IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED THERAPEUTICS CORPORATION,
1040 Spring Street,
Silver Spring, MD 20910

Plaintiff,

v.

DIANA ESPINOSA, Acting Administrator of U.S. Health Resources and Services Administration
5600 Fishers Lane,
Rockville, MD 20852,

U.S. HEALTH RESOURCES AND SERVICES ADMINISTRATION
5600 Fishers Lane,
Rockville, MD 20852,

XAVIER BECERRA, Secretary of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201,

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, SW
Washington, DC 20201,

Defendants.

Case No. 1:21-cv-1686

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff United Therapeutics Corporation (UT) brings this suit against Defendants Diana Espinosa, in her official capacity as Acting Administrator of the U.S. Health Resources and Services Administration; the U.S. Health Resources and Services Administration (HRSA); Xavier Becerra, in his official capacity as Secretary of Health and Human Services; and the U.S. Department of Health and Human Services (HHS), and alleges as follows:

PRELIMINARY STATEMENT

1. This case is about a federal program that has run off the rails. In 1992 Congress enacted the 340B Drug Pricing Program, 42 U.S.C. § 256b (known as "340B"), mandating that drug manufacturers provide substantial drug discounts to specified types of healthcare providers ("covered entities") that treat indigent, uninsured, and certain other specific vulnerable patient populations. 42 U.S.C. § 256b(a). The principal purpose of the program was to assist these covered entities and their patients financially; Congress anticipated that the covered entities would pass on the drug discounts to the vulnerable patient populations they serve. H.R. Rep. No. 102-384(II), at 12 (1992).

2. Congress did not grant the federal agency charged with administering the program—HRSA—regulatory authority to change or enlarge Congress's statutory list of "covered entities." Yet HRSA purported to find a way to do so through "informal guidance." *See AstraZeneca Pharms. v. Becerra*, No. 1:21-cv-27-LPS, 2021 WL 2458063, at *7 (D. Del. June 16, 2021) ("[T]hroughout the past 25 years, [HRSA] has dramatically expanded how covered entities may purchase 340B drugs."). First, in the mid-1990s, HRSA recognized that certain covered entities do not have an in-house pharmacy from which to dispense drugs, and therefore allowed covered entities to contract with a single outside "contract pharmacy" that would receive the shipment of 340B discounted drugs for dispensing. *See* HRSA, Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,549 (Aug. 23, 1996). More than a decade later, in 2010, HRSA altered its guidance to allow covered entities to enter "contract pharmacy" arrangements with an unlimited universe of pharmacies located anywhere in the U.S., along with other third parties, to place and/or receive orders for 340B

discounted drugs. *See* HRSA, Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

3. HRSA's 2010 policy change had a significant and predictable effect. Over time, with advice from specialized consultants, tens of thousands of pharmacies (including the nation's largest pharmacy chains) developed a business model to take advantage of the 340B program. These pharmacies signed up covered entities as contract partners all across the U.S., so that they could take advantage of 340B discounts. Under that scheme, the contract pharmacies would claim the right to 340B discounts on drugs that they had already purchased and dispensed to a percentage of their customers—apparently on the theory that a percentage of those customers had some form of existing or prior relationship with a covered entity sufficient to rationalize a 340B discount. *See* Aaron Vandervelde et al., BRG, *For-Profit Pharmacy Participation in the 340B Program*, at 5 (Oct. 2020) (Vandervelde et al.) (explaining how the pharmacies use "sophisticated software algorithms" to make these determinations).[1]

4. This effort paid off for the contract pharmacies: the pharmacies would receive 340B discounts on drugs they had *already dispensed* at an undiscounted price. *Id.* at 3; *see also* Examining Oversight Reports on the 340B Drug Pricing Program*: Hearing Before the S. Comm. on Health, Education, Labor, and Pensions*, 115th Cong. 11 (May 15, 2018) (testimony of Ann Maxwell, Assistant Inspector Gen. for Evaluation and Inspections, Off. of Inspector Gen. (OIG)) (OIG Testimony) (testifying "many contract pharmacies dispense drugs to all of their customers—340B-eligible or otherwise—from their regulatory inventory"). One national pharmacy gained

[1] https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf.

such a significant windfall that it publicly reported that any legal change disallowing this practice would be "material" to its business. *See infra* at 27.

5. These new-found profits—the "spread" between the 340B discount and the ultimate price of the dispensed drug—have been going in substantial part to contract pharmacies, as directed under their private arrangements with covered entities, and to other third parties, which Congress did not intend to benefit under the 340B program. And although it has never been publicized how much of the 340B benefit goes into the pockets of these private commercial actors, often little or none of the benefit reaches the vulnerable patient populations. *See* U.S. Government Accountability Off., *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* at 30 (June 2018) (2018 GAO Report); *see also* OIG, *Contract Pharmacy Arrangements in the 340B Program*, No. OEI-15-13-00431 at 14 (Feb. 4, 2014) (2014 OIG Report) (HHS's Inspector General finding that many covered entities "do not offer the 340B price to uninsured patients in any of their contract pharmacy arrangements.") The "algorithms" used by contract pharmacies and other third parties for determining when they are dispensing to a genuine 340B patient have never been public—and to UT's knowledge are not known by HRSA either. Additionally, HRSA lacks statutory authority to audit how contract pharmacies and other third parties make these determinations.

6. By 2020, the effect of HRSA's change in its 340B program policy was profound. The number of "contract pharmacy" arrangements nationwide grew by more than 4,000%, from 2,321 to 100,451. Vandervelde et al. at 4. The number of individual pharmacies participating in the program now exceeds 27,000. *Id.* And the number of actual claims for 340B discounts

nationwide *tripled* between 2014 and 2019. *See* Adam J. Fein, Drug Channels, *New HRSA Data: 340B Program Reached $29.9 billion in 2019; Now Over 8% of Drug Sales* (June 9, 2020).[2]

7. UT has felt the unavoidable impact of these policy changes. For example, between 2019 and 2020, UT data demonstrate that the number of 340B discount claims *doubled* for certain UT drugs.[3] *See* Letter from UT to HRSA at 4 (June 10, 2021), attached as Exhibit 1. UT is aware of no possible appropriate rationale for this increase in 340B utilization. Indeed, the number of units of these drugs on which the 340B discount was claimed appears to have exceeded any realistic estimate of any increase in patients actually treated by the covered entities at issue. As succinctly stated by the then-Ranking Member of the Senate Judiciary Committee, the 340B program "is not intended to subsidize pharmacies that team up with covered entities to turn a profit."[4]

8. In addition to compelling drug discounts to specified covered entities, the 340B statute also outlaws diversion (*i.e.,* a covered entity selling or otherwise transferring a 340B discounted drug to an individual who is not a patient of the covered entity). Multiple audits and reports, including by the HHS Inspector General and the U.S. Government Accountability Office (GAO), identified significant risks of diversion associated with the HRSA contract pharmacy policy. *See infra* at 28-31. The GAO found that contract pharmacies also are incentivized to manipulate the 340B program, because many of them receive "a fee based on a percentage of revenue generated for each 340B prescription." 2018 GAO Report at 25. As industry experts have

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[2] https://www.drugchannels.net/2020/06/new-hrsa-data-340bprogram-reached-299.html.

[3] Those drugs are: Remodulin® (treprostinil) Injection, Tyvaso® (treprostinil) Inhalation Solution, and Orenitram® (treprostinil) Extended-Release Tablets.

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

explained, the savings from the 340B program are now "distributed across a vertically integrated supply chain that includes . . . pharmacies, contract pharmacy administrators, [pharmacy benefit managers], health plans, and employer groups." Vandervelde et al. at 7. Indeed, HRSA has taken no action remotely sufficient to address those issues, and the problem continues to balloon.

9. In the absence of responsible action by HRSA, a number of manufacturers took steps to attempt to restore the 340B program to its intended and legal operation. Certain manufacturers announced they would halt sales to or through contract pharmacies altogether, with a series of specific exceptions, citing the specific limitations on HRSA's statutory authority. Other manufacturers limited the types of contract pharmacies for which 340B discounts would be appropriate. UT announced a series of measured steps, each consistent with 42 U.S.C. § 256b(a) and the agreement entered between HRSA and UT pursuant to that provision. 42 U.S.C. § 256b(a)(1) ("The Secretary shall enter into an agreement with each manufacturer . . . . Each such agreement . . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price."). Although UT recognized that any HRSA mandate to sell or ship to contract pharmacies would exceed HRSA's statutory authority, UT nevertheless continued to provide 340B discounts for purchases shipped to the contract pharmacies (and third parties) that had previously been provided with such discounts during the first three quarters of 2020. In addition, UT announced, but has not yet implemented, a 340B claims portal designed to collect data to ensure that contract pharmacy requests for 340B pricing are legally appropriate. UT has not denied any covered entity the ability to purchase product under the 340B program.

10. In the summer of 2020, HRSA officials acknowledged that HRSA's prior "contract pharmacy" *guidance* was *not actually enforceable* against manufacturers. *See*, *e.g.*,

Michelle M. Stein, Inside Health Policy, *HRSA Urges Pharma To Continue 340B Discounts At Contract Pharmacies* (Aug. 20, 2020) ("HRSA Urges Pharma") (HRSA stated: "Without comprehensive regulatory authority, HRSA is unable to develop *enforceable* policy to ensure clarity in program requirements across all the interdependent aspects of the 340B program.");[5] *cf. AstraZeneca*, 2021 WL 2458063, at *6. But HRSA then changed its view in the months that followed after receiving input from covered entity interests. *See* Letter from HRSA to President and CEO of 340B Health (Dec. 9, 2020), Exhibit L to Second Am. Compl., *Eli Lilly & Co. v. Becerra* (*Eli Lilly*), No: 1:21-cv-00081-SEB-MJD (S. D. Ind.) (Second Am. Compl.), ECF No. 103-13 (HRSA indicating to covered entity lobby representative that it was "working closely with each impacted covered entity" on how to address manufacturer policies for contract pharmacies).

11. On December 30, 2020, the Chief Legal Officer of HHS—whose opinions bind HRSA—issued a legal opinion purporting to interpret the "unambiguous" statutory text and declaring that "*to the extent* contract pharmacies are acting as *agents* of a covered entity, a drug manufacturer in the 340B Program *is obligated* to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." Advisory Opinion 20-06 On Contract Pharmacies Under The 340B Program at 1 (Dec. 30, 2020) (Advisory Opinion) (emphasis added); *AstraZeneca*, 2021 WL 2458063, at *6 ("[T]he [Advisory] Opinion is the first document in which HHS explicitly concluded that *drug manufacturers* are required *by statute* to provide 340B drugs to *multiple* contract pharmacies." (emphases in original)). And in May of 2021, HRSA issued specific threats of enforcement in a

[5] https://insidehealthpolicy.com/daily-news/hrsa-urges-pharma-continue-340b-discounts-contract-pharmacies (emphasis added).

series of letters to six manufacturers, which it has admitted are a "final agency action" subject to appropriate judicial challenge. *See infra* at 13-14. Specifically, letters issued to UT on May 17 and May 28 asserted that HRSA requires drug manufacturers enrolled in the 340B program, such as UT, to provide the 340B discount on "contract pharmacy" orders of outpatient drugs. And both letters threatened civil monetary penalties unless UT acquiesced to HRSA's view of the facts and law.

