there are ***zero*** *bona fide* complaints against UT in the administrative record. But as HRSA recognizes (at 37), the replenishment model is the "predominant" model, so the only logical way to interpret the Violation Determination is that the replenishment model is at issue.[13]

HRSA defends the replenishment model by claiming that it cannot lead to unlawful transfers. *See* HRSA MSJ at 39 (characterizing this argument as "meritless"). But HRSA offers no record support for that assertion, and HRSA's own findings and the administrative record show

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[13] HRSA's attempt to cast UT's claim that HRSA is arbitrary and capricious as being all about the "replenishment model" also mischaracterizes UT's argument. UT argued that *contract pharmacies* in general facilitate unlawful transfer. UT MSJ at 37 ("A mountain of public evidence shows that the contract pharmacy model has facilitated diversion . . . ."). HRSA is well aware of this. *See* 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."). True, the replenishment model is particularly problematic, but UT explained that its problems are "***[i]n addition***" to those that exist under any contract pharmacy model. UT MSJ at 39-40.

otherwise. HRSA itself has found hundreds of instances of unlawful transfer at contract pharmacies. *See* 2018 GAO Rep. at 37 ("Specifically, through the audits conducted since fiscal year 2012, HRSA identified at least 249 instances of diversion at contract pharmacies."). Indeed, HRSA itself has found that *the majority* of unlawful transfer takes place at contract pharmacies. *Id.* at 44 (noting contract pharmacy transfer accounts for "66 percent of" HRSA's diversion findings). Nothing in the record (or out of the record) suggests that those findings were limited to contract pharmacies *not* using the replenishment model, which HRSA acknowledges is the "predominant" model. HRSA MSJ at 37. In addition, although HRSA asserts (at 37) that *UT*'s argument "is rooted in a misunderstanding of the predominant replenishment model," the agency's own declarant admits that the agency likewise does not fully understand the model. *See* Pedley Decl. ¶ 3 ("[C]ontract-pharmacy arrangements vary, and I cannot speak to the exact details of every existing relationship between a covered entity and contract pharmacy.").[14] And again, there is *nothing* in the record that shows how contract pharmacy relationships actually work with Accredo and Caremark—the specialty pharmacies that dispense UT's drugs. *See* Barton Decl. ¶¶ 5, 25.

At bottom, HRSA's argument relies on a flawed view of the "transfer" prohibition and a dubious description of how the replenishment model works. First, HRSA says (at 38) that it does not believe unlawful transfers occur when covered entities give 340B drugs to contract pharmacies,

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[14] HRSA's 2010 guidance concluded that it is "essential" for covered entities to "purchase the drug, maintain title to the drug and assume responsibility for establishing its price" whenever they use contract pharmacies. VLTR_000105. HRSA's admission that it does not even know the details of all contract pharmacy arrangements is an implicit concession that it cannot even confirm that these "essential" features are honored with contract pharmacies. HRSA's only answer (at 40) is that these "essential" contract features were merely "included for illustrative purposes" and were not meant to be "required." But that is irreconcilable with HRSA's repeated statements through its brief that the 1996 and 2010 guidance documents somehow established "mandatory" obligations under the 340B statute. *See, e.g.*, HRSA MSJ at 5, 37.

so long as the covered entities are the ones who technically make the "purchase[] and authorize[] the order." That is wrong for the reasons explained *supra* at 10-15—an unlawful transfer is occurring under the plain statutory text whenever a covered entity gives a 340B drug to a contract pharmacy. But HRSA's premise is also flawed—*contract pharmacies* frequently make the purchases. *See, e.g.*, VLTR_005834 (covered entity complaining to HRSA that "Lilly stopped extending the 340B ceiling price on its drugs *purchased through 340B contract pharmacies*" (emphasis added)). Indeed, HRSA's declarant admits that she does not know one way or another. *See* Pedley Decl. ¶ 3 ("[C]ontract-pharmacy arrangements vary, and I cannot speak to the exact details of every existing relationship between a covered entity and contract pharmacy.").

