UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED THERAPEUTICS CORPORATION, *Plaintiff*, –v– DIANA ESPINOSA, in her official capacity as ACTING ADMINISTRATOR, HEALTH RESOURCES AND SERVICES ADMINISTRATION, *et al.*, *Defendants*.	**Case No. 1:21-cv-1686**

BRIEF OF *AMICI CURIAE* AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, AMERICA'S ESSENTIAL HOSPITALS, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, CHILDREN'S HOSPITAL ASSOCIATION, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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American Hospital Association, 340B Health, America's Essential Hospitals, Association of American Medical Colleges, National Association of Children's Hospitals d/b/a Children's Hospital Association, and American Society of Health-System Pharmacists (collectively, *Amici*) hereby file this *amicus* brief in support of Defendants' opposition to Plaintiff's motion for summary judgment and Defendants' cross-motion for summary judgment.[1]

Amici are six hospital/health system associations whose members use 340B discounts for 340B drugs dispensed through contract pharmacies to support health care programs and services offered by their hospitals to serve the needs of underserved populations. The discounts, for example, allow these members to: (1) provide and maintain more patient care services; (2) provide and maintain more uncompensated and unreimbursed care; (3) provide and maintain more services in underserved areas; (4) develop and maintain targeted programs to serve vulnerable patients; and (5) keep their doors open. Ex. A, Decl. of Maureen Testoni (Testoni Decl.) ¶¶ 7–9. These discounts are the subject of a Department of Health and Human Services (HHS) letter[2] that United Therapeutics Corporation (UT) challenges, which concluded that the restrictions and additional requirements that UT is placing on 340B providers with respect to 340B discounts for drugs dispensed through contract pharmacies are unlawful, in violation of the 340B statute.

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[1] Pursuant to Local Rule 7(o)(5), *Amici* confirm that they are not corporations; that no party's counsel authored this brief in whole or in part; that no party or party's counsel contributed money that was intended to fund preparing or submitting this brief; and that no person other than *Amici*, their members, or their counsel contributed money that was intended to fund preparing or submitting this brief.

[2] Letter from Diana Espinosa, Acting Administrator, HRSA, to Lynn Robson, Vice President & Associate General Counsel, Market Access, United Therapeutics Corporation (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-united-therapeutics-covered-entities.pdf.

Amici submit this brief to: (1) address UT's argument that the 340B statute does not require drug manufacturers to offer 340B discounts when drugs are dispensed by contract pharmacies; (2) address UT's allegation that HHS has changed its position on the issue of contract pharmacies; (3) address UT's argument that the use of contract pharmacies constitutes unlawful diversion; (4) address UT's argument that it is permitted to impose additional requirements on 340B entities that dispense discounted drugs through contract pharmacies; and (5) provide the Court with information regarding the impact of UT's policies on the patients of 340B hospitals such as *Amici's* members.

INTRODUCTION AND BACKGROUND

The 340B program, established by section 340B of the Public Health Service Act, 42 U.S.C. § 256b, requires as a condition of participating in Medicaid and Medicare Part B that pharmaceutical manufacturers sell outpatient drugs at a discounted price to certain public and not-for-profit hospitals, community health centers, and other providers that serve patients with low incomes (340B providers or covered entities). The purpose of the program is to stretch the funding 340B providers have available to meet the needs of their patients, H.R. Rep. No. 102-384(II), at 12 (1992), and a 2011 report from the U.S. Government Accountability Office (GAO) found that the 340B program has had this exact effect. Specifically, GAO found that 340B providers have used the benefit made available through the drug discounts to provide critical health care services to communities with underserved populations that could not otherwise afford these services—for instance, by increasing service locations, developing patient education programs, and providing translation and transportation services. GAO, Report to Congressional Committees, GAO-11-836, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 17–18 (Sept. 2011), https://www.gao.gov/assets/gao-11-836.pdf.

Since the beginning of the program, pharmaceutical companies have provided 340B discounts for drugs dispensed through both in-house and contract pharmacies to covered entities' patients, and since 2010 they have sold drugs at the 340B prices to hospitals and other covered entities that used multiple contract pharmacies. Since UT began participating in the 340B program (by its own declaration in 2002) until November 2020, there is no record that UT ever contested HHS's interpretation of section 340B as allowing 340B drugs to be dispensed by contract pharmacies. Today, a quarter of the benefit that 340B hospitals receive from the 340B discount comes from 340B drugs dispensed through contract pharmacy arrangements. Testoni Decl. ¶ 6. The benefit is even higher for some providers, such as critical access hospitals (small hospitals in rural areas), which report that an average of 51% of their benefit from the 340B discount comes from drugs distributed through contract pharmacies. *Id*. 340B providers use the 340B benefit to provide services to underserved populations in their communities. Recognizing the value of the 340B program, in 2010 Congress expanded it as part of the Affordable Care Act. *See* Patient Protection & Affordable Care Act, Pub. L. 111-148, § 7101, 124 Stat. 119, 821–22 (2010) (codified at 42 U.S.C. § 256b(a)(4)(M)–(O)).