12. The Advisory Opinion, on which the May 17 and 28 letters were premised, was subsequently challenged by an affected pharmaceutical manufacturer. *See AstraZeneca*, 2021 WL 2458063. On June 16, 2021, the reviewing court declared the Advisory Opinion unlawful, noting that contrary to the Advisory Opinion's reasoning, the 340B statute *did not* unambiguously obligate drug manufacturers to provide the 340B discount for drugs dispensed by contract pharmacies. *See id.* at *8-9. HHS then withdrew the Advisory Opinion on June 18, 2021. *See* Ex. 1 to Notice, *Eli Lilly & Co. v. HHS*, No. 1:21-cv-00081-SEB-MJD, ECF No. 119-1, at 2 (Advisory Opinion Withdrawal) ("The Office of the General Counsel (OCG) is withdrawing Advisory Opinion 20-06."). But HRSA *has still not withdrawn* its letters to UT which necessarily were premised upon that opinion (including the assumption that contract pharmacies were "agents" of covered entities). And HRSA continues to threaten civil monetary penalties. *Id.*

13. HRSA's May 17 and 28 letters violate the 340B statute and the Administrative Procedure Act in multiple specific respects.

14. First, HRSA's legal interpretation that pharmaceutical manufacturers are *obligated* to provide 340B discounted drugs to contract pharmacies conflicts unavoidably with the plain text of the 340B statute, which provides an *exclusive* list of "covered entities," and cannot be construed to also include other, un-enumerated entities—like contract pharmacies. As one court

has already concluded: "It is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication." *AstraZeneca*, 2021 WL 2458063, at *10. Likewise, nothing in UT's agreement with HHS (entered pursuant to 42 U.S.C. § 256b(a)) requires UT to sell to, ship to, or otherwise deal with contract pharmacies or other third-party entities.

15. Second, even if the statute could bear HRSA's addition of contract pharmacies as "agents" of the covered entities (it cannot), the statute would still not authorize HRSA to compel manufacturers to engage in a system under which contract pharmacies "replenish" commingled stocks of 340B and non-340B drugs. Under these circumstances, a manufacturer is not offering or selling the drug to a covered entity; it is instead selling and/or delivering the drug to a contract pharmacy, which is in turn dispensing that drug to a patient who may or may not have been treated by any covered entity at all. Contrary to HRSA's mistaken assumption, the title to drugs shipped to a contract pharmacy to replenish that pharmacy's supplies is *never* held by the covered entity. If it were, the contract pharmacy's later sales of those drugs to non-340B patients—which by definition happens under the replenishment model—would constitute prohibited diversion.

16. Third, the May 17 and 28 letters, which inform UT of HRSA's determination that UT violated the law and threaten to impose civil monetary penalties (hereinafter, the "Violation Determination") are arbitrary and capricious, contrary to law, and/or unreasonable for at least seven reasons:

(A) The Violation Determination was based on an Advisory Opinion that embodied a fundamental error of law and has been declared invalid. Recognizing that error of law, HHS has withdrawn the Advisory Opinion. Because the Violation Determination relied on the now defunct Advisory Opinion, the Violation Determination lacks a legal

foundation. And, even if the Violation Determination could be separated from the withdrawn Advisory Opinion, the Violation Determination now lacks *any* adequate basis or reasoning;

(B) To the extent that any legal rationale can now be divined from the Violation Determination, it rests on the same fundamental error as the now defunct Advisory Opinion. The Violation Determination, applying the withdrawn Advisory Opinion, concludes that an obligation for pharmaceutical manufacturers to deal with contract pharmacies flows from the *unambiguous* text of 340B. Even if 340B does not foreclose the Advisory Opinion's interpretation (it does), the statute categorically does not *command* it, and this is fatal under the law in this Circuit, s*ee infra* at 36, 45;

(C) The Violation Determination is necessarily predicated on the same conclusion as the defunct Advisory Opinion, that the contract pharmacies at issue for UT *are* agents of covered entities. But HRSA has no evidence, and conducted no analysis, establishing that is correct as a factual matter. Instead, the Violation Determination simply assumes it to be true, apparently based on the now withdrawn Advisory Opinion, which in turn assumed it *may* be true, also without evidence. HRSA has identified *no* supporting factual evidence to support this assumption for even one contract pharmacy, much less all 27,000+ of them: HRSA fails to supply any legal or factual reasoning to support its conclusion that all relevant third parties are actually "agents" of covered entities under relevant law. HRSA does not know whether they are or are not, has not made any such finding relevant to UT, and would need to examine each commercial contractual relationship to reach any such conclusion. In short, HRSA's policy is predicated on a staggering and unsupported leap of logic;

(D) the Violation Determination, which necessarily relied upon the now withdrawn Advisory Opinion, similarly assumes without any record support that covered entities retain "title" to 340B discounted drugs, even when the drugs are distributed directly to contract pharmacies to "replenish" the stocks of drugs that contract pharmacies previously sold and dispensed to patients: those "replenishment" drugs will then be sold to other individuals, including those not treated by the covered entities at issue;

(E) The Violation Determination represents a radical shift in interpretation and policy from HRSA's earlier 1996 and 2010 guidance documents, *see AstraZeneca*, 2021 WL 2458063, at *6 ("[T]he [Advisory] Opinion is the first document in which HHS explicitly concluded [that pharmaceutical manufacturers are subject to the regulatory requirements HRSA now seeks to impose]."), but neither the letters nor the Advisory Opinion on which they are based addresses, or gives a reasoned rationale for, this change;

(F) The Violation Determination failed to consider a very important part of the regulatory problem: that there is significant potential for, *and substantial public evidence regarding*, diversion and fraud under the agency's contract pharmacy policy. To the extent this policy could be legally implemented at all (it cannot), HRSA was obligated to grapple with and explain these critical consequences of its new interpretation. HRSA cannot compel manufacturers to participate in a contract pharmacy replenishment scheme if HRSA cannot perform, and authorize manufacturers to perform, statutory audits on contract pharmacies and other third parties who are using undisclosed algorithms to determine which drug purchases are entitled to 340B discounts; and

(G) the Violation Determination threatens civil monetary penalties for alleged "overcharges" but in fact UT has not made *any* overcharges.

17. UT wrote to HRSA on June 10, 2021 explaining why HRSA could not implement its contract pharmacy policy and why the civil monetary penalties threatened in the Violation Determination could not be appropriate. UT asked HRSA to respond as soon as possible, by withdrawing the letters. HRSA failed to respond at all, despite the withdrawal of the Advisory Opinion.

18. UT is committed to supporting the goals that Congress enacted the 340B statute to advance, and its current policy is crafted with that aim in mind. But HRSA cannot legally force UT to engage in a program that enriches national pharmacy corporations at UT's direct expense and at the expense of the intended beneficiaries of Congress's program. UT is entitled to relief in the form of (i) a declaration declaring the Violation Determination unlawful under 42 U.S.C. § 256b and the Administrative Procedure Act, (ii) a vacatur setting aside the Violation Determination, and (iii) appropriate declaratory and preliminary and permanent injunctive relief prohibiting HRSA from proceeding with enforcement under the Violation Determination.

PARTIES

19. Plaintiff United Therapeutics Corporation is a biotechnology company focused on the development and commercialization of innovative products to address the unmet medical needs of patients with chronic and life-threatening cardiovascular and infectious diseases and cancer. United Therapeutics is a Delaware corporation having a place of business at 1040 Spring Street, Silver Spring, Maryland 20910.

20. Diana Espinosa is the Acting Administrator of HRSA and the head of HRSA. In that capacity, Administrator Espinosa has ultimate responsibility for activities at HRSA, including the actions complained of herein. Her governmental activities occur nationwide.

21. HRSA is an agency of the United States and a division of HHS. Its headquarters and principal place of business is at 5600 Fishers Lane, Rockville, MD 20852. Its governmental activities occur nationwide.

22. Xavier Becerra is the Secretary of HHS and the head of HHS. In this capacity, Secretary Becerra has ultimate responsibility for activities at HHS, including the actions complained of herein. His governmental activities occur nationwide.

23. HHS is a department of the United States. Its headquarters and principal place of business are at 200 Independence Avenue, S.W., Washington, DC 20201. Its governmental activities occur nationwide.

JURISDICTION, VENUE, EXHAUSTION, AND FINAL AGENCY ACTION

24. This Court has jurisdiction pursuant to 28 U.S.C. § 1331. This action arises under the Administrative Procedure Act (APA), 5 U.S.C. §§ 701-706. Plaintiff's prayers for a declaratory judgment and preliminary and permanent injunctive relief are authorized by the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202; the APA, 5 U.S.C. §§ 701-706; and 28 U.S.C. § 1361.

25. Venue is proper in this District under 28 U.S.C. § 1391(e)(1) because at least one Defendant is an officer or agency of the United States and resides in this District.

26. On May 17 and 28, HRSA issued the Violation Determination to UT, declaring that HRSA considered UT's contract pharmacy policy to be contrary to the 340B statute and threatening the imposition of civil monetary penalties. The Violation Determination is final agency action because it "mark[s] the consummation of the agency's decision-making process" and is an action "by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (citation omitted); *see*

also Sackett v. EPA, 566 U.S. 120, 126–27 (2012). The Violation Determination qualifies as a final agency action because it announces HRSA's unequivocal determination and subjects UT to civil monetary penalties each day it does not accept the agency's interpretation. *See Ipsen Biopharmaceuticals, Inc. v. Azar*, 943 F.3d 953, 959 (D.C. Cir. 2019). HRSA's counsel has also admitted that a materially identical Violation Determination directed to pharmaceutical manufacturer AstraZeneca Pharmaceuticals on May 17 was a final agency action, subject to judicial review. *See AstraZeneca Pharms. v. Becerra*, Case No. 21-27-LPS, H'rg Tr. at 21:13-16, ECF No. 76 (D. Del. May 27, 2021) ("Should [manufacturer] choose to amend its complaint to challenge HRSA's determination in the May 17 cease-and-desist letter, the statutory question would then properly be before the Court."); *id.* at 30:19-21 ("[T]he May 17th letter is sort of the culmination of [the agency's] . . . review of [pharmaceutical manufacturer's] policy.").

27. There is no statutorily mandated requirement that UT seek relief from the agency before bringing this suit in this Court. There is also no regulatory pathway to challenge HRSA's determination that would protect UT against accruing exposure to possible civil monetary penalties during the period of agency review. *See* 5 U.S.C. § 704. Thus, administrative exhaustion is not a prerequisite to suit.

28. In any event, immediate judicial review is warranted because UT has made exhaustive efforts to obtain relief from HRSA. Specifically, UT raised the issues presented by this suit in multiple communications with HRSA. Thus, any further attempt to seek relief directly from HRSA would be futile. *See AstraZeneca*, 2021 WL 2458063, at *7 ("If [a manufacturer] tries to raise the legal issue presented here in [administrative] proceedings, the result is preordained.").[6]

[6] HRSA has also continued to defend its position in multiple suits. *See AstraZeneca*, 2021 WL 2458063, at *1-2, 7 (detailing the course of litigation and HHS's defense of its Advisory

Review is also appropriate because UT faces significant harm from HRSA's action, and UT has no other adequate remedy.

BACKGROUND

A. Statutory Framework

29. The 340B Drug Pricing Program, established by Congress in 1992, was designed to assist statutorily identified covered entities, which "provide direct clinical care to large numbers of uninsured Americans," H.R. Rep. No. 102-384 (II), at 12, and to provide relief to the covered entities' patients specifically, *see* 61 Fed. Reg. at 43,549 (noting that "savings realized from participation in the [340B] program" should be used "to help subsidize prescriptions for [covered entities'] lower income patients").