Second, even if an unlawful transfer does not occur when a covered entity gives 340B drugs to contract pharmacies (it does), a transfer indisputably occurs every time a contract pharmacy gives 340B drugs to *non-340B patients.* 42 U.S.C. § 256b(a)(5)(B) (prohibiting transfer or sale to anyone "who is not a patient of the [covered] entity"). HRSA does not deny that this would be an unlawful transfer; it just says as a factual matter that it never happens. *See* HRSA MSJ at 39 ("[E]ach order for 340B drugs is explicitly tied to distributions of those drugs to eligible patients . . . ."). But HRSA's position is wrong and is indeed at odds with its Department's own Inspector General. The "replenishment" model *inherently* results in unlawful transfers because it posits that a contract pharmacy's *own* inventory is refilled with 340B drugs that "may be dispensed to any . . . patient." Pedley Decl. ¶ 11. And on the front end, contract pharmacies using the replenishment model have no idea whether any individual patient is 340B eligible. *See* VLTR_007977 (OIG finding that under replenishment model "contract pharmacies do not know at the time they dispense the drugs whether patients' prescriptions are 340B-eligible."). That determination is made *after* the drug is dispensed, and then serves as the basis for a "replenishment

order" which replenishes regular, intermingled stock. Then, on the back-end, the contract pharmacy dispenses this intermingled stock indiscriminately to 340B patients and non-340B patients alike. *See Examining Oversight Reports on the 340B Drug Pricing Program, Hearing of S. Comm. on Health, Educ., Lab., & Pensions*, 115th Cong. 11 (May 15, 2018), https://www.congress.gov/115/chrg/CHRG-115shrg30195/CHRG-115shrg30195.pdf (testimony of Ann Maxwell, Assistant Inspector Gen. for Evaluation & Inspections, Off. of Inspector Gen.) ("[C]ontract pharmacies dispense drugs to all of their customers—340B eligible *or otherwise*—from their *regular* inventory." (emphasis added)). In other words, at no step in the process—neither before the replenishment order nor after—does a contract pharmacy ensure that the specific patient it is dispensing drugs to is a 340B-eligible patient. Indeed, HRSA's own declarant acknowledges this. *See* Pedley Decl. ¶¶ 9, 11 (recognizing that contract pharmacies use stock replenished at 340B prices as "neutral inventory" that "may be dispensed to any subsequent patient").[15] And again, the replenishment model—even as HRSA describes it—cannot be squared with HRSA's own 2010 contract pharmacy guidance, which (among other things) identified as "essential elements" of any contract pharmacy arrangement that the covered entity will "maintain

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[15] The amici assert (at 15) that unlawful transfers are no longer a problem because HRSA recently "changed its rules" after a "legal challenge to its [audit] methodology" in 2019, and that now "diversion findings for 340B hospitals have plummeted." What amici omit is that the *reason* diversion findings have plummeted is because HRSA's methodological change ensured the agency would stop *finding* unlawful transfers. Specifically, a covered entity challenged HRSA's guidance interpreting who is and is not a patient of a covered entity. *See Genesis Health Care, Inc. v. Azar*, 2019 WL 6909572 (D.S.C. Dec. 19, 2019). Instead of defending its position, HRSA abandoned it, *id.* at *2, and then apparently stopped issuing diversion findings *altogether* where the basis for diversion would have been that a non-340B patient obtained a 340B drug. *See* GAO, *HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements* at 15 (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf (2020 GAO 340B Rep.) ("Following a covered entity's 2019 legal challenge . . . [HRSA stopped] issu[ing] diversion findings for dispensing 340B drugs to ineligible individuals as defined by HRSA guidance because the 340B statute does not provide criteria for determining patient eligibility.").

title to the drug" and assume responsibility for setting drug prices for covered entity patients. VLTR_000105. The logical upshot of the replenishment model, as described by HRSA's declarant, is that every covered entity patient receiving a covered outpatient drug through the replenishment model pays whatever price the *pharmacy* decides to charge—without any benefit from the 340B discount at all. Pedley Decl. ¶¶ 4-8. The covered entity has *no say* in that pricing. There is no dispute that the replenishment model works that way.