Although the 340B statute requires discounts to be offered only to statutorily-defined covered entities, it does not otherwise limit the size of the program or authorize a pharmaceutical company to do so. The Conference Committee Report accompanying the original enactment stated that the HHS Secretary was not authorized "to limit in any way the volume of purchases that can be made [by covered entities] at the price reduction." H.R. Rep. No. 102–384(II), at 16. Importantly, while the statute requires that the drugs be purchased by a covered entity, it does not limit where the drugs must be dispensed. *See* 42 U.S.C. §§ 256b(a)(1), (4).

Nevertheless, in the midst of the most devastating pandemic in 100 years, UT abandoned its practice of complying with the statute, as interpreted by HHS, and notified covered entities and the Health Resources and Services Administration (HRSA)—the HHS division that manages the 340B program—that it would not accept orders by covered entities for drugs dispensed by covered entities' contract pharmacies unless the covered entity, during the first three quarters of 2020, "utilized" the contract pharmacy "for a valid 340B purchase" of a UT drug.[3] If a covered entity does not have its own in-house pharmacy, it can request an exception from UT.[4]

UT also announced plans to condition any use of contract pharmacies by a covered entity on an agreement to give UT access to the covered entity's claims data.[5] Five other major drug companies (which, along with UT, are among the largest companies in an industry that between 2000 and 2018 generated $8.6 trillion dollars in profits[6]) also adopted policies that restrict 340B discounts when a contract pharmacy is relied on to dispense 340B discounted drugs, and one of those manufacturers (Sanofi) similarly adopted a policy to condition the use of contract pharmacies on an agreement to provide claims data.[7]

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[3] *See* Letter from Kevin Gray, Senior Vice President, Strategic Operations, United Therapeutics Corporation, to 340B Covered Entities (Nov. 18, 2020), https://www.dropbox.com/s/swyrookjcwqxe58/United%20Therapeutics%20Letter%2011.20.2020%20%281%29.pdf?dl=0.

[4] *Id.*

[5] *Id.*

[6] Fred D. Ledley et al., *Profitability of Large Pharmaceutical Companies Compared with Other Large Public Companies*, 323(9) J. Am. Med. Ass'n 834–43 (Mar. 3, 2020), https://jamanetwork.com/journals/jama/fullarticle/2762308.

[7] *See* Limited Distribution Plan Notice for Eli Lilly and Company Products (undated), https://www.340bhealth.org/files/200901_Eli_Lilly_and_Company_Limited_Distribution_Plan_Public_Notice.pdf; Sanofi Notice (July 2020), https://www.340bhealth.org/files/Sanofi_Notice_10_1_20.pdf; Letter from Odalys Caprisecca, Executive Director, Strategic Pricing & Operations, AstraZeneca, to 340B Partners (Aug. 17, 2020), https://www.dropbox.com/s/gethwns6m7zzkoh/AstraZeneca%20Retail%20Communication%20-%20340B%20-%20Final.pdfld1=0; Novo

The contract pharmacy arrangements that UT and the other drug companies are refusing to honor have existed since the beginning of the 340B program. When a 340B provider uses a contract pharmacy outside its premises, it enters into a written contract. The 340B provider orders and pays for 340B drugs, which are shipped directly to the contract pharmacy to be dispensed to the provider's patients. The pharmacy receives a fee for performing this service.

Under this arrangement, some providers use a "separate" inventory model, but most use a "replenishment" inventory model. For the separate inventory model, the provider's 340B drugs are kept in stock at the contract pharmacy, separate from non-340B drugs. The contract pharmacy dispenses those drugs to the provider's patients. For the more common replenishment model, no 340B drugs are kept in stock. When filling prescriptions for the provider's patients, the contract pharmacy uses drugs from its own stock, and the provider purchases replacement drugs at the discounted 340B price to replenish the pharmacy's stock. The replacement drugs are delivered to the contract pharmacy, which then passes on the payments it received when it dispensed the drugs, less an agreed upon dispensing fee, thus ensuring that the provider receives the benefit of the 340B discount as Congress intended. These arrangements are typically done using a computerized tracking system following rules designed to ensure that only eligible patients of providers are receiving drugs for which the provider receives the 340B discount. *See, e.g.*, 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. Under either arrangement, it is the 340B provider that purchases the 340B discounted drug—not the contract pharmacy. UT's

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Nordisk Notice (Dec. 1, 2020), https://www.340bhealth.org/files/Novo_Nordisk_12-1-2020.pdf; Novartis Statement (Oct. 30, 2020), https://www.novartis.us/news/statements/new-policy-related-340b-program.

restriction on providing 340B discounts to 340B hospitals applies to drugs dispensed under either model.