30. The 340B statute's core mechanism to accomplish this goal is an instruction that HHS enter into "agreement[s]" with pharmaceutical manufacturers providing that certain statutorily defined "covered entit[ies]" be required to pay no more than a certain ceiling price for the pharmaceutical manufacturer's covered outpatient drugs. 42 U.S.C. § 256b(a)(1). That ceiling price is determined by finding the difference between the manufacturer's Average Manufacturer Price and its Medicaid rebate amount for the covered outpatient drug, as calculated under the Medicaid Drug Rebate Program statute. *Id.* § 256b(a)(1)–(2), (b). The 340B statute obligates the manufacturer to offer this price to the covered entities, but sets out no obligation to sell, distribute to, or otherwise deal with *other* third parties, such as contract pharmacies or third-party administrators. Nor could it.

Opinion); *see also* Defs.' Mot. for Summ., *Sanofi-Aventis U.S., LLC v. U.S. HHS*, No. 3:21-cv-00634-FLW-LHG, ECF No. 89 at 46-49 (D.N.J. June 16, 2021) (defending the Advisory Opinion as in accordance with the 340B statute and not arbitrary or capricious).

31. The 340B statute meticulously enumerates the categories of covered entities that may enjoy this benefit under the 340B program. To qualify as a covered entity under 42 U.S.C. § 256b(a)(4), the entity must be one of the following:

(A) A Federally-qualified health center (as defined in section 1905(*l*)(2)(B) of the Social Security Act).

(B) An entity receiving a grant under section 256a of this title.

(C) A family planning project receiving a grant or contract under section 300 of this title.

(D) An entity receiving a grant under subpart II of part C of subchapter XXIV (relating to categorical grants for outpatient early intervention services for HIV disease).

(E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV.

(F) A black lung clinic receiving funds under section 937(a) of title 30.

(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act.

(H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.

(I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

(J) Any entity receiving assistance under subchapter XXIV (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).

(K) An entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2) of this title (relating to treatment of

tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).

(L) A subsection (d) hospital (as defined in section 1186(d)(1)(B) of the Social Security Act) that—

(i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this subchapter;

(ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act; and

(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

(M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act, or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act, that would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.

(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act), and that meets the requirements of subparagraph (L)(i).

(O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act, or a sole community hospital, as defined by section 1186(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.

32. These covered entities were selected because they "generally care for underserved populations." *Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 822 (D.C. Cir. 2020).

33. By statute, HRSA publishes a list of all specific institutions that qualify as "covered entities." *See* 42 U.S.C. § 256b(a)(9); *see also* HRSA, 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1227 (Jan. 5, 2017).

34. The term "contract pharmacy" generally refers to a for-profit pharmacy that, as HRSA has admitted, does not qualify as a "covered entity" under the statute but has entered into an arrangement with a covered entity related to the provision of 340B drugs. *See* Email from Rear Admiral Krista M. Pedley, Director, Office of Pharmacy Affairs, HRSA to Lilly USA, LLC (June 11, 2020) ("Contract pharmacies . . . are only a mode for dispensing 340B drugs and not independent covered entities."), attached as Exhibit C to *Eli Lilly* Second Am. Compl., ECF No. 103-4; *id.* ("encourag[ing]"—but not compelling—manufacturer to "reconsider its decision to discontinue contract pharmacy 340B discounts").

35. The agreement that HHS enters into with pharmaceutical manufacturers is known as a Pharmaceutical Pricing Agreement and Addendum (PPA). The PPA, and its terms, are not negotiable. *See Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 118 (2011). Indeed, "[t]he statutory and contractual obligations, in short, are one and the same." *Id.* Nothing in the PPA

requires manufacturers to sell to, ship to, or otherwise deal with contract pharmacies, third-party administrators or any party other than covered entities. Indeed, HRSA's generic agreement defines "covered entity" specifically, and *does not* define that term to include "agents" of such an entity. *See* Sample PPA, *available at* https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/pharmaceutical-pricing-agreement-example.pdf.

36. Congress also gave HHS tools to make pharmaceutical manufacturers abide by their agreements, including the authority to impose substantial "civil monetary penalties" on any manufacturer who "knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds" the statutory ceiling price. 42 U.S.C. § 256b(d)(1)(B)(vi)(III).

37. Although it is nominally optional for pharmaceutical manufacturers to participate in the 340B program, *see Astra*, 563 U.S. at 117–18, manufacturers have no choice as a practical matter. Manufacturers are ineligible for their covered outpatient drugs and their drugs and biologics, as applicable, to be payable under Medicaid and Medicare Part B unless they participate in the 340B program. *Id.* § 1396r-8(a)(1), (5).

38. Congress enacted a number of provisions to ensure that the 340B program was not manipulated.

39. First, Congress specifically prohibited covered entities from taking certain actions. A covered entity may not cause "duplicate discounts or rebates" for covered outpatient drugs, which occur when a manufacturer sells a unit of covered outpatient drug to a covered entity at the 340B discounted price and then also is invoiced for a Medicaid rebate on that same unit. As a result, the covered entity cannot dispense 340B discounted covered outpatient drugs to Medicaid beneficiaries (thereby triggering a manufacturer rebate obligation to Medicaid) without taking certain steps to guard against a duplicate discount. *Id.* § 256b(a)(5)(A). Covered entities are also

forbidden from engaging in "diversion"—*i.e.*, "resell[ing] or otherwise transfer[ring] [a 340B discounted] drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B).

40. Second, Congress requires covered entities to permit *both* HHS and the manufacturers of 340B drugs to "audit" "the records of the entity that directly pertain to the entity's compliance with the" bars on duplicate discounting and diversion. *Id.* § 256b(a)(5)(C).

41. Finally, Congress specifically directed HHS to implement "improvements" in covered entity compliance with the statute's bars on diversion and duplicate discounting. *Id.* § 256b(d)(2)(B). Among other things, HHS was directed to have a process for imposing sanctions on covered entities that violate these statutory prohibitions. *Id.* § 256b(d)(2)(B)(v).

B. The Emergence Of Contract Pharmacies

1. HRSA's 1996 Guidance

42. Until 1996, covered entities obtained and dispensed 340B drugs only through their own in-house pharmacies.

43. In 1996, however, HRSA opened the door to the use of contract pharmacies through the issuance of guidance. *See* HRSA, Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549 (Aug. 23, 1996).

44. The contract pharmacy doorway opened in 1996, however, was quite narrow. Covered entities could contract with only a single contract pharmacy location—for the purpose of "facilitat[ing] program participation for those eligible covered entities that do not have access to appropriate 'in-house' pharmacy services." 61 Fed. Reg. at 43,551; *see also* HRSA Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 72 Fed. Reg. 1540 (Jan. 12, 2007) (confirming that the state of play under the 1996 guidance was that a "covered entity could contract with *only one* pharmacy to provide all pharmacy services for any particular site of the covered entity" (emphasis added)). The 1996 guidance did not *obligate* manufacturers to sell or

ship to contract pharmacies—instead, the guidance conveyed HRSA's non-binding interpretation of how covered entities could choose to do business. *See* 61 Fed. Reg. at 43,550 ("We believe that these guidelines create no new law and create no new rights or duties."); *see also HRSA Urges Pharma* at 1.

45. HRSA's 1996 guidance did not identify statutory support for its recognition of contract pharmacies. Instead, HRSA candidly admitted that "[t]he statute is silent as to permissible drug distribution systems" and that the statute did not contain a "requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself." *Id*. at 43,549. But HRSA nonetheless asserted that its contract pharmacy guidance was lawful because, in its view, it was "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.* From the outset, HRSA recognized that, even under its own strained reading of the statute, any obligation to deal with a contract pharmacy must be predicated on the existence of an agency relationship between the covered entity and the contract pharmacy. *See* 61 Fed. Reg. at 43,550 ("The contract pharmacy would act as an agent of the covered entity. . . . This situation is akin to a covered entity having its own pharmacy.").

46. The 1996 guidance also contained multiple important parameters on contract pharmacies' ability to dispense 340B drugs. Specifically, a contract pharmacy should only dispense a 340B drug either (a) "[u]pon presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient, and the signature of a legally qualified health care provider affiliated with the covered entity" or (b) *after* "receipt of a prescription ordered by telephone on behalf of an eligible patient by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an

eligible patient." *Id.* at 43,556. HRSA stated those guidelines were added because "[t]he contractor should have some type of assurance that the patient to whom the contractor is dispensing the 340B drug is a patient of a covered entity participating in the 340B Program." *Id.* at 43,553.

47. Although the statutory footing of contract pharmacies was unsound, at least in the initial years following the issuance of the 1996 guidance, the more limited nature of the 1996 guidance, as well as the fact that the single contract pharmacy would typically maintain a separate physical inventory of 340B drugs that it would dispense to the covered entity's patients, helped limit 340B program abuses.

2. HRSA Issues New Guidance In 2010

48. In 2010, HRSA shifted course and issued guidance that fundamentally changed its policy. HRSA, Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

49. HRSA's 2010 guidance changed the landscape in a critical way: Rather than just using *one* contract pharmacy location (*i.e.*, a local pharmacy that could easily identify covered entity patients and dispense 340B discounted medication only to those patients), covered entities could instead enter arrangements with an unlimited number of contract pharmacies. *Id.* at 10,273.

50. Like in its prior guidance, however, HRSA identified no statutory basis for its pronouncements, but claimed that it "impose[d] [no] additional burdens upon manufacturers, nor create[d] any new rights for covered entities under the law." *Id.*

51. HRSA's new guidance also established that covered entities were required to include certain "essential elements" in their contract pharmacy arrangements, including that "[t]he covered entity . . . purchase the drug, maintain title to the drug and assume responsibility for establishing its price." *Id.* at 10,277. Thus, the guidance rested on the legal fiction that contract pharmacies would operate as a mere vessel for covered entities, subject to their control. For

example, the guidance provides that "[t]he contract pharmacy, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of section 340B drugs to individuals who are not patients of the covered entity." *Id.* at 10,278. HRSA thereafter made no effort to confirm if these elements were indeed incorporated in the contract pharmacy arrangements. To the contrary, HRSA learned instead that contract pharmacies often operate on a "replenishment" model, where title to the drugs shipped to the pharmacy *does not* remain in the hands of the covered entity; the covered entity, contrary to the guidance requirements, has *no responsibility at all for setting drug prices* or no control over any other detail of how, when or to whom the drugs are actually dispensed. *See* 2014 OIG Report at 14 (many "covered entities use administrators that determine 340B eligibility *after* drugs *dispensed*, which means that their contract pharmacies do not know at the time they dispense the drugs whether patients' prescriptions are 340B-eligible" (emphasis altered)).

52. HRSA's 2010 policy was non-binding, which HRSA itself acknowledged to a publication in the industry. In an August 20, 2020 article in *Inside Health Policy*, HRSA stated that it "strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements," but that "[w]ithout comprehensive regulatory authority, HRSA is unable to develop enforceable policy to ensure clarity in program requirements across all the interdependent aspects of the 340B Program." *HRSA Urges* Pharma at 1.

C. Contract Pharmacy Abuses Explode

53. Since HRSA issued the 2010 guidance, the GAO found that the use of contract pharmacies has "increased more than fifteen-fold, from about 1,300 to approximately 20,000 [as of 2018]." 2018 GAO Report at 10. A more recent study put the increase at 4,228%, with now "more than 27,000 individual pharmacies (almost one out of every three pharmacies)" participating

in the 340B program as contract pharmacies. Vandervelde et al. at 4. And instead of using just one contract pharmacy, by 2020, covered entities were using an average of *22*. *Id.* at 7.

