Nos. 21-3167, 21-3379, 21-3168 & 21-3380

In the United States Court of Appeals for the Third Circuit

SANOFI-AVENTIS U.S. LLC,
Plaintiff-Appellant,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,
Defendants-Appellees.

NOVO NORDISK INC.,
Plaintiff-Appellant,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,
Defendants-Appellees.

On Appeal from the United States District Court
for the District of New Jersey
Nos. 3:21-cv-634 & 3:21-cv-806 (Hon. Freda L. Wolfson)

BRIEF FOR ASTRAZENECA PHARMACEUTICALS LP AS AMICUS CURIAE IN SUPPORT OF APPELLANTS

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CORPORATE DISCLOSURE STATEMENT

AstraZeneca Pharmaceuticals LP, a limited partnership organized under the laws of the State of Delaware, is a wholly owned subsidiary of AstraZeneca plc, which is a publicly traded company organized under the laws of England and Wales. No other publicly held company owns 10% or more of the voting interest in AstraZeneca Pharmaceuticals LP.

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INTEREST OF AMICUS CURIAE

Amicus curiae AstraZeneca Pharmaceuticals LP submits this brief in support of Plaintiff-Appellants Sanofi-Aventis U.S., LLC and Novo Nordisk Inc.*

1. A proud participant in the 340B program, AstraZeneca has provided billions of dollars in discounts to program beneficiaries. Like several manufacturers, including Sanofi and Novo, AstraZeneca has recently modified its policy regarding contract pharmacy arrangements to address growing problems with the program. *See, e.g.*, Sanofi Br. at 2. In August 2020, AstraZeneca announced to covered entities that, effective October 1, 2020, AstraZeneca would "only … process 340B pricing through a single Contract Pharmacy site for those Covered Entities that do not maintain their own on-site dispensing pharmacy." *AstraZeneca v. Becerra*, No. 1:21-cv-27 (D. Del. July 9, 2021), ECF No. 86-1 at 20.

Under AstraZeneca's policy, all covered entities may obtain 340B-discounted drugs from AstraZeneca without limit. If a covered entity

* All parties have consented to this filing. *See* Fed. R. App. P. 29(a)(2). No counsel for any party authored this brief in whole or in part; and no entity or person, aside from amicus curiae and its counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

maintains its own on-site pharmacy, AstraZeneca will deliver its products to that pharmacy. AstraZeneca treats any pharmacy registered at the covered entity's address as an "on-site" pharmacy, regardless who actually owns or operates the pharmacy. For any covered entity that does not have an on-site pharmacy, AstraZeneca recognizes one contract pharmacy designated by the covered entity and will deliver 340B-discounted drugs to that pharmacy. *Id.*

Since October 2020, almost 2700 covered entities that lack an on-site pharmacy have registered a contract pharmacy to which AstraZeneca continues to deliver 340B-discounted drugs. AstraZeneca is committed to working with all covered entities to ensure that every patient can obtain needed medicines at prices they can afford.

2. Much like Sanofi and Novo, AstraZeneca has been embroiled in a dispute with the Department of Health and Human Services (HHS) and its sub-agency, the Health Resources & Services Administration (HRSA), about the lawfulness of its new contract pharmacy policy. Because HHS and HRSA lack substantive rulemaking authority under Section 340B, *see PhRMA v. HHS*, 43 F. Supp. 3d 28, 47 (D.D.C. 2014); *PhRMA v. HHS*, 138 F. Supp. 3d 31, 36 (D.D.C. 2015), they can only enforce obligations that are contained in the statute itself. At the heart of the dispute thus lies a legal disagreement

about the statute's meaning: What obligation, if any, does Section 340B impose on manufacturers with respect to drugs sold by contract pharmacies?

Judge Leonard P. Stark of the U.S. District Court for the District of Delaware has already considered that question in the context of AstraZeneca's contract pharmacy policy—and has answered it, twice. In a pair of well-reasoned decisions, Judge Stark held that the text of the 340B Statute imposes no such obligation. *See AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47 (D. Del. 2021) (*AstraZeneca I*); *AstraZeneca Pharms. LP v. Becerra*, 2022 WL 484587 (D. Del. Feb. 16, 2022) (*AstraZeneca II*). Judge Stark explained that Section 340B requires manufacturers to sell statutorily discounted drugs *to covered entities*, not to make them available for sale *by contract pharmacies*. He accordingly rejected the government's attempts to enforce against AstraZeneca a purported statutory command "to deliver 340B drugs to an unlimited number of contract pharmacies." *AstraZeneca I*, 543 F. Supp. 3d at 61.