On May 17, 2021, HRSA sent letters to all six pharmaceutical companies finding (consistent with its historical position) that the drug companies' refusal to provide 340B discounts for drugs dispensed through contract pharmacies is unlawful.[8] HRSA also notified UT and Sanofi that the additional conditions they sought to impose on covered entities that use contract pharmacies are illegal. On May 28, HRSA sent a follow-up letter to UT reiterating its position.[9] UT challenges HRSA's letter in its complaint, Compl. ¶¶ 94–104, ECF No. 1, and in its motion for summary judgment, ECF No. 14.

[8] Letter from Diana Espinosa, Acting Administrator, HRSA, to Odalys Caprisecca, Executive Director, US Strategic Price & Operations, AstraZeneca Pharmaceuticals, LP (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-astrazeneca-covered-entities.pdf; Letter from Diana Espinosa, Acting Administrator, HRSA, to Derek L. Asay, Senior Director, Government Strategy, Eli Lilly & Company (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-eli-lilly-covered-entities.pdf; Letter from Diana Espinosa, Acting Administrator, HRSA, to Dan Lopuch, Managed Market Finance, Novartis Pharmaceuticals Corporation (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-novartis-pharmaceuticals-covered-entities.pdf; Letter from Diana Espinosa, Acting Administrator, HRSA, to Farruq Jafery, Vice President, Pricing, Contract Operations & Reimbursement, Novo Nordisk, Inc. (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-novo-nordisk-covered-entities.pdf; Letter from Diana Espinosa, Acting Administrator, HRSA, to Gerald Gleeson, Vice President & Head, Sanofi US Market Access Shared Services, Sanofi (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-sanofi-covered-entities.pdf; Letter from Diana Espinosa, Acting Administrator, HRSA, to Lynn Robson, Vice President & Associate General Counsel, Market Access, United Therapeutics Corporation (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-united-therapeutics-covered-entities.pdf.

[9] Decl. of David Barton in Supp. of Pl.'s Mot. for Summ. J., Ex. C (Letter from Krista M. Pedley, Assistant Surgeon General & Director, OPA, HRSA, to Lynn Robson, Vice President & Associate General Counsel, Market Access, United Therapeutics Corp. (May 28, 2021)), ECF No. 14-11.

DISCUSSION

UT devotes much of its memorandum to criticizing the 340B program and HRSA's oversight thereof. But that is a distraction and irrelevant to the central and dispositive issue in this case, which is whether the 340B statute requires drug companies to provide 340B discounts to 340B providers for drugs that are dispensed by contract pharmacies on behalf of the providers and to provide those discounts without imposing restrictive conditions not found in the statute. The answer is yes: UT is required to provide discounts for drugs that are dispensed by a contract pharmacy on behalf of the 340B provider and has no authority to place limits or conditions on those discounts.

I. THE PLAIN MEANING OF THE 340B STATUTE REQUIRES PARTICIPATING DRUG MANUFACTURERS TO GIVE DISCOUNTS ON 340B DRUGS DISPENSED BY CONTRACT PHARMACIES.

As UT recognizes, in addressing a question of statutory interpretation, we begin the with text of the statute. *See* Mem. of Law in Supp. of Pl.'s Mot. for Summ. J. (Pl.'s Mem.), ECF No. 14-1, at 26. The 340B statute provides that:

> The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . *purchased by* a covered entity . . . does not exceed an amount equal to the [ceiling price].

42 U.S.C. § 256b(a)(1) (emphasis added). The statute does not say "purchased *and dispensed* by" a covered entity. Thus, it requires drug manufacturers to offer discounts to all 340B covered entities and does not distinguish between drugs that are dispensed directly by the entity and drugs dispensed by an outside pharmacy with which the entity has a contract. "As long as the statutory scheme is coherent and consistent, there generally is no need for a court to inquire beyond the plain language of the statute." *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 240–41 (1989). Contrary to UT's assertion otherwise, Pl.'s. Mem. 27, the 340B statute's plain language *does*

require manufacturers to provide discounts for drugs purchased by 340B providers regardless of whether they are dispensed by contract pharmacies.

UT's principal statutory argument is that it cannot be required to provide 340B discounts when its drugs are dispensed by contract pharmacies because the statute makes no reference to contract pharmacies. *Id.* This might make sense if the statute mentioned dispensing as a relevant consideration, but it does not. In fact, an earlier version of the bill that was *not* enacted did refer to dispensing and pharmacies. That unenacted version stated that 340B discounts would be required only for 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 2 (1992) (emphasis added). If that language had been retained, UT would be permitted to limit 340B discounts to *only* covered entities with on-site pharmacy services, since only those drugs would be "purchased *and dispensed by*, or under a contract entered into *for on-site pharmacy services*." *Id.* (emphasis added).

Congress had a sound reason to drop the "purchased and dispensed by, or under contract" language: at the time the bill was passed, fewer than 5% of 340B providers had on-site dispensing services. *See* 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). If Congress had retained this language, the discounts that it intended to provide would have been unavailable to almost all 340B providers. The elimination of this phrase made *where* the 340B drug is dispensed legally irrelevant to whether a 340B provider is entitled to purchase the drug at the 340B price: all that matters is that the drug is "purchased by a covered entity." 42 U.S.C. § 256b(a)(1).