54. UT has likewise experienced a substantial increase in 340B activity. Between 2019 and 2020, the number of 340B discount claims for certain UT drugs *doubled.* Ex. 1 at 4. UT is aware of no plausible, legitimate cause for such an immense increase.

55. At the same time, the average distance between a covered entity and its contract pharmacies has also changed dramatically. Instead of an average of 34 miles in 2010, covered entities are now separated from their contract pharmacies by an average of *334* miles—strongly suggesting that many contract pharmacies are not dispensing medication to the covered entity's patients. Vandervelde et al. at 7.

56. As the number of contract pharmacies exploded, the business arrangements between contract pharmacies and covered entities began to look nothing like the model envisioned by the 1996 guidance, where a single contract pharmacy was simply acting as a conduit for a covered entity. Under that guidance, covered entities and contract pharmacies were instructed to use a "Bill to/Ship to" arrangement where the covered entity purchased the drugs and specified that the drugs would be shipped to the contract pharmacy. *See* 61 Fed. Reg. at 43,552. Contract pharmacy arrangements now generally involve a "replenishment model." Under that scheme, the contract pharmacy makes no effort at keeping 340B discounted drugs separate from its other non-340B stock, but instead maintains one single inventory from which it dispenses drugs to non-340B patients and 340B patients alike. At the time the contract pharmacy sells a drug, it does not know whether the individual purchaser is a patient of a 340B covered entity, and ignores the various anti-diversion safeguards discussed in HRSA's policy guidance. *See* OIG Testimony at 11 (testifying "many contract pharmacies dispense drugs to all of their customers—340B-eligible or

otherwise—from their regular inventory"). In other words, in such situations, the covered entity does not take or hold title to any particular drug shipment to the covered pharmacy.

57. Only later does the contract pharmacy attempt to determine whether the patient qualified for a 340B discount. To do so, the contract pharmacy and covered entity often utilize a third-party administrator—a company that is often paid per claim that it evaluates. That third-party administrator often makes that determination by using a complex, black-box algorithm to determine whether the patient to whom the drug was dispensed can be linked somehow to a covered entity. Vandervelde et al. at 5. The contract pharmacy then uses this determination to order stock at the 340B price to "replenish" those that were dispensed. The mechanism by which the 340B patients, and therefore units to be replenished at the 340B price, are identified is not regulated by HRSA and has never been made public, raising concerns that in many cases the "algorithm" may be little more than a guesstimate. The statute does not appear to give HRSA authority to audit contract pharmacies and other third parties, and thus HRSA may have no accurate sense of how these determinations are actually made.

58. Of the approximately 27,000 contract pharmacies participating in the 340B program, more than half of all profits are realized by four of the largest, for-profit pharmacy companies. Vandervelde et al. at 7; *see also* 2018 GAO Report at 20 (stating the majority (75%) of 340B contract pharmacies are chain pharmacies).

59. "The enormous growth in 340B contract pharmacy arrangements seems to boil down to a single factor: outsized profit margins." Vandervelde et al. at 4. For the period "between 2013 and 2018, the [National Community Pharmacists Association] reported that the average gross margin on all prescription medicines ranged between 22% and 23%." *Id.* For 340B purchased medicines, industry experts have estimated the average gross margin to be 72%. *Id.*

60. There are multiple ways that contract pharmacies can profit from their arrangement with covered entities. Typically, the contract pharmacy will bill a patient's third-party insurer at full price, or else charge the patient out of pocket for a 340B drug that the contract pharmacy obtained at a fraction of that price. *See* GAO, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements*, GAO-20-108 at 5 (Dec. 2019) (explaining that contract pharmacies "purchase [340B program] drugs at the 340B Program price for all eligible patients regardless of the patients' income or insurance status" and "receiv[e] reimbursement from patients' insurance that may exceed the 340B prices paid for the drugs"). Sometimes, the contract pharmacy and covered entity enter a percentage-based profit sharing scheme, where the contract pharmacy receives "a fee based on a percentage of revenue generated for each 340B prescription." 2018 GAO Report at 25. Other times, the contract pharmacy collects a flat fee per dispensed prescription. *Id.* Fees based on a percentage of revenue "ranged from 12 to 20 percent of the revenue generated." *Id.* at 27. Flat fees vary, but some fees for brand drugs are as high as **$1,750.** *Id.* at 26.

61. Indeed, HRSA is well aware that the contract pharmacy arrangement creates a massive revenue stream for national for-profit pharmacy chains. For example, in 2017, the current Director of HRSA's Office of Pharmacy Affairs testified that contract pharmacy profiteering from their arrangement with covered entities was "a business matter between the parties and their contract." *Examining HRSA's Oversight of the 340B Drug Pricing Program; Hearing Before the H. Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 115 Cong. 79 (July 18, 2017) (testimony of Capt. Krista M. Pedley, Director, Off. of Pharmacy Affairs, HRSA). She conceded, however, that HRSA does not prohibit contract pharmacies from sharing the spread between the 340B discount and the reimbursement. *Id.*

62. Although those savings were intended to benefit low-income care providers and their patients, the "profits on 340B purchased medicines are now distributed across a vertically integrated supply chain that includes . . . pharmacies, contract pharmacy administrators, [pharmacy benefit managers], health plans, and employer groups." Vandervelde et al. at 7. At least one national pharmacy chain publicly disclosed that 340B profits were material to its business operations. Walgreens Boots Alliance, Inc., Form 10-K, at 23 (Oct. 15, 2020), https://bit.ly/2MoLX9d.

63. Contract pharmacies frequently share none of this profit with the patients that Congress intended to benefit. The GAO found that only 54% of covered entities who responded to its request for data reported offering some discount on 340B drugs to low-income, uninsured patients in their contract pharmacy arrangements. 2018 GAO Report at 30.

64. The exponential growth in the use of contract pharmacies also creates massive risks to the integrity of the 340B program, including by multiplying the chances that statutorily barred diversion will occur.

65. Although there is little transparency regarding how the retrospective identification of 340B patients (and therefore 340B units) is performed, the evidence shows that third-party administrators are strongly incentivized to broadly interpret which contract pharmacy patients would have been patients of 340B covered entities. That is because the third-party administrators take another portion of the 340B profits generated, collecting around $5 to $7 per each prescription filled by a covered entity's contract pharmacy that the administrator determines originated from the covered entity and is 340B eligible. 2018 GAO Report at 28. Typically, a smaller fee (around $1.90) is charged when the administrator evaluates a prescription that originated from the covered entity but may not be eligible for a 340B discount. *Id.*

66. The publicly available evidence confirms that this system of perverse incentives has resulted in widespread abuses. As detailed in a report issued by GAO, HRSA has identified hundreds of instances of diversion, notwithstanding that it exercises very limited oversight. 2018 GAO Report at 37; *see also* GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-83, at 28 (Sept. 2011) ("Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies."). Indeed, approximately, two-thirds of violations for diversion uncovered by HRSA audits "involved drugs distributed at contract pharmacies." 2018 GAO Report at 44.

67. HRSA, however, has repeatedly turned a blind eye to these abuses. As early as 2010, HRSA was made aware of concerns regarding the potential for abuse. *See* 75 Fed. Reg. at 10,274 (commenter noting that the guidelines proposed "d[id] not adequately describe safeguards that will combat drug diversion and duplicate discounts"). But HRSA has largely taken a hands-off approach to ensuring that contract pharmacies are providing 340B drugs only to patients of covered entities.

68. For example, HRSA previously advised covered entities to implement multiple audit and other programs to police their contract pharmacy arrangements and halt diversion and other abuses, but as HHS's Inspector General reported in 2014: "[M]ost covered entities [it studied] do not conduct all the oversight activities" HRSA recommends. *See* 2014 OIG Report at 2. The upshot is that, as the GAO concluded, HRSA "does not know the scope of the assessments [conducted by covered entities] and whether they are effective at identifying the full extent of non-compliance." 2018 GAO Report at GAO Highlights. "Given these weaknesses," the GAO

concluded, "HRSA does not have a reasonable assurance that covered entities adequately identified and addressed non-compliance with 340B Program requirements." *Id.*

69. And, although covered entities and contract pharmacies are supposed to implement plans to ensure 340B compliance, HRSA does not review the covered entity's oversight plan for the entity's contract pharmacy at the outset—indeed, it only collects the plan if an audit is conducted. *Opportunities to Improve the 340B Pricing Program: Hearings Before the H. Subcomm. on Health of the Comm. on Energy and Commerce*, 115 Cong. 37, 40 (July 11, 2018) (July 11, 2018 H. Subcomm. Hearing) (testimony of Debra Draper, Director, Health Care Team, GAO).

70. HRSA itself has disclaimed any legal authority over the financial arrangements between covered entities and contract pharmacies as embodied in the contracts between covered entities and contract pharmacies. *Id.* at 40 ("The other issue is that HRSA doesn't have legal authority over those arrangements. They discuss it as a private business matter between the covered entity and contract pharmacies and third-party administrators."). As a GAO witness summarized, HRSA has left the "method of ensuring compliance . . . up to the covered entities." *Id.* at 43. In practice, this often means a lack of oversight at all. For example, GAO found that one covered entity "reported auditing claims of five randomly selected patients quarterly when they serve 900 patients on a monthly basis." *Id.* This is important for multiple reasons. *First*, it demonstrates that HRSA does not police the detailed contractual relationships between covered entities, third-party administrators, and contract pharmacies—and thus does not know whether they actually constitute the type of principal-agent fiduciary agreements that the agency's Chief Legal Officer has said is required to trigger a manufacturer obligation to sell, distribute or ship to those agencies. *See* Advisory Opinion at 1 ("*[T]o the extent* contract pharmacies are acting as

agents of a covered entity, a drug manufacturer in the 340B program is obligated to deliver its covered drugs to those covered pharmacies ….” (emphasis added)). *Second*, as indicated, it demonstrates that HRSA does not necessarily have statutory audit authority over contract pharmacies or other third parties or authority to compel them to submit to a statutory audit by manufacturers. *See* 42 U.S.C. § 256b(a)(5)(C) (requiring only that a *covered entity* permit the government or the drug manufacturer to audit *the covered entity's* records directly pertaining to compliance with the diversion and duplicate discount prohibitions). If no direct statutory audit of contract pharmacies and other third parties is available to manufacturers, the manufacturers will have no recourse to halt fraud by those entities.

71. Even where HRSA does audit covered entities to ensure compliance and discover violations, HRSA does “not require all covered entities to provide evidence that they have taken corrective action and are in compliance with program requirements prior to closing an audit.” July 11, 2018 H. Subcomm. Hearing at 54 (Rep. H. Morgan Griffith). Indeed, even in the very limited cases where HRSA conducted re-audits [of covered entities who had compliance issues], it found repeated instances of similar noncompliance. *Id.* at 55 (GAO witness testifying that HRSA should require “more rigorous information . . . from the covered entities as to what they've done”). Again, to UT's knowledge, HRSA has never audited directly any third-party administrator or contract pharmacy to address compliance concerns under its policy. *See* 42 U.S.C. § 256b(a)(5)(C). Instead, HRSA appears to audit covered entities, and then does so poorly. Indeed, the volume of negative audit findings resulting from covered entity audits has not substantially declined over the years and remains at unacceptably high levels. *See* HRSA, Office of Pharmacy Affairs, 340B Drug Pricing Program: Program Integrity, http://www.hrsa.gov/opa/program-integrity/index.html (last reviewed May 2021) (posting HRSA's covered entity audit results by fiscal year from FY

2012 to FY 2021, with nearly 50 negative audit findings so far in FY 2021), *available at* http://www.hrsa.gov/opa/program-integrity/index.html.