HRSA ultimately retreats (at 39) to the position that the Violation Determination adequately addresses unlawful transfers (and duplicate discounting)[16] because it explained that manufacturers concerned with these problems can conduct audits. But that is no answer because, as UT has explained (UT MSJ at 17) and as *HRSA does not dispute*, the statute *does not* grant manufactures the right to audit contract pharmacies or third-party administrators. *Cf.* HRSA MSJ at 41 ("[M]anufacturers must audit *the covered entity* . . . ." (emphasis added)). But those are the most important entities to audit and where the most pervasive problems are occurring. Third-party administrators are hired by covered entities to "help determine patient eligibility and manage 340B inventory," 2018 GAO Rep. at 2, and they "develop and operate the software algorithms that determine 340B eligibility and enable the for-profit pharmacies to influence which prescriptions are classified as 340B," Baasch Decl. Ex. A, Vandervelde at 8, ECF No. 14-3. Amici's discussion on this point reinforces the importance of auditing these entities. They explain (at 5) that a

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[16] Just like in the Violation Determination, HRSA's brief failed to address the duplicate discount problem prevalent under contract pharmacy arrangements. Amici, on the other hand, claim (at 17) that only a small portion of HRSA's duplicate discount findings "related to contract pharmacies." But that is because, like manufacturers, HRSA lacks "complete information on covered entities' use of contract pharmacies" and so "does not have the information needed to effectively oversee the 340B Program, including information that could be used to better target its audits" to find duplicate discounts related to contract pharmacies. 2018 GAO Rep. at 37; *see also* UT MSJ at 20-21.

"computerized tracking system" (*i.e.*, an algorithm) run by third-party administrators determines which contract pharmacy customers were 340B eligible patients, and then makes corresponding replenishment orders. Amici then link to a website explainer on this algorithm,[17] which explains that the "software uses logic based on configurations, *chosen by the [covered] entity*, to virtually separate 340B from non-340B transactions," and that "certain configurations are associated with *greater risk of noncompliance.*" *Supra* at n.17. Audits of *just the covered entity* and *not* also the third-party administrators and this algorithm would be insufficient to detect duplicate discounts and other problems, such as 340B discounts given for prescriptions not genuinely related to patient treatment by a covered entity.[18] This is a fundamental flaw in HRSA's policy; audits of "covered entities" only will not remedy it.

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

HRSA also wrongly claims (at 40-42) that it "reasonably concluded that UT's claims-data policy is unlawful." UT's claims-data policy is not unlawful, and HRSA's opposite conclusion was not "reasonable."

UT's claims data portal policy requires covered entities using a contract pharmacy to provide readily available, de-identified basic claims data to UT via a third-party platform;

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[17] Apexus, 340B Split-Billing Software Key Attributes (July 3, 2019), https://www.340bpvp.com/Documents/Public/340B%20Tools/340b-split-billing-software-key-attributes.docx.

[18] HRSA claims (at 38) that it audits how covered entities use their software, but any suggestion that its audit efforts are capable of or aimed at detecting impropriety is dubious: The agency lacks statutory authority to audit contract pharmacies or other third parties, and it has admitted 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." 2020 GAO 340B Rep. at 15-16. There is additionally no record evidence of HRSA conducting a single audit of the algorithms that are being used under the replenishment model.