Equally unavailing is UT's argument that HHS's contract pharmacy policy is illegal because contract pharmacies are not included in the statute's list of *covered entities*. Pl.'s Mem. 27. *Amici* agree that a contract pharmacy is not a covered entity under the 340B statute, but UT's

argument ignores the fact that the 340B discounted drugs are being "purchased by" a 340B hospital or other covered entity. The contract pharmacy is the dispenser, not the purchaser, and the statute does not dictate how or where 340B drugs must be dispensed to a covered entity's patients. Thus, under the statute, the use of contract pharmacies is allowed and UT's efforts to restrict their use is unlawful.[10]

Finally, UT also wrongly argues that HHS's "agency" theory has no basis in the statute and that Congress would have specified that manufacturers had to deal with covered entities' agents if it had intended to require them to do so. *Id.* at 29–30. UT refuses to recognize that the nomenclature used to characterize the relationship between a covered entity and a contract pharmacy is irrelevant so long as the statutory requirement that the drug is "purchased by a covered entity" for its patients is met. Moreover, although at times it has described the relationship between a covered entity and a contract pharmacy as a "principal-agent" relationship, HHS has never suggested that its use of the terms "agency" and "agent" were intended to invoke the strict common-law definition, which varies from state to state. As explained in the Restatement (Third) of Agency, "[s]ome statutes and many cases use agency terminology when the underlying relationship falls outside the common-law definition. Moreover, the terminology of agency is widely used in commercial settings and academic literature to characterize relationships that are

[10] The recent decision in *AstraZeneca Pharms. LP. v. Becerra*, No. 1:21-cv-27 (D. Del. June 16, 2021), ECF No. 79, does not support UT's argument. Reviewing AstraZeneca's challenge to the HHS General Counsel's December 30, 2020 Advisory Opinion, which HHS has withdrawn, the court rejected both the government's and AstraZeneca's arguments that the statute was clear as to whether pharmaceutical companies participating in the 340B program are required to provide discounts for 340B drugs dispensed by contract pharmacies, but held that "HHS's current interpretation of the statute is permissible." *Id.* at 23. Although it held (incorrectly, *Amici* believe) that the statute is not clear, the court did not find HHS's interpretation to be inconsistent with the statute.

not necessarily encompassed by the legal definition of agency." Restatement (Third) of Agency § 1.01 cmt. (2006).

In addition, an analysis of the statutory provisions that refer to other agency-like relationships relied on by UT, *see* Pl.'s Mem. 29–30, demonstrates that they do not support UT's claim that Congress would have referenced contract pharmacies if it had intended them to be part of the statutory scheme. Pharmacies are an integral part of the drug distribution system because they dispense drugs to patients. The reason they are not mentioned in the statute is because they are not the entity that is purchasing the 340B discounted drug. The reason the 340B statute specifically provides at subsection (d)(3)(B)(vi) that associations or organizations that represent the interests of covered entities can bring claims on the covered entities' behalf through the ADR process is because without this provision associations could not bring claims since they are not covered entities. Similarly, contrary to UT's argument, *id.*, there was no need for Congress to include language in the 340B statute referring to contract pharmacies the way it referenced contracts in 38 U.S.C. § 8126(h)(3)(A), an unrelated statute involving contracts between commercial entities and certain federal agencies. Unlike the commercial entities covered by that provision, contract pharmacies are not purchasing the covered outpatient drugs at 340B discounts.

II. THE MAY 17, 2021 LETTER REPRESENTS HHS'S LONGSTANDING POLICY ON CONTRACT PHARMACIES.

Since the beginning of the 340B program, HHS has repeatedly recognized the statutory requirement to offer 340B providers covered drugs at or below 340B ceiling prices when they are dispensed by a contract pharmacy, and UT has not suggested that it failed to comply with that requirement before November 2020. As detailed below, HHS's statements have been consistent and comprehensive, and they demonstrate that HHS has never wavered in its interpretation of the statute. UT's claim that during the first four years of the program covered entities could only use

in-house pharmacies and that HHS suddenly changed its policy on contract pharmacies, Pl.'s Mem. 9, is wrong.

In 1996, HRSA issued the first "final guidelines" addressing the use of contract pharmacies. 61 Fed. Reg. 43,549. Those guidelines recalled that since the beginning of the 340B program, HHS had recognized that 340B providers were permitted to use contract pharmacies to dispense 340B drugs, so long as they complied with the prohibition on drug diversion. *Id.* at 43,550 ("As early as 1993 [shortly after the statute was enacted], several covered entity groups . . . came forward to assist the Department in developing a workable mechanism to use outside pharmacies."). At the same time, HRSA noted that "[t]here is no requirement for a covered entity . . . to dispense drugs itself" and that "[i]t is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities." *Id.* at 43,549.