72. In the fiscal year 2019 audits conducted by HRSA, HRSA officials reported to GAO that there were instances where HRSA "did not issue eligibility findings for a failure to oversee 340B Program compliance at contract pharmacies through internal audits and other measures as set forth in guidance because the 340B statute does not address contract pharmacy use." GAO, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, GAO-21-107, at 15-16 (Dec. 2020). Similarly, the agency "did not issue 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." *Id.* at 15.

D. Pharmaceutical Manufacturers Including UT Implement Policies Aimed At Curbing Contract Pharmacy Abuses

73. As indicated, neither the HRSA 1996 policy nor its 2010 contract pharmacy policy compelled manufacturers to sell or ship to such pharmacies. 61 Fed. Reg. at 43,550 (1996 guidance "create[d] no new law and create[d] no new rights or duties"); 75 Fed. Reg. at 10,273 (2010 guidance "impose[d] [no] additional burdens upon manufacturers, nor create[d] any new rights for covered entities"). Given HRSA's consistent failure to address the abuses of the 340B program, UT and five other pharmaceutical manufacturers issued varying contract pharmacy policies in their own effort to combat the rampant abuses in the program.

74. On November 13, 2020, UT notified HRSA that it would begin implementing two narrowly tailored contract pharmacy policies with the goal of stemming abuses going forward without upsetting the status quo or creating hardship for covered entities or their patients.

75. UT's first policy is directed at stemming the further growth in contract pharmacies. For orders placed by a contract pharmacy on or after November 20, 2020, UT will accept the order only if the particular contract pharmacy was used by the related covered entity to make a valid 340B purchase of a UT covered outpatient drug during the first three quarters of the 2020 calendar year (January 1 through September 30, 2020). Covered entities and contract pharmacies can check their eligibility by visiting the website UTAssist.com and selecting "Our Services" followed by "Product Distribution."

76. If a covered entity does not have a contract pharmacy that meets this requirement *and* the covered entity does not have its own on-site pharmacy, then that covered entity may contact UT to designate a single 340B contract pharmacy. UT will then accept 340B orders from that designated contract pharmacy. This exception within UT's first policy is consistent with HRSA's 1996 guidance, which envisioned that covered entities would contract with a single third-party pharmacy—a limitation that HRSA considered to be consistent with the 340B statute. *See* 61 Fed. Reg. 43,549. And UT's first policy gives covered entities far more leeway than HRSA's 1996 guidance. UT implemented this policy on November 20, 2020.

77. UT's second policy is directed at ensuring the integrity of the 340B program. Covered entities using a contract pharmacy will be required to regularly provide claims data to UT via a third-party platform, among other things, allowing UT to confirm that contract pharmacies are genuinely acting on behalf of a covered entity. This requirement has been delayed and is currently scheduled to take effect September 1, 2021.

78. These reasonable measures ameliorate the most problematic contract pharmacy aspects of the 340B program in its current form. The first requirement stops the growth of contract pharmacies while ensuring that eligible covered entities continue to receive 340B discount pricing.

And the second requirement will help ensure that participants are abiding by the 340B program's requirements and are eligible to receive 340B pricing.

E. HHS Issues And Relies Upon An Advisory Opinion Contending That The Statute Unambiguously Mandates Its Contract Pharmacy Policy

79. On December 30, 2020, HHS's General Counsel issued an "Advisory Opinion" on contract pharmacies. *See* Advisory Opinion at 1 ("Recently, certain drug manufacturers participating in the 340B Program are declining to distribute covered outpatient drugs through contract pharmacies at the ceiling price.").

80. The Advisory Opinion made several important new pronouncements and is the only logical or apparent predicate for the Violation Determination. It relied upon two assumptions: that contract pharmacies or other third parties were in fact agents of covered entities, and that the covered entities retained title at all times to the drugs dispensed. Both concepts were integral to prior HRSA guidance allowing the use of contract pharmacies. *See supra* at 21-23.

81. First, the Advisory Opinion marks the first time a government agency concluded that pharmaceutical manufacturers are "***obligated***" to transmit their drugs at the 340B discounted price to an unlimited number of contract pharmacies, so long as those contract pharmacies are "acting as agents of a covered entity." Advisory Opinion at 1; *see AstraZeneca*, 2021 WL 2458063, at *6 ("The [Advisory] Opinion is the first document in which HHS explicitly concluded that *drug manufacturers* are required *by statute* to provide 340B drugs to *multiple* contract pharmacies." (emphases in original)). The Advisory Opinion identified no evidentiary basis for concluding that any contract pharmacy is acting as an agent of a covered entity, much less that all 27,000 are. *Id*. Even if HRSA had authority to undertake this activity, this would be a gargantuan task, requiring the government to review thousands of contract pharmacy and third-party administrator agreements, to assess the application of state agency law in each circumstance, and

to make specific findings for each such contract pharmacy arrangement. The Advisory Opinion did not purport to do this, and to UT's knowledge HRSA has never attempted to do so either. And no explanation at all is offered in the Violation Determination of how any agency relationship could be substantiated. Indeed, it appears highly likely that many contract pharmacies and other third parties would disclaim the types of legal obligations to covered entities that necessarily accompany a principal-agent relationship. *See* Restatement (Second) of Agency § 1 cmt. b ("The agency relation results if, but only if, there is an understanding between the parties which . . . creates a fiduciary relation in which the fiduciary is subject to the directions of the one on whose account he acts. It is the element of continuous subjection to the will of the principal which distinguishes the agent from other fiduciaries."); *see also* HRSA, 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632, 80,633 (Dec. 14, 2020) (acknowledging that HRSA may need to "resolve [in administrative proceedings] whether a pharmacy is part of a 'covered entity'"). And it seems impossible to reconcile the concept of agency with the widespread contract pharmacy "replenishment" model, which instead appears to be a commercial arrangement not tied to any principles of agency law. Nor did HRSA purport to provide any mechanism for drug manufacturers to evaluate in advance whether any contract pharmacy is in fact the agent of a covered entity, or whether the covered entity retains title to the drugs shipped to any contract pharmacy.

82. Second, although HRSA had previously stated the 340B statute was silent as to permissible drug distribution systems, the Advisory Opinion asserted that the statute unambiguously compelled manufacturers to honor contract pharmacy arrangements through its requirement that manufacturers must "offer" covered outpatient drugs at or below the ceiling price for "purchase by" covered entities. Advisory Opinion at 2 ("It is difficult to envision a less

ambiguous phrase and no amount of linguistic gymnastics can ordain otherwise."). The Advisory Opinion claimed that a covered entity purchases and holds "title" to the 340B drugs, even though they are *delivered* to a different party, like a contract pharmacy. *See id.* at 3. According to the Advisory Opinion, this is the case regardless of whether the delivery location is "the lunar surface, low-earth orbit, or a neighborhood pharmacy." *Id.*

83. Third, in a footnote, the Advisory Opinion expressly blessed the replenishment model that is in widespread use by contract pharmacies. *Id.* at 6 n.6. The Advisory Opinion did not examine how contract pharmacies actually operate, and HRSA appears to have limited information on those operations. Nor did the Advisory Opinion explain how the replenishment model could be reconciled with the core concepts upon which the Advisory Opinion is based—"title" being held by covered entities, and contract pharmacies operating merely as "agents" of covered entities. In fact, a covered entity does not retain title to drugs shipped to a contract pharmacy under the replenishment model, where 340B drugs are dispensed by the pharmacy to non-covered-entity patients. *See AstraZeneca*, 2021 WL 2458063, at *11 n.19 ("Under the now-prevalent 'replenishment model' . . . . [t]he covered entities never physically possess the drugs.").

84. In light of HRSA's shifting positions on contract pharmacies, five pharmaceutical manufacturers are already engaged in litigation with HRSA and HHS because of HRSA's disputes with their company-specific policies. *See Eli Lilly & Co. v. Becerra*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind.); *AstraZeneca Pharms. v. Becerra*, No. 1:21-cv-00027-LPS (D. Del.); *Sanofi-Aventis U.S., LLC v. U.S. Dep't of HHS*, No. 3:21-cv-00634-FLW-LHG (D.N.J.); *Novo Nordisk Inc. v. U.S. Dep't of HHS*, 3:21-cv-00806-FLW-LHG (D.N.J.); *Novartis Pharms. Corp. v. Espinosa*, 1:21-cv-01479-DLF (D.D.C.).

85. To date, one of those courts has substantively addressed claims regarding the Advisory Opinion. It found that the Advisory Opinion is "legally flawed" because it wrongly concluded the agency's contract pharmacy framework was mandated by the statute's unambiguous text. *AstraZeneca*, 2021 WL 2458063, at *8. Although that court indicated in *dicta* that HRSA may be able to reach a "*permissible*" interpretation requiring shipment to contract pharmacies because the statute is silent on that issue, *id.* at *9, *11, that logical leap is foreclosed under D.C. Circuit case law: Congressional silence does not equal ambiguity that an agency can bend to its will. *See, e.g., Aid Ass'n for Lutherans v. USPS*, 321 F.3d 1166, 1174 (D.C. Cir. 2003) (rejecting as "entirely untenable under well-established case law" the argument "that the disputed regulations are permissible because the statute does not expressly foreclose the construction advanced by the agency").

86. On June 18, 2021, following issuance of the court decision concluding the Advisory Opinion was "legally flawed," *AstraZeneca*, 2021 WL 2458063, at *8, HHS withdrew the Advisory Opinion, which served as the foundation for HRSA's Violation Determination here, *see* Advisory Opinion Withdrawal at 2.

F. HHS Issues Its Determination That UT Must Eliminate Its Policies Or Else Face Civil Monetary Penalties

87. On May 17, 2021, HRSA sent its May 17 letter, stating that HRSA had determined that UT's contract pharmacy policies violated the 340B statute. *See* Letter from HRSA to UT (May 17, 2021), attached as Exhibit 2. HRSA also sent materially similar decisions to five other pharmaceutical manufacturers.

88. That letter contained HRSA's Violation Determination; it announced that HRSA "has completed its review of [UT's] policy" and concludes that UT's "actions have resulted in overcharges and are in direct violation of the 340B statute." *Id.* at 1. It noted that its conclusion

is, in part, based on "complaints" from certain unidentified "covered entities." *Id.* HRSA has never shared those complaints with UT, despite UT's requests that HRSA do so.

89. The letter did not contain any legal analysis. Instead, it reiterated the conclusion of the Advisory Opinion that UT was bound to provide covered drugs to contract pharmacies, and that nothing in the statutory requirement to provide drugs to *covered entities* was "qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs." *Id.* Thus, HRSA's determinations appeared to be the agency's implementation of the now defunct Advisory Opinion's legal analysis, which was issued by the Department's Chief Legal Officer and was binding on HRSA. *See* Statement of Organizations, Functions, and Delegations of Authority, 86 Fed. Reg. 6349, 6351 (Jan. 21, 2021) (General Counsel "[f]urnishes all legal services" at HHS, "[s]upervises all legal activities," and "[r]eviews and approves all administrative complaints and enforcement actions . . . to ensure that [they are] legally sound").