The government has signaled its intent to appeal its losses in the Delaware court, *see AstraZeneca v. Becerra*, No. 1:21-cv-27 (D. Del. Feb. 23, 2022), ECF No. 114 at 8, but it has not yet done so. Because briefing in these consolidated cases is already advanced, the Court's decision here could bear

upon whether the agency can take further action against AstraZeneca regarding its contract pharmacy policy. AstraZeneca therefore submits this brief to explain why the 340B Statute is best read as not requiring manufacturers to deliver discounted drugs (or otherwise make them available) to contract pharmacies—much less to an *unlimited* number of contract pharmacies. If Judge Stark's decision is appealed, then AstraZeneca would also present its arguments in that context as well.

SUMMARY OF ARGUMENT

Unlike pharmaceutical manufacturers, HHS and HRSA are creatures of statute that "literally ha[ve] no power to act … unless and until Congress confers power upon [them]." *City of Philadelphia v. Att'y Gen.*, 916 F.3d 276, 284 (3d Cir. 2019). As Judge Stark correctly recognized (twice), an obligation to make 340B-discounted drugs available to contract pharmacies is not "contained in the [340B] statute." *AstraZeneca I*, 543 F. Supp. 3d at 61. That silence means the agencies have no authority to sanction manufacturers for failing to deliver 340B-discounted drugs to unlimited contract pharmacies.

A. The key statutory language requires manufacturers to "offer" discounted drugs to the fifteen categories of healthcare providers defined as covered entities. A manufacturer complies with this so-called "must-offer"

requirement by making its drugs available for sale at discounted prices to the covered entities themselves. If Congress wanted manufacturers to deliver discounted drugs (or otherwise make them available) to contract pharmacies as well, it would have said so—rather than leaving such a dramatic expansion of the 340B program to guesswork.

B. Other textual clues reinforce that the 340B Statute's silence on contract pharmacies was deliberate. The must-offer provision does not mention contract or agency arrangements, even though other parts of Section 340B do. Indeed, another provision of the Veterans Health Care Act, which created the 340B program, dealt *specifically* with contract pharmacy purchases.

The current contract pharmacy system is inconsistent with the statutory prohibition on "diversion," which forbids a covered entity from selling or transferring drugs to anyone who is not a patient of the covered entity. Under the system as it works today, diversion occurs twice: first, when the contract pharmacy takes title to the drugs from the covered entity and assimilates the drugs into its own inventory; and second, when the drugs are sold to any customer who walks into the pharmacy, even if he is not a patient of the covered entity. Recognizing this problem, HRSA's 1996 and 2010 guidance

required covered entities to maintain title to the drugs even when in the physical custody of a contract pharmacy. But the current system violates that requirement.

C. Legislative history further confirms that Congress did not intend to require delivery of 340B-discounted drugs to contract pharmacies. The Veterans Health Care Act was enacted to make low-cost medications available to the Department of Veterans Affairs and covered entities, to help them better serve their indigent clientele. Congress never intended to facilitate the re-sale of medications at higher prices for the purpose of generating arbitrage revenue, which is how the current contract pharmacy system works. And Congress specifically considered statutory language that would have expressly permitted covered entities to use *on-site* contract pharmacies. But even that was a step too far, and Congress omitted *all* mention of contract pharmacies.

D. Throughout the 340B litigation, HHS and HRSA have advanced a number of additional arguments, none of which has merit. They have noted that the statute requires the HHS Secretary to ensure that manufacturers are appropriately paid for drugs "purchased by" a covered entity. But that language imposes obligations on the Secretary, not on manufacturers; and it

is just as silent as the must-offer provision regarding contract pharmacies. HHS and HRSA have also relied on a presumption that covered entities and contract pharmacies have a principal-agent relationship. But they never substantiated that argument factually, and ultimately they abandoned it.

