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

---

[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