90. HRSA has never given UT notice of any other legal analysis on which it has or will rely.

91. HRSA demanded both that UT not "impose conditions on covered entities' access to 340B pricing, including the production of claims data" and that UT "immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy." *Id.* at 1-2.

92. HRSA then threatened significant financial penalties for non-compliance with its demands: "Continued failure to provide the 340B price to covered entities utilizing contract pharmacies, and the resultant charges to covered entities of more than the 340B ceiling price, may result in [civil monetary penalties]." *Id.* at 2.

93. Finally, HRSA "request[ed] that [UT] provide an update on its plan to restart selling, without restriction, 340B covered outpatient drugs at the 340B price to covered entities with contract pharmacy arrangements by June 1, 2021." *Id.*

94. On May 26, 2021, UT contacted HRSA to explain the agency appeared to misconstrue UT's policy and that HRSA seemed to take issue specifically with one, not both of UT's policies. *See* Letter from UT to HRSA at 1 (May 26, 2021), attached as Exhibit 3. In light of the significance of the Violation Determination's assertions, UT also requested an extension of the response deadline to June 18, 2021. *Id.* at 2.

95. On May 28, 2021, HRSA wrote again and restated the basis for its Violation Determination. *See* Letter from HRSA to UT (May 28, 2021), attached as Exhibit 4. HRSA clarified that it objected to both of UT's policies. *See id.* at 1. HRSA also granted an extension until June 10, 2021. *Id.* at 2. And HRSA referred multiple times to "340B contract pharmacy orders," and indicated that it believes that UT will deny such orders. But nothing in the statute requires any manufacturer to provide 340B discounts to a contract pharmacy that orders drugs.

96. On June 10, 2021, UT submitted a letter to HRSA attempting to clarify how its policies complement the purposes of the 340B program, how the policies are designed to operate, and why they are consistent with the statute. UT further explained why the Violation Determination, and the Advisory Opinion upon which it is based, misconstrues the statute and otherwise violates well-established principles of administrative law. *See* Ex. 1.

97. First, UT explained that its policies complement the 340B program because they are designed to ensure a degree of program integrity and to prevent diversion, all without preventing a single covered entity from providing discounted drugs to its patients, even, if necessary, through a contract pharmacy.

98. Second, UT explained that, even though the statute does not require pharmaceutical manufacturers to honor *any* contract pharmacy arrangements, UT's policies allow each and every covered entity to use at least one contract pharmacy, if not multiple—it is merely designed to prevent the continued proliferation of contract pharmacies and increasing program abuses going forward. And UT explained that its requirement that covered entities submit claims data is consistent with the objective of ensuring that any "agency" relationship between the covered entity and a contract pharmacy is *bona fide*.

99. Third, UT explained that it anticipated that if any covered entities had in fact complained to HRSA about UT's policies, the number of those complaints should have been vanishingly small because UT's claims data policy was not even in effect yet, and UT's policy limiting the number of contract pharmacies that covered entities could use in the future would be relevant in only a very small number 340B purchases. UT therefore requested to see what complaints, if any, HRSA was basing its Violation Determination on.

100. Fourth, UT explained that its policies are consistent with the statute and that HRSA's contrary conclusion violates normal principles of statutory interpretation and administrative law.

101. Fifth, UT explained that in all events HRSA appeared to be operating under a misconception when it determined that UT was subject to civil monetary penalties. Civil monetary penalties may be imposed only on a manufacturer who "*knowingly and intentionally*" overcharges a covered entity. 42 U.S.C. § 256b(d)(1)(B)(vi)(III) (emphasis added). UT explained that its policies should *never* result in a covered entity overcharge—much less a knowing and intentional one. That is because when UT denies a 340B contract pharmacy order under its policies, it *does not* convert the order to a commercial order—it just denies the order altogether, while still offering

the covered entity itself the 340B discount. Under these circumstances, UT cannot "overcharge" any entity, because there has been no "charge" at all. Further, if the covered entity then itself orders the drug at the 340B price, UT fills that order at the 340B price.

102. Accordingly, UT requested that HRSA assure UT "as soon as possible that [it would] withdraw [its] threat of enforcement." Ex. 1 at 12.

103. Moreover, to UT's knowledge, the one contract pharmacy that handles the highest volume of UT's 340B discounted dispensing does not in fact have a principal-agency relationship with the covered entities, and in fact receives orders from a third-party administrator that may likewise lack an agency relationship with the relevant covered entities. Even under the Chief Legal Counsel's legal interpretation of the 340B statute, a covered entity cannot trigger any obligation by UT to ship to that contract pharmacy.

104. HRSA did not reply to UT's substantive response to the Violation Determination, did not share with UT complaints it has received, and took no steps to rescind the erroneous Violation Determination or otherwise withdraw its threat of enforcement.

CLAIM I: HRSA'S VIOLATION DETERMINATION
VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT
AGENCY ACTION THAT IS NOT IN ACCORDANCE WITH LAW
Violation of 5 U.S.C. § 706; 42 U.S.C. § 256b

105. The foregoing paragraphs are incorporated by reference as if set forth in full herein.

106. The Administrative Procedure Act prohibits Defendants from acting in any way that is not in accordance with law.

107. The 340B statute requires participating manufacturers to "offer each *covered entity*" covered outpatient drugs. 42 U.S.C. § 256b(a)(1) (emphasis added). The statute sets out a comprehensive list of entities that qualify as a "covered entity." *See id.* § 256b(a)(4).

108. Contract pharmacies do not qualify under the statute as a "covered entity." *See id.*; *see also Colautti v. Franklin*, 439 U.S. 379, 392 n.10 (1979) ("As a rule, a definition which declares what a term means excludes any meaning that is not stated." (cleaned up)); *United States v. Philip Morris USA*, 566 F.3d 1095, 1115 (D.C. Cir. 2009) (similar); *AstraZeneca*, 2021 WL 2458063, at *20 ("It is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication."); *see also id.* at *10 ("Congress knows how to write statutes that cover agents and contractors, but it did not do so in the 340B statute.").

109. Congress also expressly prohibited covered entities from "resell[ing] or otherwise transfer[ring] [340B drugs] to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B).

110. When covered entities permit contract pharmacies to take possession of 340B discounted drugs, the covered entities have "resold" or "otherwise transferred" those drugs to the contract pharmacy in violation of the statute. *Id*.

111. Notwithstanding the fact that contract pharmacies do not qualify as covered entities under the statute and covered entities are statutorily barred from selling or transferring drugs other than to patients, HRSA purports to sidestep Congress's decision to limit 340B participation to enumerated covered entities simply by declaring contract pharmacies to be "agents" of covered entities.

112. This justification also fails because Congress explicitly addressed when a third-party can "represent[] the interests of . . . covered entities"—specifically, associations or organizations may represent covered entities in administrative dispute resolution proceedings before the agency. 42 U.S.C. § 256b(d)(3)(B)(vi). But pharmaceutical manufacturers are not

required to provide 340B drugs to these entities (much less to entities the statute does not contemplate and refer to at all, like contract pharmacies). *See AstraZeneca*, 2021 WL 2458063, at *10 (stating to the extent the statute addresses issue, it "militate[s] against the view set out in the [Advisory Opinion]").

113. Whereas Congress clearly distinguished between covered entities and entities acting on behalf of covered entities, HRSA's interpretation effectively conflates separate entities as all being the same "covered entity." *See Digital Realty Trust, Inc. v. Somers*, 138 S. Ct. 767, 776-77 (2018) ("When a statute includes an explicit definition, we must follow that definition, even if varies from a term's ordinary meaning."); *see also AstraZeneca*, 2021 WL 2458063, at *10.

114. Under the statute, UT is not required to supply covered outpatient drugs at a 340B price to contract pharmacies.

115. Likewise, nothing in UT's agreement with HHS requires UT to sell to, ship to, or otherwise deal with contract pharmacies (or other third-party entities).

116. HRSA's Violation Determination violates the plain language of the 340B statute by determining that UT is obligated to supply 340B discounted drugs to contract pharmacies and is otherwise unlawful and in excess of HRSA's statutory powers.

117. HRSA's Violation Determination also violates the plain language of the 340B statute by determining that UT is forbidden from requesting claims data from covered entities. The agency has not offered any interpretation of the statute—neither in the Violation Determination, the now withdrawn Advisory Opinion, nor anywhere else—that would prohibit UT from making this request.

118. HRSA's Violation Determination constitutes final agency action, as HRSA has itself admitted, for which UT has no other adequate remedy at law.

119. For the foregoing reasons, HRSA's Violation Determination, declaring UT's policy in violation of the 340B statute, violates the 340B statute and is therefore not in accordance with law.

CLAIM II: HRSA'S VIOLATION DETERMINATION VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT AGENCY ACTION THAT IS ARBITRARY, CAPRICIOUS, AN ABUSE OF DISCRETION, AND NOT IN ACCORDANCE WITH LAW Violation of 5 U.S.C. § 706; 42 U.S.C. 256b.

120. The foregoing paragraphs are incorporated by reference as if set forth in full herein.

121. The Administrative Procedure Act prohibits Defendants from acting in any way that is arbitrary and capricious, an abuse of discretion, or not in accordance with law.

122. The 340B statute requires covered entities to dispense 340B discounted drugs to the covered entities' patients *only*. 42 U.S.C. § 256b(a)(5)(B).

123. Under contract pharmacies' replenishment model, contract pharmacies dispense 340B discounted drugs from their commingled supply of drugs to patients who are *not* patients of a covered entity. *See AstraZeneca*, 2021 WL 2458063, at *11 n.19 ("At the time of dispensing, the pharmacies do not know whether the prescriptions were written by medical providers at covered entities and qualify for 340B discounts.").

124. When covered entities permit contract pharmacies that use the replenishment model to dispense drugs to patients who are *not* patients of a covered entity, the covered entity and contract pharmacy engage in statutorily prohibited diversion. *See* 42 U.S.C. § 256b(a)(5)(B).

125. HRSA's Violation Determination violates the plain language of the 340B statute by determining that UT is obligated to supply 340B discounted drugs to contract pharmacies,

including those who use the replenishment model, and is otherwise unlawful and in excess of HRSA's statutory powers.

126. HRSA's Violation Determination also violates the plain language of the 340B statute by determining that UT is forbidden from requesting claims data from covered entities as part of a portal process for receiving requests for 340B orders. The agency has failed to offer any interpretation of the statute that would prohibit UT from making this request.

127. HRSA's Violation Determination constitutes final agency action, as HRSA has itself admitted, for which UT has no other adequate remedy at law

128. For the foregoing reasons, HRSA's Violation Determination, declaring UT's policy in violation of the 340B statute, violates the 340B statute and is therefore not in accordance with law.

CLAIM III: HRSA'S VIOLATION DETERMINATION VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT AGENCY ACTION THAT IS ARBITRARY, CAPRICIOUS, AN ABUSE OF DISCRETION, AND NOT IN ACCORDANCE WITH LAW Violation of 5 U.S.C. § 706.

129. The foregoing paragraphs are incorporated by reference as if set forth in full herein.

130. The Administrative Procedure Act prohibits Defendants from acting in any way that is arbitrary and capricious, an abuse of discretion, or not in accordance with law.

131. Even if the 340B statute could be read to require manufacturers to supply 340B drugs to an unlimited number of "agents" of covered entities, HRSA's Violation Determination violates the Administrative Procedure Act in numerous respects, including (but not limited to) those described below.