ARGUMENT

THE 340B STATUTE DOES NOT REQUIRE MANUFACTURERS TO PROVIDE DISCOUNTS FOR DRUGS DELIVERED TO CONTRACT PHARMACIES

As a condition of participating in Medicaid, a pharmaceutical manufacturer must enter into an agreement with the HHS Secretary that "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1). The central obligation imposed by this provision—known as Section 340B's "must-offer" requirement—is that manufacturers must "offer each covered entity covered outpatient drugs" at discounted prices. AstraZeneca's policy does so.

A. The "Must-Offer" Provision Requires Manufacturers to Offer 340B Drugs to Covered Entities Only

The word "offer" is not statutorily defined, but its ordinary meaning is to make available, or "presenting" for acceptance or rejection. *Offer*, Black's

Law Dictionary (11th ed. 2019). In specifying to whom the offer must be made, the statute enumerates fifteen types of healthcare providers that qualify as "covered entities" and thus are entitled to receive discounts on covered outpatient drugs. 42 U.S.C. § 256b(a)(4)(A)-(*O*) (defining what "the term 'covered entity' means"). In combination, these provisions mean that a manufacturer must make its drugs available to those enumerated entities for purchase at statutorily discounted prices.

AstraZeneca's contract pharmacy policy undoubtedly does so: AstraZeneca makes its products available for purchase by a covered entity—in any amount, without limitation—simply by virtue of being a covered entity. But the must-offer provision does not compel manufacturers to deliver 340B-discounted drugs (or otherwise make them available) to *any* contract pharmacies, much less to an *unlimited* number of contract pharmacies. As Judge Stark noted, "[p]harmacies are not mentioned anywhere in the statutory text—neither in § 256b(a)(1), which (as both parties agree) contains the relevant command, nor in § 256b(a)(4), which provides the definition of 'covered entity.'" *AstraZeneca I*, 543 F. Supp. 3d at 59; *see* JA_ [Op.78] (recognizing that Section 340B is "silent" regarding "what role (if any) contract pharmacies play" in the 340B program).

Section 340B's failure to mention contract pharmacies is particularly noteworthy given the precision with which the statute specifies the entities eligible for preferential pricing under the must-offer requirement. Not only does the statute define in strict terms what "the term 'covered entity' means," 42 U.S.C. § 256b(a)(4), but it also draws fine-grained distinctions *within* those fifteen categories: Where the covered entity "is a distinct part of a hospital, the hospital shall not be considered a covered entity." *Id.* § 256b(a)(6). As Judge Stark put it, "[i]t is hard to believe that Congress enumerated 15 types of covered entities with [such] a high degree of precision and intended to include contract pharmacies as a 16th option by implication." *AstraZeneca I*, 543 F. Supp. 3d at 60; *see AstraZeneca II*, 2022 WL 484587, at *6.

B. Other Features of Section 340B Confirm that It Does Not Require Manufacturers to Facilitate Delivery to Contract Pharmacies

Giving the must-offer provision its plain meaning suffices to answer the relevant dispute. But several additional features of Section 340B, when the statute is read as a whole, reinforce this reading.

First, Congress easily could have required manufacturers to make 340B-discounted drugs available to "each covered entity *or pharmacies operating under an agency or contract relationship with a covered entity*,"

but it did not do so. That absence is telling: When Congress intends to include agents within the scope of federal law, it does so expressly. *See, e.g.*, 42 U.S.C. § 1320a-7b(b)(3)(C) (safe harbor for purchases made through "person authorized to act as a purchasing agent for" healthcare provider). Indeed, the 340B Statute itself carefully distinguishes in other respects between a covered entity and its agents, *see id.* § 256b(d)(3)(B)(vi) (authorizing claims asserted "on behalf of covered entities by associations or organizations representing the interests of … covered entities"), and prescribes rules for outside businesses affiliated with a covered entity, *see id.* § 256b(d)(2)(B)(iv) (describing an identification system for a covered entity's "distributors"). Yet Congress limited the must-offer provision only to covered entities.

The considered nature of that choice becomes even clearer in the particular statutory context. Congress enacted the 340B program as part of the Veterans Health Care Act of 1992 (VHCA), Pub. L. 102-585, 106 Stat. 4943. Elsewhere in the VHCA, Congress dealt *specifically* with contract arrangements: Congress prescribed special treatment for discounted drugs purchased by a federal agency but "delivered through … a commercial entity operating under contract with such agency." VHCA § 603(a)(1), 106 Stat. at 4971, 4974 (codified at 38 U.S.C. § 8126(h)(3)(A)(ii)). As Judge Stark explained,

this provision shows that "Congress knows how to write statutes that cover agents and contractors, but it did not do so in the 340B statute." *AstraZeneca I*, 543 F. Supp. 3d at 60.

Second, the current contract pharmacy system is inconsistent with Section 340B's prohibition on drug "diversion." In order to ensure that discounts are made available only to covered entities, the statute commands that "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). Congress has identified this provision, which prohibits the so-called "diversion" of 340B drugs, as the key to statutory "compliance by covered entities." *Id.* § 256b(d)(2)(A) (citing "requirements specified under subsection (a)(5)"). When a covered entity acquires drugs for dispensing by its *in-house* pharmacy, compliance with the anti-diversion provision is straightforward: It is easy to ensure that a patient who acquires drugs at the covered entity's own pharmacy is a "patient of the entity."

Because of the complex system that has developed for 340B drugs dispensed at contract pharmacies, however, diversion is not just likely—it is inherent. As Judge Stark explained:

> Under the now-prevalent "replenishment model," pharmaceutical manufacturers ship prescription drugs to pharmacies for

> dispensing to all patients. 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. After 340B eligibility is later determined (typically using an algorithm), the manufacturers process chargebacks to account for the 340B drugs' discounted prices. The covered entities never physically possess the drugs.

AstraZeneca I, 543 F. Supp. 3d at 61 n.19.

Covered entities thus have only limited involvement when 340B purchases are made under the replenishment model. As the Director of HRSA's Office of Pharmacy Affairs explained in a declaration filed below, when drugs are ordered for delivery to a contract pharmacy, the covered entity does not maintain title, control, or ownership. Instead, the drug is "shipped to the contract pharmacy, where it is placed on the shelf, [and] becomes 'neutral inventory'"—that is, the drug is assimilated into *the pharmacy's* inventory, indistinguishable from any other drugs on its shelves. *Sanofi-Aventis U.S., LLC v. HHS*, No. 3:21-cv-634 (D.N.J. June 24, 2021), ECF No. 93-2 ¶ 11. At that point, the drug "may be dispensed to *any* subsequent patient," whether or not a patient of the covered entity. *Id.* (emphasis added); *see id.* ¶ 5 ("[T]he dispensed drug comes from the contract pharmacy's own inventory.").

As a result, the contract pharmacy process entails precisely the sort of diversion that the 340B Statute forbids. The drug is "transfer[red]" to "a person who is not a patient of the [covered] entity," 42 U.S.C. § 256b(a)(5)(B)—in fact, it happens twice. The first transfer is to the contract pharmacy, which acquires title and control of the drug and puts the drug into "the contract pharmacy's own inventory." The second transfer is to the pharmacy's customer, who may or may not be a patient of the covered entity ("any subsequent patient"). Unlike in-house pharmacies, where customers are almost always patients of the covered entity, a contract pharmacy by its very nature serves the general community, selling drugs to customers with prescriptions from any provider. As a result, medication that was purchased using a 340B discount may well end up in the hands of someone other than "a patient of the entity," in direct contravention of Congress's command.

In its 340B litigation, the government has argued that reading the statutory prohibition on diversion literally would outlaw practices that have prevailed since early in the 340B program: Some covered entities have sold through a single contract pharmacy since HRSA authorized their use in its 1996 Guidance, *see Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services*, 61 Fed. Reg. 43,549 (Aug. 23, 1996).

As a result, the government has argued, "to adopt [a literal] reading of the statutory prohibition on diver[sion], one would have to accept that the 340B program in that instance would have been operating in a fundamentally unlawful manner for nearly three decades." *United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-1686 (D.D.C. Oct. 25, 2021), ECF No. 27 at 47.

The government's argument simply misconstrues the anti-diversion provision—including the way that HRSA itself originally read it. The guidance HRSA issued in 1996 was "designed to facilitate program participation for those eligible covered entities that d[id] not have access to appropriate 'in-house' pharmacy services." 61 Fed. Reg. at 43,555. HRSA determined that such a covered entity should "ha[ve] the option of individually contracting for pharmacy services with the pharmacy of its choice," subject to a "limitation of one pharmacy contractor per entity." *Id.*; *see id.* ("only one site [may be] used for the contracted services"). At the same time, however, HRSA explained that safeguards were necessary to ensure "compliance with … the 340B prohibition against drug diversion"—most notably, that the covered entity was required to "retain[] title" to the 340B drugs until they were sold to a patient. *Id.* at 43,553. Even if the medication sat on the pharmacy's shelf, therefore, it would still belong to the covered entity, which could then "retain[] responsibility" for

setting its price and ensuring that it was not sold "to an individual who is not a patient of the covered entity." *Id.*

In 2010, HRSA issued guidance purporting to authorize covered entities to enter into "multiple" contract pharmacy arrangements. *Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services*, 75 Fed. Reg. 10,272, 10,272-73 (Mar. 5, 2010). To "[e]nsure against illegal diversion," HRSA again insisted that a covered entity must "maintain title to the drug." *Id.* at 10,277; *see id.* (describing title-maintenance as an "essential element[]" of "contract pharmacy arrangements"). And HRSA also reemphasized that the drugs could not be dispensed "to an individual who is not a patient of the covered entity." *Id.* at 10,278.

HRSA's 1996 and 2010 Guidance were thus based on a literal reading of Section 340B's prohibition on diversion. Both documents stressed that, although a contract pharmacy could take physical custody of the drugs, the covered entity still [1] must "maintain title," and [2] must ensure the drugs are dispensed to "a patient of the covered entity." That way, no unlawful transfer—to the contract pharmacy or to a non-patient—would occur. Yet, as the Director of HRSA's Office of Pharmacy Affairs explained, the modern replenishment system violates both of those requirements: 340B drugs

become part of "the contract pharmacy's *own* inventory," and the drugs "may be dispensed to *any* subsequent patient." *Sanofi*, No. 3:21-cv-634 (D.N.J. June 24, 2021), ECF No. 93-2 ¶¶ 5, 11 (emphasis added). Giving a literal reading to the prohibition on diversion would not mean that the 340B program was "operating in a fundamentally unlawful manner for nearly three decades." *United Therapeutics*, No. 1:21-cv-1686 (D.D.C. Oct. 25, 2021), ECF No. 27 at 47. But the replenishment system does indeed operate unlawfully now.

C. The 340B Statute's Legislative History Does Not Support Discounts for Contract Pharmacy Sales

Resort to extra-textual sources is unnecessary here, given the statute's clarity. But if the Court deems it necessary to consult legislative history "as a last resort," *In re Trump Ent. Resorts*, 810 F.3d 161, 168 (3d Cir. 2016), that history only further reinforces the text.

1. "The purpose of H.R. 2890," the bill that became the VHCA, "[wa]s to enable the Department of Veterans Affairs and certain Federally-funded clinics to obtain lower prices on the drugs that they provide to their patients." H.R. Rep. No. 102-384, pt. 2, at 7 (1992). As the accompanying House Report explained, Medicaid requires manufacturers to provide rebates based on a drug's "best price" (*i.e.*, the lowest price offered to any other commercial purchaser). *See id.* But in so doing, it creates an unintended "disincentive" for

manufacturers to offer drugs at a discount to needy purchasers. *Id.* at 9-10. In particular, Congress was concerned about rising "[p]rices paid for outpatient drugs by the DVA [*i.e.*, the Department of Veterans Affairs], and some Federally-funded clinics and public hospitals"—that is, their rising out-of-pocket expenses. *Id.* at 11. Congress accordingly gave *both* groups (the Department of Veterans Affairs and covered entities) access to "price reductions … at least as great as those which Medicaid receives under the rebate program." *Id.* at 12.

This history supports giving the must-offer provision its plain meaning. Congress enacted the VHCA to give the Department of Veterans Affairs and covered entities access to "price reductions." *Id.* The must-offer provision furthers that goal, by ensuring that covered entities can purchase drugs from manufacturers at statutorily discounted prices. But nothing in the legislative history suggests that Congress intended to facilitate—or even contemplated the possibility of—delivery of 340B-discounted drugs to contract pharmacies.

2. The government has argued that "Congress designed the [340B] program to allow covered entities to generate revenue 'to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'" *Sanofi*, No. 3:21-cv-634 (D.N.J.

June 16, 2021), ECF No. 89 at 6 n.4 (quoting H.R. Rep. No. 102-384, pt. 2, at 12). Under the contract pharmacy system, covered entities direct manufacturers to transfer 340B-discounted drugs to contract pharmacies; the pharmacies then resell those same drugs at higher prices to insured patients. The spread between the 340B price and "payments by private insurance" is treated as "revenue," which is divvied up between the covered entity and the contract pharmacy (among others). *Id.* The government has claimed that Congress always intended the 340B program to serve this revenue-generating function, so that "covered entities [can] reinvest" their share of the revenue "in patient care and services." *Id.*

The legislative history does not support this claim. The key House Report never once mentions that covered entities might resell 340B-discounted drugs at higher prices to patients and their insurers—much less does the Report contemplate that covered entities would fund themselves through generating this arbitrage revenue. Indeed, Congress gave the Department of Veterans Affairs price reductions that were comparable to those it gave to covered entities; Congress could hardly have intended for the Department to turn around and resell those discounted drugs at higher prices to its veteran clientele in order to generate revenue.

The government's argument is based solely on a half-sentence ("to stretch Federal resources as far as possible") that appears six pages into the House Report. But even that sentence, when read in full, tells a far different story: "*In giving these 'covered entities' access to price reductions* the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12 (emphasis added). The idea was to enable covered entities to acquire drugs cheaply for their poor and uninsured patients, not to generate arbitrage revenue from reselling the drugs at higher prices. Indeed, the immediately prior sentence emphasized that "'[c]overed entities' receiving these price reductions would be prohibited … from reselling or transferring the drugs to individuals other than their patients." *Id.* Yet the resale of 340B drugs to pharmacy customers with insurance—who in many cases are *not* covered entity patients—is precisely how the current contract pharmacy system generates most of its revenue.

3. Other legislative history reaffirms that the 340B program was not intended to require manufacturers to make discounted drugs available for dispensing by contract pharmacies. Congress considered expressly requiring manufacturers to provide discounts for drugs "purchased *and dispensed by,*

or under a contract entered into for on-site pharmacy services with," a covered entity. S. Rep. No. 102-259 at 2 (1992) (quoting S. 1729, 102d Cong. § 1 (1992)) (emphasis added). Yet, as Judge Stark explained, "Congress chose not to include pharmacy services in the version of the bill that it ultimately passed," and it deleted the italicized language. *AstraZeneca I*, 543 F. Supp. 3d at 60; *see AstraZeneca II*, 2022 WL 484587, at *6. Congress's decision not to authorize discounts for drugs provided through "on-site [contract] pharmacy services" shows that the 340B Statute's failure to mention *off-site* contract pharmacies—a far greater leap—was no mere oversight.

In the district court, the government attempted to draw an inference from Congress's omission from the final bill of the phrases "'and dispensed by'" and "'on-site,'" arguing that these omissions somehow prove Congress wanted to "remove any restriction on how covered entities dispense medications." *Sanofi*, No. 3:21-cv-634 (D.N.J. June 24, 2021), ECF No. 93 at 15. But as Judge Stark explained, "the government's reading focuses too much on selected words in the omitted phrase rather than on the omission of the entire phrase." *AstraZeneca II*, 2022 WL 484587, at *6 n.9. "[O]nce Congress had dropped the (far longer and more specific) contract pharmacy language—thereby limiting 340B discounts to sales made to covered entities

themselves—there was no need to specify that the covered entity who 'purchased' the drug also 'dispensed' it." *Id.* (citation omitted).

D. The Government's Other Arguments Are Unpersuasive

Throughout its 340B litigation, the government has offered a variety of additional textual arguments designed to show that the statute requires manufacturers to provide discounts for contract pharmacy sales. Some of these arguments were reflected in the "contemporaneous explanations" given by the agency at the time of its decision-making; others were "justifications belatedly advanced by advocates." *DHS v. Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1909 (2020). Judge Stark properly did not accept any of these arguments.

1. In a since-withdrawn Advisory Opinion issued by its General Counsel to address contract pharmacy sales under the 340B program, HHS located manufacturers' supposed obligation in the 340B Statute's first sentence:

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

42 U.S.C. § 256b(a)(1). According to the Advisory Opinion, "the 340B phrase 'purchased by'" obligates manufacturers to provide discounts for contract

pharmacy sales. JA_ [Advisory Opinion (ADVOP.2)]. The Advisory Opinion declared it "difficult to envision a less ambiguous phrase," which the Opinion interpreted as imposing on manufacturers an obligation—which cannot be "qualified" in any respect—to deliver drugs to unlimited contract pharmacies. *Id.* Under this view, "[t]he situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant." JA_ [Advisory Opinion (ADVOP.3)].

As Judge Stark explained, however, the purchased-by language "simply cannot bear the weight that the government places on it." *AstraZeneca I*, 543 F. Supp. 3d. at 59. Indeed, the language imposes obligations *on the HHS Secretary* ("The Secretary shall …"), requiring him to ensure that covered entities make appropriate reimbursement payments "to the manufacturer." Unlike the must-offer provision, the purchased-by language "does not directly act on covered entities and, in any event, says nothing of the permissible role (if any) of contract pharmacies." *Id.* Unsurprisingly, the agency abandoned reliance on the purchased-by language when issuing Violation Letters to AstraZeneca, Sanofi, and Novo on May 17, 2021. *See AstraZeneca II*, 2022 WL 484587, at *5 n.5 ("The Violation Letter says nothing about the 'purchased by' language.").

2. The HHS Advisory Opinion also argued that manufacturers must provide discounts for contract pharmacy sales "to the extent contract pharmacies are acting as agents of a covered entity." JA_ [Advisory Opinion (ADVOP.1)]. Under this view, "the covered entity and contract pharmacy are not distinct, but function as principal-agent." *Id.* at 6; *see AstraZeneca I*, 543 F. Supp. 3d at 60 ("The Opinion expressly relies on the assumption that contract pharmacies act as agents of covered entities.").

The government later abandoned this principal-agent argument, however, and for good reason: There is no factual or evidentiary support for it. "The determination of whether an agency relationship exists" is "a question of fact," which turns on multiple case-specific "factors" under the various laws of 50 different states. *WaveDivision Holdings, LLC v. Highland Cap. Mgmt., L.P.*, 49 A.3d 1168, 1177 (Del. 2012) (citation omitted). The government never even attempted to make that required showing.

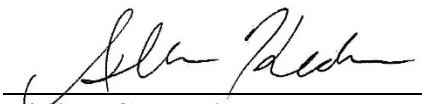
When AstraZeneca challenged this aspect of the Advisory Opinion, *see AstraZeneca*, No. 1:21-cv-27 (D. Del. Apr. 13, 2021), ECF No. 43 at 15, the government simply abandoned it, *see AstraZeneca*, No. 1:21-cv-27 (D. Del. May 4, 2021), ECF No. 56 ("[T]he AO never suggested that a drug maker's obligation to sell discounted drugs to covered entities distributing those drugs

through contract pharmacies depends on whether an agency relationship can be established"). Judge Stark noted the contradiction between the Advisory Opinion's text and the government's litigating position, *see AstraZeneca I*, 543 F. Supp. 3d at 60 n.15, but he ruled that the statute was not "intended to include agents" in any event, *id.* at 60. The principal-agent argument was notably omitted from the Violation Letters.

CONCLUSION

For the foregoing reasons, as well as those set forth by Sanofi and Novo, the district court's judgment should be reversed.

Dated: March 15, 2022



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CERTIFICATE OF BAR MEMBERSHIP

I hereby certify that I am a member of the bar of this Court.

Dated: March 15, 2022

Allon S. Kedem

CERTIFICATE OF COMPLIANCE

1. The foregoing brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 29(d) because the brief contains 4,859 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

2. The brief also complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Office 365 in Century 14-point font.

3. In accordance with Third Circuit Local Appellate Rule 31.1(c), the text of this document as electronically filed is identical to the text of the document to be submitted in paper copy, subject to Federal Rule of Appellate Procedure 30(c)(2)(B).

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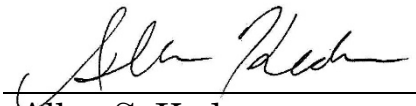

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I hereby certify that on March 15, 2022, I electronically filed the foregoing document with the United States Court of Appeals for the Third Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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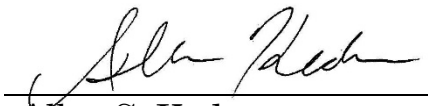

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