specifically, the Rx Number, prescribed date, fill date, NDC, quantity, pharmacy ID, prescriber ID, wholesale invoice number, and 340B covered entity ID. UT MSJ at 21. That type of basic data is already readily available to every covered entity, does not require the creation of new data, and can easily be provided. UT's policy is now scheduled to go into effect on December 1, 2021, Suppl. Decl. of David Barton in Supp. of Pl.'s Mot. for Summ. J. (Suppl. Barton Decl.) ¶ 6, and its purpose is to give UT a tool to help it detect duplicate discounts, evaluate whether a given prescriber is genuinely affiliated with a covered entity (so as to warrant 340B pricing), and to ensure that a 340B order is a *bona fide* order for a covered entity. Even if manufacturers are required to provide drugs to contract pharmacies (they are not, *see supra* at 4-23), UT's claims data portal policy is not remotely any form of unduly restrictive requirement defeating HRSA's view of the statute's purpose.

And, tellingly, HRSA (at 40-42) *identifies no statutory provision forbidding this policy*. Instead, it simply points to 1994 agency guidance as support that "historic evidence demonstrates that HRSA always has understood the statute" to prohibit this kind of requirement. "But that is history, not explanation." *Se. Ala. Med. Ctr. v. Sebelius*, 572 F.3d 912, 920 (D.C. Cir. 2009). And one would think that if HRSA "understands" the statute that way *it could point to text in the statute that supports the understanding*. But HRSA does not—not in its brief (at 40-42), the Violation Determination, VLTR_000011, *nor even in the 1994 guidance*, *see* 59 Fed. Reg. at 25,113-14. That is because there is no such text. HRSA's attempt to impose this extra-statutory prohibition is unlawful. *See La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986) (an agency "literally has no power to act . . . unless and until Congress confers power upon it").[19]

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[19] HRSA may argue in its final brief that UT's conditions are unlawful under HRSA's "non-discrimination policy," which in turn (according to HRSA), flows from the statutory Shall Offer

In any event, UT's policy complies with the 1994 guidance. Although the Violation Determination said that "the 340B statute does not permit manufacturers to impose conditions on covered entities' access to 340B pricing," VLTR_000011, HRSA now concedes (as it must) that that is not true, and that manufacturers actually may impose at least some conditions. *See* HRSA MSJ at 41 ("[M]anufacturers are permitted to require 'covered entities to sign a contract containing' provisions reflecting 'the manufacturer's normal business policies . . . .'"). HRSA (and its 1994 guidance) draws the line, however, at conditions that "*restrict* . . . access" to 340B drugs. *Id.* (emphasis added). But UT's claims data policy does not remotely do that. UT's process would only require a 15-minute, one-time investment of time to set up, and thereafter would seamlessly deliver basic data on each of the prescriptions for which 340B discounts are applied. *See* UT MSJ at 21-22; Suppl. Barton Decl. ¶¶ 7-9. ***Every*** covered entity that does business with UT can continue to obtain 340B discounts by simply providing UT this barebones prescription data. No one's access is restricted. Granted, if a covered entity refuses to provide the information, *then* its access may be restricted. But that is the same as if a covered entity refuses to "'sign a contract containing' provisions reflecting 'the manufacturer's normal business policies,'" *and HRSA has expressly blessed* that requirement. *See* HRSA MSJ at 41. And UT's claims data portal policy requests information that is very similar to data that HRSA *itself* has recommended 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

provision. But as explained *supra* at 15-18, the statute provides no support for the agency's non-discrimination policy. And the Violation Determination did not assert that UT violated the non-discrimination policy, or that the claims data policy would be lawful so long as UT also applied it to commercial orders. Instead, it said categorically that "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.

"[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). UT is also seeking this information to advance a purpose very similar to one HRSA has blessed. *Compare* HHS, Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 58 Fed. Reg. 68,922, 68,925 (Dec. 29, 1993) ("If a manufacturer asks a covered entity whether the entity is in fact participating in the section 340B discount program, the entity must supply the manufacturer with this information."), *with* Barton Decl. ¶ 31 ("Th[e] claims data will . . . help UT to determine if 340B discounts are being sought for prescriptions not actually written by prescribers of a covered entity.").

In addition, UT explained (UT MSJ at 41) that HRSA's conclusion that UT's claims data policy is unlawful ignores a critical aspect of the regulatory problem—duplicate discounting. *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43 (agency must address each important aspect of the regulatory problem). HRSA's answer (at 41) is that manufacturers must simply endure duplicate discounts, hope to catch them on the back-end via hundreds of covered entity audits, and then slog through the agency's legally-dubious "administrative dispute-resolution process" to, potentially, achieve some relief after an enormous cost. *But see Eli Lilly & Co. v. Cochran*, 2021 WL 981350, at *12 (S.D. Ind. Mar. 16, 2021) (preliminarily enjoining HRSA from "implementing or enforcing against Plaintiffs" its administrative dispute resolution process). That is not a reasonable answer. As noted *supra*, manufacturers do not appear to have any right to audit either the contract pharmacies or third-party administrators who run the algorithms that determine which prescriptions result in 340B discounts. *See* UT MSJ at 17-18. And even HRSA's own audits have been systematically deficient at finding duplicate discounts. *See* GAO, GAO-20-212, *340B Drug*

Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement at 25 (Jan. 2020), https://www.gao.gov/assets/gao-20-212.pdf ("HRSA's audits do not provide the agency with reasonable assurance that covered entities are taking the necessary steps to prevent duplicate discounts."). HRSA has no reasonable basis to force manufacturers to suffer significant financial losses in this environment instead of permitting them to request simple claims data—here, the same type of basic data that HRSA's prior guidance contemplates *would be shared*. *See supra* at 40; UT MSJ at 43 (discussing HRSA's prior guidance on sample contract terms between covered entities and contract pharmacies). This process does not genuinely restrict covered entity access to 340B discounts. *Cf. King v. S. Jersey Nat'l Bank*, 330 A.2d 1, 5-6 (N.J. 1974) (holding that the common-law right to self-help "has roots deep in the common law and has been recognized for centuries"); *Benschoter v. First Nat'l Bank*, 542 P.2d 1042, 1046 (Kan. 1975) (same); *Helfinstine v. Martin*, 561 P.2d 951, 954 (Okla. 1977) (same); *Faircloth v. Old Nat'l Bank*, 541 P.2d 362, 364 (Wash. 1975) (similar).

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

Finally, UT explained in its opening brief (at 43-45) that even if HRSA were right about the statute, its conclusion that UT is subject to *civil monetary penalties* cannot stand. That is because civil monetary penalties are available under the statute only for "knowing[] and intentional[]" "[over]charges." 42 U.S.C. § 256b(d)(1)(B)(vi). But the record *does not reveal* a single instance of an overcharge by UT. And UT has never overcharged a covered entity—much less "knowingly and intentionally." Instead, if a covered entity does not comply with UT's contract pharmacy policy, UT just declines the non-compliant order. UT does not convert the covered entity's order into a standard commercial one.

Instead of defending its position that UT is subject to civil monetary penalties, HRSA mostly just tries to dodge the issue. HRSA says that the question is "unripe" because the agency "has not yet imposed any penalties." But that is wrong. The Violation Determination conclusively announced that UT is violating the law and that HRSA could impose civil monetary penalties. The agency merely offered, as a matter of executive grace, to refrain from doing so if UT immediately complies with the agency's extra-statutory requirements. *See* VLTR_000012 ("United Therapeutics must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements . . . . The Department of Health and Human Services will determine whether [civil monetary penalties] are warranted based on United Therapeutics' willingness to comply with its obligations under [the statute]."). That offer of grace does not foreclose review of the agency's determination that UT is subject to civil monetary penalties. *See, e.g.*, *Sackett v. EPA*, 566 U.S. 120, 126-27 (2012) (holding that an EPA order was reviewable, final agency action, even though it included a proviso inviting regulated parties to "engage in informal discussion of [its] terms and requirements").