HRSA also recognized that "[a]s a matter of State law, entities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients" and that "even in the absence of Federal guidelines, covered entities have the right to contract with retail pharmacies for the purpose of dispensing 340B drugs." *Id.* at 43,550. HRSA agreed with commenters that "[b]y issuing guidelines [the Office of Drug Policy, a Division of HRSA], was not seeking to create a new right but rather [was] simply recognizing an existing right that covered entities enjoy under State law." *Id.* Finally, HRSA stated that "[u]nder section 340B, . . . *if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price*." *Id.* at 43,555 (emphasis added). In 2010, HRSA again acknowledged that "[u]nder section 340B, if a covered entity using contract pharmacy services requests to purchase a covered

outpatient drug from a participating manufacturer *the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price*." Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,278 (Mar. 5, 2010) (emphasis added). HRSA's recent letter to UT restates this longstanding position.

UT is flatly wrong in stating that the 1996 and 2010 guidances are inconsistent with HHS's current position that manufacturers are required to honor contract pharmacy arrangements. Pl.'s Mem. 36. Both guidances included the almost identical statement that "[u]nder section 340B, . . . if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute *directs the manufacturer to sell the drug at the discounted price*." 61 Fed. Reg. at 43,549, 43,555; 75 Fed. Reg. at 10,272, 10,278 (emphasis added). HHS could not have been clearer that pharmaceutical companies that choose to participate in the 340B program *must*, pursuant to the statute, provide 340B discounts for drugs delivered at contract pharmacies. Until last year, UT acquiesced.

The 1996 guidance did limit 340B providers to a single contract pharmacy. 340B providers apparently determined that they could operate within this limitation, and they never challenged it. *Amici* question whether HHS had the authority to impose this limitation, but in any event, HHS corrected any error in 2010 when it eliminated the one-pharmacy limitation, as required by the plain language of the statute, which is controlling. In the 1996 guidance, HHS disclaimed that it was creating any rights or imposing any obligations, a point UT claims is relevant, *see* Pl.'s Mem. 36, because the obligation is imposed by the statute, not the guidance. No guidance by itself can create a right or impose an obligation, although guidances inform the regulated industry of the agency's thinking and of its interpretation of the statute.

Finally, UT argues that HHS failed to explain where it found its "newfound source of purported authority to penalize manufacturers for not engaging with contract pharmacies." *Id.* at 37. Civil money penalties were not discussed in the 1996 and 2010 guidance documents because they were not added to the statute until after the 2010 guidance had been issued. *See* Patient Protection & Affordable Care Act § 7102, 124 Stat. at 823–25 (codified at 42 U.S.C. § 256b(d)(1)(B)(vi)). Moreover, HRSA's May 17, 2021 letter does not say that UT is currently subject to civil money penalties but that "continued failure to provide the 340B price to covered entities utilizing contract pharmacies . . . *may result in* [civil money penalties (CMPs)]. HHS will determine whether CMPs are warranted." Letter from Diana Espinosa to Lynn Robson, *supra* n.2 (emphasis added). UT argues that its refusal to provide the 340B discount to covered entities that use contract pharmacies does not constitute an overcharge (subject to civil money penalties) because it is refusing to fill the order, not filling the order but charging a higher price, Pl.'s Mem. 44; while perhaps creative, this argument is flatly inconsistent with the statute. Under the statute, covered entities are entitled to purchase 340B drugs at 340B prices, and UT may not refuse to sell the drugs or charge more than the ceiling price for the drugs. UT's refusal to comply with the statute is unlawful.

III. THE STATUTORY PROHIBITION ON DIVERSION DOES NOT PRECLUDE THE USE OF CONTRACT PHARMACIES.

UT argues that the statutory prohibition on diversion supports its argument that the May 17 letter conflicts with the 340B statute, Pl.'s Mem. 27, but the use of contract pharmacies does not violate the statutory prohibition on diversion. The statute provides that "a covered entity shall not resell or otherwise transfer [a 340B] drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). This prohibition imposes an obligation on covered entities to avoid reselling discounted drugs to nonpatients or transferring drugs to other non-covered healthcare

providers for prescribing to their patients, but it does not require a 340B provider to ensure that 340B drugs are physically dispensed by the employees of the covered entity. When a covered entity contracts with a pharmacy to dispense its 340B drugs, the contract pharmacy is, on behalf of the covered entity, dispensing the 340B drug to a person who *is* a patient of the covered entity, and thus is acting in a manner consistent with the statute. There is no diversion.

Moreover, UT's own policy of shipping drugs to specialty pharmacies used by certain 340B entities, which are also contract pharmacies, is inconsistent with UT's argument that shipping 340B drugs to contract pharmacies constitutes unlawful diversion. And UT's allowance of the use of contract pharmacies so long as the covered entity provides claims data, as well as its allowance for the use of a single contract pharmacy if a covered entity lacks an in-house pharmacy, similarly show how UT's diversion argument is a red herring. Delivery to contract pharmacies either constitutes diversion or does not (it does not).

IV. THE 340B STATUTE DOES NOT ALLOW UNITED THERAPEUTICS TO REQUIRE ACCESS TO CLAIMS DATA AS A CONDITION TO USE CONTRACT PHARMACIES.

Drug manufacturers may not add requirements to the 340B statute. UT argues that the 340B statute does not require it to "deal with contract pharmacies" and that it necessarily follows that when a manufacturer voluntarily chooses to do so it may place conditions on those dealings. Pl.'s Mem. 41. As explained in Section I, UT's argument that it is not required to provide 340B discounts to covered entities for drugs dispensed under contract pharmacy arrangements is inconsistent with the statute.

UT further argues that "the concept of an 'offer' does not preclude the existence of 'conditions'" and that "as a matter of basic logic, pharmaceutical manufacturers must impose at least *some* conditions on purchase of 340B drugs—such as the condition that the purchasing entity *is* 340B eligible." *Id.* 41–43 (emphasis in original). It also argues that its claims data policy

"simply provides UT a mechanism to confirm that an entity seeking 340B discounts is, in fact, a statutory covered entity." *Id.* at 41.

Pursuant to the 340B statute, HRSA already has a process that requires covered entities to be certified and then annually recertified. 42 U.S.C. 256b(a)(7); *see also 340B Eligibility*, HRSA, https://www.hrsa.gov/opa/eligibility-and-registration/index.html. Moreover, any manufacturer may confirm that an entity seeking 340B discounts is in fact an eligible and duly registered covered entity through HRSA's 340B Office of Pharmacy Affairs Information System. *340B OPAIS User Guide*, HRSA, Office of Pharmacy Affairs, 23–29, https://www.hrsa.gov/sites/default/files/hrsa/opa/publicuserguide.pdf. And at the start of the program, HRSA notified manufacturers that they "may *not* condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions." 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) (emphasis added).

In addition, while *Amici* recognize and agree with HRSA's longstanding position that manufacturers are allowed to "request standard information," *id.* at 25,114, nothing about what UT is requesting is standard. Covered entities have not in the past 28 years ever been required to provide to pharmaceutical manufacturers this highly sensitive information for contract pharmacy drug claims, and neither non-covered entities nor covered entities using their own in-house pharmacy are being asked to provide this type of claims data. In fact, HHS has consistently advised pharmaceutical manufacturers participating in the 340B program that they may *not* demand the type of information that UT is seeking as a condition to the use of contract pharmacies. In 1994, for instance, HHS notified pharmaceutical manufacturers that they "may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory

objective," *id.* at 25,112, and that "[m]anufacturers must not place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program," *id.* at 25,1113. (emphasis added). Directly relevant to this case, HHS stated that

> [c]overed entity assurances regarding the following activities may not be required: . . . (2) utilization of covered outpatient drugs only in authorized services; . . . (4) permitting the manufacturers to audit purchase, inventory, and related records prior to the publication of approved [340B] guidelines; and (5) submitting information related to drug acquisition, purchase, and inventory systems.

Id. at 25,113–14; *see also* 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210, 1,223 (Jan. 5, 2017) ("Manufacturers cannot condition the sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity"). The conditions UT's policy imposes on 340B providers are thus plainly disallowed. *See* 59 Fed. Reg. at 25,112.

Finally, the "must offer" provision was added to the statute in 2010 to ensure that manufacturers did not treat covered entities any differently than their other, non-340B buyers. *See* 42 U.S.C. 256b(a)(1).[11] Yet that is exactly what UT's policy seeks to do by imposing these conditions only on 340B providers, making UT's program inconsistent with this provision of the statute as well.

V. CONCERNS ABOUT DIVERSION AND DUPLICATE DISCOUNTS DO NOT MAKE UNITED THERAPEUTICS' POLICIES LEGAL.

As demonstrated in Section III, the 340B statute's prohibition on diversion does not make the use of contract pharmacies unlawful. In addition, UT's claims that its contract pharmacy and

[11] HRSA, *Clarification of Non-Discrimination Policy* (May 23, 2012), https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/nondiscrimination05232012.pdf.

claims data portal policies are "designed to thwart" diversion and duplicate discounts provide no support for UT's policies or arguments. Pl.'s Mem. 38. For one, citing to a 2020 GAO report, UT points to 1,500 cases of "non-compliance" since the year 2012 and claims that HRSA is failing to address these issues, *id.*, but UT fails to identify how many of these cases actually involved contract pharmacies.[12] Moreover, to the extent drug manufacturers have concerns regarding diversion or duplicate discounts, Congress enacted in the 340B statute a comprehensive scheme that authorizes the manufacturers and HHS to take specific steps to address those concerns. What Congress did not do is authorize drug manufacturers to unilaterally impose conditions on providing 340B discounts to covered entities.

Duplicate Discounts: Although not relevant to whether the statute allows it to attempt to unilaterally address duplicate discounting concerns—it does not—UT claims that duplicate discounting is rampant. *Id.* at 20. However, UT cites no evidence to connect this claim to contract pharmacies. In fact, the most recent GAO report addressing this issue indicated that between 2012 and 2019, *only 23* of the 429 duplicate discount findings related to contract pharmacies. GAO, GAO-21-107, *HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements* 14 (Table 1) (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf (2020 GAO Report). Moreover, Congress did not give drug manufacturers the authority to unilaterally halt providing discounts to covered entities merely because they have concerns about duplicate discounts. Instead, Congress provided drug companies and HHS with the authority to address suspected duplicate discounts through audits. 42 U.S.C. §§ 256b(a)(5), (d)(2). If after an audit and

[12] Indeed, UT tries to have it both ways, arguing inconsistently that its policies are designed to address increased noncompliance resulting from an explosive growth of contract pharmacies, Pl.'s Mem. 37, and that its policies will have an extremely limited effect on the marketplace, *id.* at 19. Both cannot be true.

a hearing, the HHS Secretary (not the manufacturer) finds that a covered entity has violated the prohibition on duplicate discounts (or diversion), the covered entity must pay a refund to the manufacturer. *Id.*; *see also* Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19, 61 Fed. Reg. 65,406 (Dec. 12, 1996) (establishing guidelines for audits, as required by section 256(a)(5)(C)).

Congress therefore clearly considered the risks of duplicate discounts in the 340B program and specifically addressed them; in order to protect 340B providers from the potentially onerous burdens that giving unlimited audit authority to manufacturers would have permitted, Congress required that audits only be done in accordance with guidance from HHS regarding the number, duration, and scope of the audits. *Cf. Fin. Planning Ass'n v. S.E.C.*, 482 F.3d 481, 488 (D.C. Cir. 2007) (agency not allowed to broaden statutory exemptions where "legislative 'intent' does not support an exemption . . . broader than the exemption set forth in the text of [the statute]" and where Congress "already expressly addressed" the issue in another provision of the statute); *id.* at 490 (finding statutory scheme inconsistent with interpretation that gives agency authority to expand provision's coverage). UT identifies no authority to support its inconsistent approach.

Diversion: UT contends that "a mountain of public evidence shows that the contract pharmacy model has facilitated diversion," Pl.'s Mem. 37, but misrepresents what constitutes that "mountain." What UT fails to acknowledge is that before 2019, HRSA was issuing audit findings on diversion based on rules that it has since abandoned after a legal challenge to its methodology. *See* 2020 GAO Report 15 n.26, 21. As a result of that challenge, in the fall of 2019, HRSA changed its rules to more closely follow the 340B statute. *Id.* Since that time, diversion findings for 340B hospitals have plummeted to *only 10* for fiscal year 2020, of which half involved issues unrelated

to contract pharmacies. Testoni Decl. ¶¶ 11–12.[13] And as with duplicate discounts, the statute clearly provides tools to address diversion—namely audits conducted by HRSA and the manufacturers—rendering UT's plan to restrict contract pharmacies and to require covered entities to provide claims information indefensible and inconsistent with the statute. Contrary to UT's assertion, Pl.'s Mem 39, HRSA and manufacturers (pursuant to an approved audit workplan) have authority under the statute to audit covered entities *and their contract pharmacies*. HRSA, *Best Practices for Covered Entities: Resolving Contract Pharmacy Related Non-Compliance*, OPA Update (last reviewed July 2018), https://www.hrsa.gov/opa/updates/2018/june.html.

UT also ignores the fact that covered entities are responsible for ensuring that the statutory requirements are met when they use third-party administrators and contract pharmacies and could be required to provide records regarding those relationships as part of an audit by HRSA or the manufacturer.[14] UT apparently believes that HRSA is not doing an adequate job and in fact spends much of its brief criticizing HRSA's lack of oversight. *See* Pl.'s Mem. 16–17, 20–21, 38–39, 42. Nonetheless, Congress did not give drug manufacturers the authority to unilaterally halt providing discounts to covered entities or to impose restrictive conditions on this basis but, as discussed above, instead provided 340B manufacturers and HHS with tools (audit authority) to address suspected diversion and duplicate discounts. As HHS stated in the preamble to its final regulation establishing civil money penalties, *see* 82 Fed. Reg. at 1,223, drug manufacturers cannot lawfully impose conditions on the sale of 340B drugs to 340B providers.

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[13] Contrary to UT's assertion, Pl.'s Mem. 39, HHS has never required a covered entity to verify patient eligibility at the time of service. In fact, when this issue was raised in 2010, HHS specifically chose not to do so. *See* 75 Fed. Reg. at 10,277. In 1996, HRSA suggested this approach as one potential model, but HHS was clear that other approaches were also acceptable. 61 Fed. Reg. at 43,551.

[14] *See FY21 Data Request List (DRL)* (Aug. 17, 2020), https://www.340bhealth.org/files/FY21_Data_Request_List.pdf.

CONCLUSION

UT's policies of refusing to offer 340B drugs at discounted prices when dispensed through certain contract pharmacies and of requiring access to claims data as a condition for using contract pharmacies are inconsistent with the 340B statute, are at odds with HHS's longstanding interpretation of the statute, and jeopardize 340B hospitals' ability to care for patients during the nation's most serious public health crisis in a century. For the reasons set forth above, this Court should uphold HHS's correct interpretation of the statute, deny UT's motion for summary judgement, and grant summary judgment to Defendants.

Dated: August 10, 2021

Respectfully submitted,

/s/ William B. Schultz

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Exhibit A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED THERAPEUTICS CORPORATION, *Plaintiff*, –v– DIANA ESPINOSA, in her official capacity as ACTING ADMINISTRATOR, HEALTH RESOURCES AND SERVICES ADMINISTRATION, *et al.*, *Defendants*.	Civil Action No. 1:21-cv-1686

DECLARATION OF MAUREEN TESTONI IN SUPPORT OF AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, AMERICA'S ESSENTIAL HOSPITALS, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, CHILDREN'S HOSPITAL ASSOCIATION, AND THE AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS' *AMICUS* BRIEF IN SUPPORT OF DEFENDANTS

I, Maureen Testoni, state as follows under the penalty of perjury:

1. I am the President and Chief Executive Officer of 340B Health, a national, not-for-profit organization headquartered in Washington, D.C. Our vision and mission are to be the leading 340B advocate and resource in helping hospitals serve their patients, so that 340B hospitals and health systems fulfill their mission to provide care for patients with low income and those living in rural communities.

2. The information set forth in this affidavit is based upon my personal knowledge.

3. Following Eli Lilly's June 2020 announcement that it would cease offering Cialis® at 340B pricing to 340B entities if dispensed by a contract pharmacy, 340B Health conducted a "Contract Pharmacy Survey." The survey was administered to all 340B Health hospital members (about 1500), and 340B Health received responses from 435 hospitals between July 14 and August 8, 2020. The respondent mix was 64% disproportionate share hospitals (DSH), 24% critical access

hospitals (CAH) (a designation given to small hospitals located in rural areas; they are often financially vulnerable), and 12% other hospital types. Data were cleaned to remove duplicates.

4. A second survey, the 340B Health Annual Survey, was launched on November 3, 2020. Responses were received from 489 hospitals between November 3, 2020 and January 7, 2021. The respondent mix included 61% DSH hospitals, 28% CAH hospitals, and 11% other hospital types. Data were cleaned to remove duplicates.

5. The following information in paragraphs 6-10 is derived from those two 340B Health surveys.

6. Respondents to the Annual Survey reported that discounts for drugs dispensed through a contract pharmacy provided over half of the total 340B benefit from the 340B discounts for CAH hospitals (51%) and about a quarter of the total such benefit for all 340B hospital types (27%).

7. Respondents to the Contract Pharmacy Survey reported that the reduction or elimination of the discounts for drugs dispensed through contract pharmacies would lead to cuts in programs and services for people with low income and/or living in rural areas.

8. Respondents to the Contract Pharmacy Survey reported using the discount benefit from 340B drugs dispensed through contract pharmacies to support programs and services offered by 340B hospitals. For example, respondents reported that the discount benefit from 340B drugs dispensed through contract pharmacies allows them to:

- Maintain/provide more patient care services (97%)
- Maintain/provide more uncompensated and unreimbursed care (93%)
- Maintain/provide more services in underserved areas (83%)
- Develop/maintain targeted programs to serve vulnerable patients (73%)
- Keep the doors open (70%)

9. Respondents to the Contract Pharmacy Survey reported that a reduction or elimination of discounts for drugs dispensed through a contract pharmacy would harm the ability of 340B hospitals to maintain programs and services. Specific services that would be harmed include:

- Patient care services (94%)
- Uncompensated and unreimbursed care (86%)
- Services in underserved areas (81%)
- Programs to serve vulnerable patients (73%)

10. Sixty percent of respondents to the Contract Pharmacy Survey reported that a reduction in the discounts from 340B drugs dispensed through contract pharmacies could lead the hospital to close.

11. 340B Health periodically reviews and analyzes the 340B entity audit results that HRSA posts on the program integrity page of its website. That analysis includes audit results for fiscal year 2020 that were posted by HRSA as of July 16, 2021.

12. For audits of 340B hospitals in fiscal year 2020 posted as of July 16, 2021, there were ten findings of diversion out of a total of 160 audits for hospitals. Only five of those ten are related to a contract pharmacy.

On this 5th day of August 2021, I declare under penalty of perjury that the foregoing is true and correct.

Maureen Testoni
President and
Chief Executive Officer
340B Health