132. First, under the APA, agency decisions are arbitrary and capricious if they rest on an invalid legal rationale or no rationale at all. *See Fox v. Clinton*, 684 F.3d 67, 75 (D.C. Cir. 2012) ("We will not uphold an agency adjudication where the agency's judgment . . . was neither

adequately explained in its decision nor supported by agency precedent." (quoting *Siegel v. SEC*, 592 F.3d 147, 158–64 (D.C. Cir. 2010)).

133. Both are true here. The Violation Determination rests on an invalidated legal rationale embodied in the Advisory Opinion, namely that the 340B statute unambiguously provides that manufacturers are required to provide 340B drugs to contract pharmacies. HHS has chosen to withdraw its Advisory Opinion. *See* Advisory Opinion Withdrawal. At best then, the Violation Determination now rests on an invalid and withdrawn legal rationale and must be withdrawn as well.

134. At worst, the Violation Determination rests on no rationale at all. Absent reliance on the withdrawn Advisory Opinion, the Violation Determination is void of any legal basis or analysis. Indeed, it amounts to no more than impermissible agency *ipse dixit*. *See Tripoli Rocketry Ass'n, Inc. v. Bureau of Alcohol, Tobacco, Firearms, & Explosives*, 437 F.3d 75, 77 (D.C. Cir. 2006) ("Not only must an agency's decreed result be within the scope of its lawful authority, but the process by which it reaches that result must be logical and rational.").

135. Second, even if the Court could divine some legal basis from the text of the Violation Determination itself, under the APA, an agency interpretation that a statute "unambiguous[ly]" commands a certain outcome is arbitrary and capricious if the statute is in fact ambiguous on the required outcome. *See, e.g.*, *American Lung Ass'n v. EPA*, 985 F.3d 914, 944 (D.C. Cir. 2021).

136. HRSA's Violation Determination (and the withdrawn Advisory Opinion on which it is based) purports to conclude that the 340B statute *unambiguously* requires pharmaceutical manufacturers like UT to provide 340B discounted drugs to an unlimited number of contract pharmacies.

137. As HRSA has previously conceded, however, the 340B statute is (at best) "silent as to permissible drug distribution systems." 61 Fed. Reg. at 43,549.

138. HRSA's newfound conclusion that the 340B statute unambiguously authorizes the contract pharmacy drug distribution system (including with the replenishment model) is arbitrary and capricious. *See AstraZeneca*, 2021 WL 2458063, at *8 ("[T]he [Advisory] Opinion wrongly determines that purportedly unambiguous statutory language mandates its conclusion regarding covered entities' permissible use of an unlimited number of contract pharmacies.").

139. Third, under the APA agency conclusions are arbitrary and capricious if they lack supporting factual evidence. *See Int'l Ladies' Garment Workers' Union v. Donovan*, 722 F.2d 795, 825 & n.69 (D.C. Cir. 1983).

140. The Violation Determination concludes that contract pharmacies are the agents of covered entities. That conclusion is based on an *assumption* in the now withdrawn Advisory Opinion that *some* contract pharmacies *may* be agents of covered entities.

141. On information and belief, HRSA had no evidence supporting its conclusion that contract pharmacies are agents of covered entities that UT deals with when the agency issued the Violation Determination (just as the withdrawn Advisory Opinion lacked information to establish that contract pharmacies *might* be agents under certain circumstances).

142. HRSA fails to supply any legal or factual reasoning to support its conclusion that any relevant third parties are actually "agents" of covered entities under relevant law—HRSA does not know whether they are or are not, and its policy is predicated on a staggering and unsupported leap of logic. *See* Restatement (Second) of Agency § 14J ("One who receives goods from another for resale to a third person is not thereby the other's agent in the transaction: whether he is an agent for this purpose or is himself a buyer depends upon whether the parties agree that his duty is to act

primarily for the benefit of the one delivering the goods to him or is to act primarily for his own benefit.").

143. HRSA's conclusion that contract pharmacies operate as agents of covered entities is arbitrary and capricious.

144. Fourth, the Violation Determination (and the legally flawed Advisory Opinion on which it is based) purports to conclude that covered entities retain "title" to 340B discounted drugs when contract pharmacies take stock of and dispense those drugs.

145. Neither the Violation Determination nor the Advisory Opinion, however, sets forth *any* evidence supporting HRSA's conclusion that any covered entities—much less all—retain "title" to 340B drugs when they are using contract pharmacies to hold and dispense those drugs. *See AstraZeneca*, 2021 WL 2458063, at *11 n.19 ("The covered entities never physically possess the drugs.").

146. HRSA's conclusion that covered entities retain "title" to 340B drugs under the contract pharmacy distribution model is arbitrary and capricious.

147. Fifth, under the APA, agencies must acknowledge and provide a non-arbitrary justification for why they are departing from a past policy or statutory interpretation. *See Ramaprakash v. FAA*, 346 F.3d 1121, 1124-25 (D.C. Cir. 2003) ("Agencies . . . must provide a reasonable analysis indicating that prior policies and standards are being deliberately changed, not casually ignored.").

148. HRSA concluded in 1996 that covered entities could use only *one* contract pharmacy location. And HRSA previously concluded that covered entities should dispense 340B discounted drugs to covered entity patients only upon presentation of a prescription bearing the covered entity's name or receipt of a prescription order by telephone by the covered entity.

149. HRSA's 2010 guidance eliminated these limitations, but did not purport to bind or impose any obligations on pharmaceutical manufacturers.

150. In the Violation Determination (and the Advisory Opinion on which it is based), HRSA failed to even acknowledge, must less reasonably justify, the agency's departure from these previous positions.

151. The failure of the Violation Determination (and the Advisory Opinion on which it is based) to acknowledge and reasonably justify the agency's shift in policy from the 1996 and 2010 guidance documents is arbitrary and capricious.

152. Sixth, under the APA, agencies must consider each "important aspect of the [regulatory] problem," *Motor Vehicle Mfrs. Ass'n v. State Farm*, 463 U.S. 29, 43 (1983), and must provide a reasoned explanation of how it addressed each important aspect, *see Mfrs. Ry. Co. v. Surface Transp. Bd.*, 676 F.3d 1094, 1097 (D.C. Cir. 2012) (Kavanaugh, J.) ("We must vacate" where agency "failed to reasonably explain and justify" its decision.).

153. The 340B statute itself provides that preventing "diversion" is an important aspect of any drug dispensation model under the 340B program. 42 U.S.C. § 256b(a)(5).

154. A substantial amount of publicly available evidence—including from HHS's own Inspector General and the U.S. Government Accountability Office—has demonstrated that there is a pronounced risk of diversion under the contract pharmacy distribution model.

155. UT's contract pharmacy policies are a measured response to rampant abuses in the 340B program, including undisputed findings by multiple authorities that covered entities and contract pharmacies have engaged in statutorily prohibited diversion.

156. The Violation Determination, however, (and the Advisory Opinion on which it is based) forbids UT from placing *any* "conditions" on how it offers 340B discounted drugs to covered entities, including a mere requirement that covered entities provide claims data.

157. The Violation Determination (and the Advisory Opinion on which it is based) fails entirely to grapple with the diversion problem, and in fact facilitates rampant diversion within the 340B program and prevents pharmaceutical manufacturers like UT from taking any reasonable steps to combat diversion, without providing any explanation (much less a reasoned one) for this perverse outcome.

158. The Violation Determination also fails to address the fact that neither HRSA nor apparently pharmaceutical manufacturers are statutorily authorized to audit contract pharmacies and other third parties that use undisclosed algorithms to determine which drug purchases are entitled to 340B discounts.

159. The failure of the Violation Determination (and the Advisory Opinion on which it is based) to consider and address how the agency's contract pharmacy interpretation would facilitate abuse and diversion is arbitrary and capricious.

160. Seventh, the Violation Determination threatened UT with civil monetary penalties for alleged "overcharges."

161. Under the 340B statute, however, civil monetary penalties can be imposed only for "knowing[] and intentional" overcharges. 42 U.S.C.§ 256b(d)(1)(B)(vi).

162. The Violation Determination claimed that the threat of enforcement and civil monetary penalties was based on covered entity complaints, and HRSA's analysis of the same.

163. HRSA, however, has not provided UT with those complaints or offered UT an opportunity to respond to HRSA's analysis. UT strongly doubts that any genuine evidence exists that could justify HRSA's enforcement threat.

164. When a 340B purchase order does not comply with UT's policies, UT does *not* overcharge the entity—it instead refuses to fill the order, meaning there is no "charge" at all.

165. HRSA presented no evidence that UT is overcharging covered entities, or even their contract pharmacies—much less knowingly and intentionally.

166. For the foregoing reasons, HRSA's Violation Determination is arbitrary, capricious, an abuse of discretion, and/or not in accordance with law.

REQUEST FOR RELIEF

UT respectfully requests that the Court enter judgment in its favor and grant the following relief:

1. A declaration pursuant to 28 U.S.C. § 2201 that:

   a. The 340B statute does not require pharmaceutical manufacturers to provide 340B discounted drugs to contract pharmacies;

   b. UT's contract pharmacy policies are fully compliant with the 340B statute;

   c. UT's contract pharmacy policies do not subject UT to civil monetary penalties under the 340B statute; and

   d. HRSA's Violation Determination is arbitrary, capricious, an abuse of discretion, and not in accordance with law.

2. An order vacating and setting aside HRSA's Violation Determination as unlawful.

3. Temporary, preliminary, and permanent injunctive relief barring Defendants and any entities acting in concert with them from initiating and/or pursuing any enforcement actions against UT in connection with UT's contract pharmacy policies.

4. An order awarding UT its costs and attorneys' fees pursuant to 28 U.S.C. § 2412.

5. Such other and further relief as the Court deems just and proper.

Dated: June 23, 2021

Respectfully submitted,

/s/ Philip J. Perry

Philip J. Perry (DC Bar No. 434278)
Andrew D. Prins (DC Bar No. 998490)
Ryan S. Baasch (DC Bar No. 144370)
Gregory B. in den Berken (DC Bar No. 252848)
LATHAM & WATKINS LLP
555 Eleventh Street NW
Suite 1000
Washington, D.C. 20004-1304
Phone: (202) 637-2200
Fax: (202) 637-2201
Email: philip.perry@lw.com

Attorneys for Plaintiff

EXHIBIT 1

Christopher H. Schott
Direct Dial: +1 (202) 637-2208
chris.schott@lw.com

555 Eleventh Street, N.W., Suite 1000
Washington, D.C. 20004-1304
Tel: +1.202.637.2200 Fax: +1.202.637.2201
www.lw.com

LATHAM & WATKINS LLP

FOIA-EXEMPT CONFIDENTIAL COMMERCIAL INFORMATION

June 10, 2021

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

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

Re: United Therapeutics Corporation 340B Contract Pharmacy Policies

Dear Rear Admiral Pedley:

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

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

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

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

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

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

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

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

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

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

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

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

DISCUSSION

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

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

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

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

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

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

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

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

[8] 2014 OIG Report at 2.

[9] *Id.*

[10] GAO Report Summary of Findings.

[11] *Id.*

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

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

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

[13] *See* GAO Report at 30.

[14] 2014 OIG Report at 14

[15] Vandervelde et al. at 7.