HRSA's tepid defense of its conclusion that UT is actually "overcharging" does not withstand scrutiny either. HRSA says (at 42) that, even if UT does not "automatically 'convert' 340B orders to commercial orders, the fact that the covered entity does not have ***access*** to the statutory ceiling price and the covered entity had to ***forego*** the 340B benefit constitutes an overcharge." (emphases added). But that concept appears nowhere in the statute. Instead, HRSA says (at 42) that it has "long made clear" that the 340B program should work this way. That is irrelevant.[20] *See Se. Ala. Med.*, 572 F.3d at 920 ("history" is "not explanation," and "no amount

[20] It also appears to be wrong. Most of HRSA's historic statements do not actually take a definitive position on the issue. *See, e.g.*, HHS, 340B Drug Pricing Program Ceiling Price and

of historical consistency can transmute an unreasoned statutory interpretation into a reasoned one"). 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). An overcharge is "[a] monetary charge in excess of the proper or agreed amount." *Overcharge*, Oxford English Dictionary (3d. ed. 2019), https://www.oed.com/view/Entry/134386. When there is no charge (as might happen when a covered entity does not comply with UT's contract pharmacy policy), as a matter of basic logic, there cannot be a "charge in *excess*" of anything.

CONCLUSION

For the foregoing reasons, the Court should grant UT's motion for summary judgment and deny Defendants' cross-motion for summary judgment.

Date: August 31, 2021

Respectfully submitted,

/s/ Philip J. Perry

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Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210, 1,226 (Jan. 5, 2017) (suggesting this "could be considered" an overcharge); HHS, 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57,233, 57,234 (Sept. 20, 2010) ("HRSA may consider claims of overcharge" to include refusal to sell).

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED THERAPEUTICS CORPORATION, Plaintiff, v. DIANA ESPINOSA, Acting Administrator of U.S. Health Resources and Services Administration, U.S. HEALTH RESOURCES AND SERVICES ADMINISTRATION, XAVIER BECERRA, Secretary of Health and Human Services, and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	Case No. 1:21-cv-01686

SUPPLEMENTAL 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. I submitted a declaration in this matter on July 17, 2021, explaining, among other things, UT's two contract pharmacy policies designed to ensure 340B program integrity and support covered entities' patients. I am now submitting this supplemental declaration to provide additional information regarding UT's second contract pharmacy policy—the "Claims Data Portal Policy."

5. Under UT's Claims Data Portal 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. 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.

6. The Claims Data Portal Policy has not yet been implemented. It was originally scheduled to take effect in May 2021, and was initially delayed until September 1, 2021. UT has decided to further delay implementation of the Claims Data Portal Policy until December 1, 2021, and has submitted a notification to the Health Resources and Services Administration to that effect.

7. When UT's Claims Data Portal Policy becomes active, the third-party platform will be easy to use and will require only a minimal upfront administrative time commitment for covered entities, followed by bi-monthly data submissions that will similarly require only minimal administrative time commitment.

8. **Setup on the platform:** A covered entity will be able to register on the third-party platform in as little as 15 minutes. A user seeking to register a covered entity with the third-party

platform will have to provide information about themselves (name, email), the covered entity (which entity(s) the account is associated with), and then confirm agreement with the Terms of Use.

9. **Periodic data submissions on the platform**: After setup, covered entities will make data submissions twice per month. The first data submission can take from 2–10 minutes, depending on how the covered entity maps the fields in their data submission file to the data fields that UT will require. *See supra* ¶ 5. Once the data mapping is complete, the actual bi-monthly file upload process takes 1–2 minutes. In total, the commitment of time to provide the claims data is likely to be less than an hour per year. Additionally, covered entities using third-party administrators may be able to expend even less time on the data submissions. Some third-party administrators submit data for their covered entity customers, and some third-party administrators also prepare the data submission files for direct submission by their covered entity customers.

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

Executed this 30th day of August, 2021, in the State of Texas.

David Barton