[16] *Id.*

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

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

B. UT's Policies

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

1. Policy on Multiple Contract Pharmacies

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

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

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

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

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

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

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

Because UT's policy does not prohibit any covered entity from participating in the 340B program and UT continues to offer the 340B ceiling price to covered entities, it was surprising to see HRSA's letters reference covered entity complaints. Specifically, your May 17 letter referred to "an analysis of the complaints HRSA has received from covered entities," and your May 28 Letter referred to "specific complaints from covered entities regarding their inability to purchase several United Therapeutics covered outpatient drug products at or below the 340B ceiling price through the pharmacies that dispense medications to their patients." UT was not previously privy to these complaints and has substantial doubts about them—as explained herein. We request the opportunity to review the complaints and any related analysis by the agency.

2. Policy Requiring Covered Entities to Submit Claims Data

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

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

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

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

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

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

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

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

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

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

[22] Advisory Opinion at 1.

[23] 42 U.S.C. § 256b(a)(4).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[33] 42 U.S.C. § 256(a)(5)(B).

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

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

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

D. UT Has Not Overcharged Anyone

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

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

[35] *Id.* § 256(a)(9).

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

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

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

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

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

Sincerely,

Christopher H. Schott
Partner
Latham & Watkins LLP

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

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

EXHIBIT 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

May 17, 2021

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

Dear Ms. Robson:

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

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

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

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

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

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

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

HRSA requests that United Therapeutics provide an update on its plan to restart selling, without restriction, 340B covered outpatient drugs at the 340B price to covered entities with contract pharmacy arrangements by **June 1, 2021**, to 340Bpricing@hrsa.gov.

Thank you for your commitment to the 340B Program.

Sincerely,

Diana Espinosa

Diana Espinosa
Acting Administrator

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

EXHIBIT 3

Christopher H. Schott
Direct Dial: +1 (202) 637-2208
chris.schott@lw.com

555 Eleventh Street, N.W., Suite 1000
Washington, D.C. 20004-1304
Tel: +1.202.637.2200 Fax: +1.202.637.2201
www.lw.com

LATHAM & WATKINS LLP

FOIA-EXEMPT CONFIDENTIAL COMMERCIAL INFORMATION

May 26, 2021

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

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

Re: United Therapeutics Corporation 340B Contract Pharmacy Policy

Dear Rear Admiral Pedley:

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

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

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

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

* * * * *

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

LATHAM & WATKINS LLP

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

Sincerely,

Christopher H. Schott
Partner
Latham & Watkins LLP

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

May 26, 2021

LATHAM & WATKINS LLP

Attachment A

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

* * * * *

United Therapeutics CORPORATION

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

To: 340B Covered Entity

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

Date: May 11, 2021

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

Dear 340B Covered Entity:

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

Orders placed on or after November 20, 2020:

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

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

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

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

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

EXHIBIT 4

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

May 28, 2021

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

Dear Ms. Robson:

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

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

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

As outlined in the May 17, 2021, letter, HRSA requests that United Therapeutics provide an update on its plan to restart selling, without restriction, 340B covered outpatient drugs at the 340B price to covered entities with contract pharmacy arrangements by **June 10, 2021**, to 340Bpricing@hrsa.gov. Please also include in your response the restrictions outlined above.

Sincerely,

Krista M. Pedley

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

CIVIL COVER SHEET

JS-44 (Rev. 11/2020 DC)

I. (a) PLAINTIFFS
UNITED THERAPEUTICS CORPORATION

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF 88888
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANTS
DIANA ESPINOSA, U.S. HEALTH RESOURCES AND SERVICES ADMINISTRATION, XAVIER BECERRA, and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)
Philip J. Perry, Andrew D. Prins,
Ryan S. Baasch, Gregory in den Berken
LATHAM & WATKINS LLP
555 ELEVENTH STREET NW,SUITE 1000
WASHINGTON, DC 20004; (202) 637-2200

ATTORNEYS (IF KNOWN)

II. BASIS OF JURISDICTION
(PLACE AN x IN ONE BOX ONLY)

- ○ 1 U.S. Government Plaintiff
- ○ 3 Federal Question (U.S. Government Not a Party)
- ◉ 2 U.S. Government Defendant
- ○ 4 Diversity (Indicate Citizenship of Parties in item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) **FOR DIVERSITY CASES ONLY!**

	PTF	DFT		PTF	DFT
Citizen of this State	○ 1	○ 1	Incorporated or Principal Place of Business in This State	○ 4	○ 4
Citizen of Another State	○ 2	○ 2	Incorporated and Principal Place of Business in Another State	○ 5	○ 5
Citizen or Subject of a Foreign Country	○ 3	○ 3	Foreign Nation	○ 6	○ 6

IV. CASE ASSIGNMENT AND NATURE OF SUIT

(Place an X in one category, A-N, that best represents your Cause of Action and one in a corresponding Nature of Suit)

○ A. *Antitrust*
- ☐ 410 Antitrust

○ B. *Personal Injury/ Malpractice*
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Medical Malpractice
- ☐ 365 Product Liability
- ☐ 367 Health Care/Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Product Liability

○ C. *Administrative Agency Review*
- ☐ 151 Medicare Act

Social Security
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

Other Statutes
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 890 Other Statutory Actions (If Administrative Agency is Involved)

○ D. *Temporary Restraining Order/Preliminary Injunction*

Any nature of suit from any category may be selected for this category of case assignment.

(If Antitrust, then A governs)

○ E. *General Civil (Other)* OR **○ F. *Pro Se General Civil***

Real Property
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent, Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

Personal Property
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

Bankruptcy
- ☐ 422 Appeal 27 USC 158
- ☐ 423 Withdrawal 28 USC 157

Prisoner Petitions
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Conditions
- ☐ 560 Civil Detainee – Conditions of Confinement

Property Rights
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent – Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016 (DTSA)

Federal Tax Suits
- ☐ 870 Taxes (US plaintiff or defendant)
- ☐ 871 IRS-Third Party 26 USC 7609

Forfeiture/Penalty
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

Other Statutes
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 430 Banks & Banking
- ☐ 450 Commerce/ICC Rates/etc
- ☐ 460 Deportation
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions
- ☐ 470 Racketeer Influenced & Corrupt Organization
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act (TCPA)
- ☐ 490 Cable/Satellite TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 896 Arbitration
- ☒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes
- ☐ 890 Other Statutory Actions (if not administrative agency review or Privacy Act)

○ **G. *Habeas Corpus/ 2255*** ☐ 530 Habeas Corpus – General ☐ 510 Motion/Vacate Sentence ☐ 463 Habeas Corpus – Alien Detainee	○ **H. *Employment Discrimination*** ☐ 442 Civil Rights – Employment (criteria: race, gender/sex, national origin, discrimination, disability, age, religion, retaliation) *(If pro se, select this deck)*	○ **I. *FOIA/Privacy Act*** ☐ 895 Freedom of Information Act ☐ 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	○ **J. *Student Loan*** ☐ 152 Recovery of Defaulted Student Loan (excluding veterans)
○ **K. *Labor/ERISA (non-employment)*** ☐ 710 Fair Labor Standards Act ☐ 720 Labor/Mgmt. Relations ☐ 740 Labor Railway Act ☐ 751 Family and Medical Leave Act ☐ 790 Other Labor Litigation ☐ 791 Empl. Ret. Inc. Security Act	○ **L. *Other Civil Rights (non-employment)*** ☐ 441 Voting (if not Voting Rights Act) ☐ 443 Housing/Accommodations ☐ 440 Other Civil Rights ☐ 445 Americans w/Disabilities – Employment ☐ 446 Americans w/Disabilities – Other ☐ 448 Education	○ **M. *Contract*** ☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholder's Suits ☐ 190 Other Contracts ☐ 195 Contract Product Liability ☐ 196 Franchise	○ **N. *Three-Judge Court*** ☐ 441 Civil Rights – Voting (if Voting Rights Act)

V. ORIGIN

◉ 1 Original Proceeding ○ 2 Removed from State Court ○ 3 Remanded from Appellate Court ○ 4 Reinstated or Reopened ○ 5 Transferred from another district (specify) ○ 6 Multi-district Litigation ○ 7 Appeal to District Judge from Mag. Judge ○ 8 Multi-district Litigation – Direct File

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)

5 U.S.C. §§ 701-706

VII. REQUESTED IN COMPLAINT ☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23 **DEMAND $** **JURY DEMAND:** Check YES only if demanded in complaint **YES** ☐ **NO** ☒

VIII. RELATED CASE(S) IF ANY (See instruction) **YES** ☒ **NO** ☐ If yes, please complete related case form

DATE: June 23, 2021 **SIGNATURE OF ATTORNEY OF RECORD** /s/ Philip J. Perry

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44
Authority for Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and services of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil cover sheet. These tips coincide with the Roman Numerals on the cover sheet.

I. COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence: Use 11001 to indicate plaintiff if resident of Washington, DC, 88888 if plaintiff is resident of United States but not Washington, DC, and 99999 if plaintiff is outside the United States.

III. CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.

IV. CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint. You may select only one category. You must also select one corresponding nature of suit found under the category of the case.

VI. CAUSE OF ACTION: Cite the U.S. Civil Statute under which you are filing and write a brief statement of the primary cause.

VIII. RELATED CASE(S), IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

UNITED THERAPEUTICS CORPORATION

Plaintiff(s)

v.

DIANA ESPINOSA et al.

Defendant(s)

Civil Action No. 1:21-cv-1686

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Diana Espinosa
Acting Administrator of U.S. Health Resources and Services Administrator
5600 Fishers Lane
Rockville, MD 20852

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Philip J. Perry
LATHAM & WATKINS LLP
555 Eleventh Street NW
Suite 100
Washington, DC 20004

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:21-cv-1686

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

UNITED THERAPEUTICS CORPORATION

Plaintiff(s)

v.

DIANA ESPINOSA et al.

Defendant(s)

Civil Action No. 1:21-cv-1686

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* U.S. Health Resources and Services Administrator
5600 Fishers Lane
Rockville, MD 20852

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Philip J. Perry
LATHAM & WATKINS LLP
555 Eleventh Street NW
Suite 100
Washington, DC 20004

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:21-cv-1686

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❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

UNITED THERAPEUTICS CORPORATION

Plaintiff(s)

v.

DIANA ESPINOSA et al.

Defendant(s)

Civil Action No. 1:21-cv-1686

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Xavier Becerra
Secretary of U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Philip J. Perry
LATHAM & WATKINS LLP
555 Eleventh Street NW
Suite 100
Washington, DC 20004

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:21-cv-1686

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

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❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

UNITED THERAPEUTICS CORPORATION

Plaintiff(s)

v.

DIANA ESPINOSA et al.

Defendant(s)

Civil Action No. 1:21-cv-1686

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Philip J. Perry
LATHAM & WATKINS LLP
555 Eleventh Street NW
Suite 100
Washington, DC 20004

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:21-cv-1686

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

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❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

UNITED THERAPEUTICS CORPORATION

Plaintiff(s)

v.

DIANA ESPINOSA et al.

Defendant(s)

Civil Action No. 1:21-cv-1686

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Office of the U.S. Attorney for the District of Columbia
ATTN: Civil Process Clerk
555 Fourth Street, N.W.
Washingtone, D.C. 20530

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Philip J. Perry
LATHAM & WATKINS LLP
555 Eleventh Street NW
Suite 100
Washington, DC 20004

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

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❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

UNITED THERAPEUTICS CORPORATION

Plaintiff(s)

v.

DIANA ESPINOSA et al.

Defendant(s)

Civil Action No. 1:21-cv-1686

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* United States Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Philip J. Perry
LATHAM & WATKINS LLP
555 Eleventh Street NW
Suite 100
Washington, DC 20004

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

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❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: