No. 22-01676

In the United States Court of Appeals for the Third Circuit

ASTRAZENECA PHARMACEUTICALS LP,
Plaintiff-Appellee,

v.

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

On Appeal from the United States District Court
for the District of Delaware
No. 21-17 (Hon. Leonard P. Stark)

BRIEF FOR APPELLEE ASTRAZENECA PHARMACEUTICALS LP

Allon Kedem
Jeffrey L. Handwerker
Sally L. Pei
Stephen K. Wirth
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Ave., NW
Washington, DC 20001
(202) 942-5000
allon.kedem@arnoldporter.com

Counsel for AstraZeneca Pharmaceuticals LP

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.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Rules & Regulations

Legislative Materials

Executive Branch Materials

Other Authorities

STATEMENT OF THE ISSUES

Section 340B of the Public Health Service Act requires a pharmaceutical manufacturer, as a condition of participating in Medicaid, to enter into an agreement with the Secretary of the Department of Health and Human Services (HHS) 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 questions presented are:

1. Whether Section 340B requires a manufacturer to offer covered outpatient drugs at discounted prices for distribution through an unlimited number of contract pharmacies.

2. Whether HHS exceeded its authority under Section 340B, or otherwise violated the Administrative Procedure Act, by determining that AstraZeneca's contract pharmacy policy—under which AstraZeneca offers 340B pricing to all covered entities and also processes 340B pricing through a single contract pharmacy site for covered entities that do not maintain their own on-site dispensing pharmacy—is in direct violation of the 340B Statute.

STATEMENT OF RELATED CASES AND PROCEEDINGS

In addition to the related actions identified in the Government's brief,[1] AstraZeneca identifies *Nat'l Ass'n of Cmty. Health Ctrs. v. Sanofi-Aventis U.S. LLC*, No. 210112-2 (HHS ADR Bd.); *Open Door Cmty. Health Ctrs. v. AstraZeneca Pharm., L.P.*, No. 210112-1 (HHS ADR Bd.); *Little Rivers Healthcare, Inc. v. AstraZeneca Phar., L.P.*, No. 210202-5 (HHS ADR Bd.); *Womencare, Inc., d/b/a/ Familycare Health Ctr. v. AstraZeneca Pharm., L.P.*, No. 210207-7 (HHS ADR Bd.).

[1] Pursuant to this Court's April 28, 2022 Order, the Government filed an opening brief in this case incorporating by reference arguments from its Principal and Response Brief for the Federal Defendants in *Sanofi Aventis U.S., LLC v. HHS*, Nos. 21-3167, 21-3379 (Dkt. 36), and *Novo Nordisk Inc. v. HHS*, Nos. 21-3168, 21-3380 (Dkt. 32). Unless otherwise noted, all citations to the Government's arguments and briefing are to the Principal and Response Brief. Citations to the brief filed in this case are designated "Gov't Supp. Br."

INTRODUCTION[2]

The 340B drug pricing program, 42 U.S.C. § 256b (Section 340B), imposes a specific obligation on drug manufacturers: They must "offer" their outpatient medications at discounted rates to certain healthcare facilities, called "covered entities," that cater to underserved populations.

AstraZeneca's policy complies with that requirement. Under the policy, *all* covered entities may obtain 340B-discounted drugs from AstraZeneca without limit. If a covered entity maintains its own on-site pharmacy, AstraZeneca will deliver its products to that pharmacy. AstraZeneca also 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.

---

[2] Before the Government filed its notice of appeal in this case, AstraZeneca submitted a brief as amicus curiae in support of appellants Sanofi-Aventis U.S. LLC and Novo Nordisk Inc. *See* Dkt. 19 at 3-4, No. 21-3167 (Mar. 15, 2022). Now that this case has been consolidated for disposition with the Sanofi and Novo appeals, this brief supersedes AstraZeneca's amicus brief.

Unhappy with the policy choices that Congress made in Section 340B, the Government asks this Court to rewrite it. The Government reads the statute as imposing an additional, unstated obligation on manufacturers to transfer their discounted drugs for sale by contract pharmacies, including an unlimited number of for-profit pharmacies. But the Government never identifies any statutory text that would impose such a requirement—indeed, it never even says *which provision* it thinks is relevant.

Instead, the Government's argument proceeds backwards: The Government begins from the *assumption* that the statute requires manufacturers to deliver discounted drugs to contract pharmacies and then argues that nothing "limits" or "eliminates" that requirement. Yet the Government never justifies its underlying assumption. Nor could it. As *every* judge to consider the issue has held, Section 340B is "silent" on the role of contract pharmacies under the program. That silence means the statute does not impose contract pharmacy obligations on manufacturers. In a free society, market participants retain their common law rights to set the terms of their business affairs unless and until the law says otherwise; it is administrative agencies, which possess only the authority that Congress gives them, who need affirmative authorization to act.

As Judge Leonard P. Stark explained below, to the extent "the statute offers any clues on the issue, they militate *against* the [Government's] view." JA 22 (emphasis added). In a pair of thorough and well-reasoned decisions, he analyzed the text, context, structure, and legislative history of Section 340B, and he concluded that they all contradict the Government's position. No "requirement" to deliver 340B-priced drugs to contract pharmacies "is contained in the statute." JA 24.

That conclusion should not surprise the Government: It is the same position that the Government itself took from 1992, when Congress created the 340B program, through December 2020, when the Government first asserted that the 340B statute imposes contract pharmacy obligations on drug manufacturers. Even if the Government's newfound position were textually defensible (and it is not), the unexplained about-face would doom any attempt to penalize AstraZeneca for its contract pharmacy policy—which is the same one-pharmacy approach that the Government endorsed for most of the 340B program's lifespan.

For these reasons, the Court should affirm Judge Stark's ruling and hold that the 340B statute does not require manufacturers to recognize an unlimited number of contract pharmacy arrangements.

STATEMENT OF THE CASE

A. Congress Creates the 340B Program

In 1992, Congress created a new health care program to give the Department of Veterans Affairs and certain federally funded clinics and hospitals access to discounted medications. *See* Veterans Health Care Act of 1992 (VHCA), Pub. L. 102-585, 106 Stat. 4943. By adding Section 340B to the Public Health Service Act, Congress required drug manufacturers to offer their products to these health care providers at statutorily discounted prices.

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). *Id.* But in so doing, it created an unintended "disincentive" for manufacturers to offer drugs at a discount to needy purchasers. *Id.* at 9-10. The VHCA remedied that disincentive, by "exclud[ing]" such discounts from the best-price formula. *Id.* at 11; *see* S. Rep. No. 102-259, at 1 (1992).

In addition, and of particular relevance here, Congress took steps in the VHCA to provide discounted drugs directly to needy purchasers. Congress was concerned about rising "[p]rices paid for outpatient drugs by the [Department of Veterans Affairs], and some Federally-funded clinics and public hospitals"—that is, their rising out-of-pocket expenses. H.R. Rep. at 11. Congress accordingly sought to give *both* groups (the Veterans Department and federal-funding recipients) access to "price reductions . . . at least as great as those which Medicaid receives under the rebate program." *Id.* at 12.

2. As enacted, Section 340B "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities," known as covered entities, that provide healthcare to certain underserved populations. *PhRMA v. HHS*, 43 F. Supp. 3d 28, 31 (D.D.C. 2014) (*Orphan Drug I*) (citation omitted). As a condition of receiving coverage and reimbursement for its drugs under Medicaid and Medicare Part B, a manufacturer must enter into a pharmaceutical pricing agreement with the Department of Health and Human Services (HHS). 42 U.S.C. § 256b(a)(1). The statute requires the agreement to contain provisions imposing obligations on each party. The HHS Secretary must "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 340B ceiling price]." *Id.* And manufacturers must "offer each covered entity covered outpatient drugs for purchase" at a specified discount price "if such drug is made available to any other purchaser at any price." *Id.* This latter provision is known as Section 340B's "must-offer" requirement.

Covered entities under Section 340B (as originally enacted) were "generally disproportionate share hospitals—hospitals that serve indigent populations." *Orphan Drug I*, 43 F. Supp. 3d at 31. Congress has added to the list of covered entities over time, and today there are fifteen clearly delineated categories, including: federally qualified health centers; federal grant recipients; and certain types of hospitals. 42 U.S.C. § 256b(a)(4)(A)-(*O*).

Notably, however, Congress has *never* included contract pharmacies in the defined list of covered entities. In drafting what would become Section 340B, Congress considered language that would have permitted covered entities to dispense 340B drugs through on-site contractors providing pharmacy services. *See* S. Rep. at 1-2 (quoting S. 1729, 102d Cong. § 1 (1992)). But that provision was not enacted.

B. HRSA's 340B Program Guidance, the Explosive Growth of the Program Since 2010, and AstraZeneca's Response

Contract pharmacies were not originally part of the 340B program. Over time, however, they have come to play an outsized role, with for-profit chains generating billions of dollars in arbitrage revenue—and corresponding program abuses.

1. In 1994, the Health Resources and Services Administration (HRSA), the HHS subcomponent that administers the 340B program, issued "program guidelines" designed to facilitate participation by covered entities. 59 Fed. Reg. 25,110 (May 13, 1994). Under these guidelines, a covered entity was allowed to use "a purchasing agent without forfeiting its right to" 340B pricing. *Id.* at 25,113. But the guidelines made clear that all 340B drugs would still need to be "distribut[ed] to the entity" itself before being dispensed to patients. *Id.*

In 1996, HRSA issued new guidelines for the 340B program. 61 Fed. Reg. 43,549 (Aug. 23, 1996) (1996 Guidance). The agency explained that, "[d]uring the early period of program implementation, it became apparent that only a very small number of the 11,500 covered entities used in-house pharmacies." *Id.* at 43,550. It thus issued guidance "designed to facilitate program participation for those eligible covered entities that d[id] not have

access to appropriate 'inhouse' pharmacy services." *Id.* 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.*

At the same time, HRSA determined that safeguards were necessary to ensure "compliance with . . . the 340B prohibition against drug diversion." *Id.* at 43,553. Most notably, the 1996 Guidance provided that a covered entity was required to "retain[] title" to the 340B drugs until they were sold to a patient. *Id.* Even if the medication sat on the pharmacy's shelf, therefore, it would still belong to the covered entity, which would "retain[] responsibility" for setting its price and ensuring it was not sold "to an individual who is not a patient of the covered entity." *Id.* In issuing this guidance, HRSA acknowledged that the 340B statute "is silent as to permissible drug distribution systems," *id.* at 43,549, but stated that the agency was offering this "necessary program guidance" in view of the "many gaps in the legislation," *id.* at 43,550.

2. In 2010, HRSA issued new (but similarly non-binding) guidance that, for the first time, indicated HRSA's support for covered entities entering into "multiple" contract pharmacy arrangements—that is, an *unlimited* number of contract pharmacies. 75 Fed. Reg. 10,272, 10,272-73 (Mar. 5, 2010)

(2010 Guidance). To "[e]nsure against illegal diversion," HRSA again insisted that a covered entity must "maintain title to the drug and assume responsibility for establishing its price." *Id.* at 10,277; *see id.* (title-maintenance is an "essential element[]" of "contract pharmacy arrangements"). HRSA also reemphasized that the drugs may not be dispensed "to an individual who is not a patient of the covered entity." *Id.* at 10,278. Despite criticisms that these statements were insufficient to protect against diversion and improper duplicate discounts, HRSA placed no limits on the number of contract pharmacies per covered entity, nor on their geographic location. *Id.* at 10,276.

The 2010 Guidance triggered a surge in contract pharmacies receiving 340B-discounted drugs. In just seven years, the number of contract pharmacies in the United States ballooned from 1,300 to nearly 20,000.[3] As of October 2020, more than 27,000 pharmacies, comprising more than 100,000 contracts, were participating in the 340B program.[4] The majority (75%) are

---

[3] U.S. Gov't Accountability Off., *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 2 (June 2018) (2018 GAO Rep.), https://www.gao.gov/assets/700/692697.pdf

[4] Berkeley Rsch. Grp., *For-Profit Pharmacy Participation in the 340B Program* 4 (Oct. 2020) (BRG Rep.), https://bit.ly/3owtUwa.

national, for-profit retail pharmacies; the five largest—CVS, Walgreens, Walmart, Rite-Aid, and Kroger—account for 60% of *all* 340B contract pharmacies.[5]

This boom has been fueled by the prospect of outsized profit margins for major pharmacy chains and other intermediaries. The contract pharmacy system works like this:

> 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.

JA 24 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 has explained, 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,

---

[5] 2018 GAO Rep. 20-21.

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. Decl. of Krista Pedley ¶ 11, *Sanofi-Aventis U.S., LLC v. HHS*, No. 3:21-cv-634 (D.N.J. June 24, 2021), ECF No. 93-2. 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.").

Covered entities and contract pharmacies use this system to "generate revenue." Gov't 2d S.J. Br. at 6 n.3, *AstraZeneca v. Becerra*, No. 21-17 (July 23, 2021), ECF No. 93. Once a pharmacy acquires the drugs at a steep 340B discount, the pharmacy then resells 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 divided between the covered entity and the contract pharmacy (among others). *Id.* For-profit pharmacies thus "are reaping sizeable 340B discounts on drugs and then turning around and upselling them to fully insured patients covered by Medicare, Medicaid, or private health insurance in order to maximize their

spread."[6] Pharmacy profit margins on 340B brand name drugs are now a staggering 72%—more than triple regular margins.[7] But these profits are often *not* passed along even to uninsured patients, who "pay the full non-340B price for their prescription drugs at contract pharmacies."[8]

The explosive growth of contract-pharmacy arrangements has facilitated the very risks that Congress sought to avoid when it enacted Section 340B. Numerous studies show that contract pharmacies engage in drug diversion and duplicate discounts; covered entities refuse to self-police; and HRSA's oversight has been "inadequate."[9] The promise of outsized profits, combined with lax federal oversight, has created a perfect storm of abuse.

---

[6] Letter from S. Judiciary Comm. to HRSA Adm'r 3 (Mar. 27, 2013), https://bit.ly/3dvnDfK.

[7] BRG Rep. 3.

[8] HHS-OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 2 (Feb. 2014), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf; *see* 2018 GAO Rep. 30.

[9] U.S. Gov't Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 21 (2011), https://www.gao.gov/assets/330/323702.pdf; *see, e.g.*, 2018 GAO Rep. 45 (criticizing "weaknesses in HRSA's oversight [that] impede its ability to ensure compliance with 340B Program requirements at contract pharmacies").

3. In the summer of 2020, AstraZeneca announced that, effective October 1, it would revert to the approach set forth in HRSA's 1996 Guidance. Under this policy, AstraZeneca continues to make its products available at 340B-discounted prices—in unlimited quantities—to all covered entities. For covered entities that do not maintain their own on-site dispensing pharmacy, AstraZeneca will also deliver discounted drugs to a single contract pharmacy site for each covered entity. But AstraZeneca will no longer deliver 340B drugs to an unlimited number of contract pharmacies. JA 126.

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.

AstraZeneca described its new policy to HRSA in several letters and offered repeatedly to meet to discuss further. JA 116-19, 133-35, 141-42. But HRSA refused, responding only once—to warn that it was "considering whether AstraZeneca's proposed policy constitutes a violation of the 340B statute and whether sanctions would apply," including statutory "civil monetary penalties." JA 130-31.

C. HHS Issues an Advisory Opinion Interpreting Section 340B, and Judge Stark Sets It Aside as Unlawful

1. On December 30, 2020, HHS's General Counsel issued an Advisory Opinion setting forth the agency's view on the legal question whether the 340B statute compels manufacturers to provide discounts for contract pharmacy sales. JA 276-83. To answer that question, the Opinion relied exclusively on the first sentence of Section 340B, which requires the Secretary to "enter into an agreement with each manufacturer" under which the manufacturer is paid no more than the statutory ceiling price for drugs "purchased by a covered entity." JA 277 (quoting 42 U.S.C. § 256b(a)(1)) (emphasis in original). The Opinion declared that it was "difficult to envision a less ambiguous phrase" than this purchased-by language. *Id.* Therefore, the Opinion stated, "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." JA 276. And that delivery obligation, the Opinion concluded, is absolute: "The situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant." JA 278.

Shortly after the Advisory Opinion was issued, AstraZeneca filed this action in the U.S. District Court for the District of Delaware. JA 74.

AstraZeneca challenged the Opinion's numerous substantive and procedural flaws, including: that the Opinion was promulgated without notice and comment; that it exceeded the agency's statutory authority; and that it was substantively arbitrary and capricious. JA 105-10.

2. On June 16, 2021, the Hon. Leonard P. Stark (then Chief Judge of the District of Delaware) issued a detailed opinion finding the Advisory Opinion unlawful. JA 2-27. The ruling included several key conclusions about Section 340B, HRSA's prior guidance, and the Advisory Opinion.

First, Judge Stark rejected the Government's "repeated contention that the [Advisory] Opinion merely restates a position that the government has held throughout the entirety of the 340B program." JA 12. He found instead that the Opinion "treads new ground" because it is materially different from the 1996 and 2010 Guidance along several dimensions. *Id.* (quotation marks omitted). Most notably, he observed, "AstraZeneca's new policy . . . would not have run afoul of the 1996 Guidance—yet it directly contradicts the Opinion." JA 14. Judge Stark thus concluded that "the government's interpretation of manufacturers' obligations under the 340B program has not remained constant but has, instead, evolved over time." JA 14-15.

Second, on the merits, Judge Stark determined that Section 340B is "silent" regarding whether manufacturers must provide discounts for contract pharmacy sales. JA 5. The Advisory Opinion relied on the statute's first sentence ("purchased by"), but that sentence "does not directly act on covered entities and, in any event, says nothing of the permissible role (if any) of contract pharmacies." JA 20. Judge Stark also examined Section 340B's must-offer provision, but concluded that it too "says nothing" about contract pharmacies. *Id.* Given the "[t]he statute's total omission of contract pharmacies," he concluded, the Advisory Opinion's attempt to impose such a statutory obligation was "legally flawed." JA 19, 21.

While Judge Stark described the agency's interpretation of the statute as "permissible," JA 25, he also explained that, to the extent "the statute offers any clues on the issue, they militate *against* the view set out in the [Advisory] Opinion." JA 22 (emphasis added). "Congress knows how to write statutes that cover agents and contractors," he noted, but "did not do so in the 340B statute." JA 23. In addition, Congress considered but did not enact language allowing contracts for *on-site* pharmacy sales, "suggest[ing] that Congress did not clearly intend to require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies." *Id.*

In response to Judge Stark's ruling, HHS withdrew the Advisory Opinion. JA 35. The Government then argued that the withdrawal had mooted AstraZeneca's claims. *Id.* Judge Stark disagreed: He granted judgment for AstraZeneca on its claim that the Advisory Opinion was arbitrary and capricious, and he vacated the Opinion and set it aside. JA 28-30.

D. HRSA Issues the May 17 Letter, and Judge Stark Sets It Aside as Unlawful

On May 17, 2021—while briefing on the Advisory Opinion was still ongoing—HRSA sent AstraZeneca a letter asserting that the agency had reviewed AstraZeneca's contract pharmacy policy and determined that the policy had "resulted in overcharges" and was "in direct violation of the 340B statute." JA 157. The May 17 Letter ordered AstraZeneca to resume 340B sales to contract pharmacies and to "credit or refund all covered entities for overcharges." JA 158. HRSA also threatened that "[c]ontinued failure to provide the 340B price" for contract pharmacy sales may result in civil monetary penalties, including for "knowingly and intentionally" overcharging covered entities. *Id.* AstraZeneca amended its Delaware complaint to challenge the letter. JA 37.

On February 16, 2022, Judge Stark issued the opinion now on appeal, finding the May 17 Letter unlawful. JA 31-50. Most significantly, he concluded

the letter was "based on the same legally flawed reading of the 340B statute that plagued the [Advisory] Opinion." JA 39 (quotation marks omitted). Judge Stark again rejected the agency's view that the statute imposes a "clear statutory command with respect to drug manufacturers' obligations" regarding contract pharmacy sales. JA 43. And he again determined that "the agency's position has shifted over time," which "provides an independent basis for the Court to award AstraZeneca relief." JA 49.

Judge Stark then reiterated several "key points" about the statutory text. JA 42. "Most importantly," he explained, Section 340B "never mentions pharmacies, which is a strong indication that the statute does not compel any particular outcome with respect to covered entities' use of pharmacies." *Id.* (cleaned up). Indeed, "[i]t is difficult to imagine that Congress enumerated 15 types of covered entities with a high degree of precision and then intended to impliedly sweep in sales implicating contract pharmacies." *Id.* (cleaned up). Judge Stark also pointed to the legislative history—in particular, to Congress's consideration but rejection of language referring to contract pharmacies—which "indicates that Congress did not clearly intend for drug manufacturers to be required to facilitate sales of covered drugs for dispensing by an unlimited number of contract pharmacies." JA 42-43.

In subsequent remedial orders, Judge Stark granted summary judgment to AstraZeneca on its claims against the May 17 Letter; vacated the letter and set it aside; and remanded to the agency. JA 51-53.

SUMMARY OF THE 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) (citation omitted). That principle decides this case. As Judge Stark correctly recognized (twice), an obligation to deliver 340B-discounted drugs to contract pharmacies is not "contained in the [340B] statute." JA 24. That silence means the agencies have no authority to penalize manufacturers for failing to deliver 340B-discounted drugs to unlimited contract pharmacies. The May 17 Letter, in which HRSA claims authority to sanction AstraZeneca for its contract pharmacy policy, must accordingly be set aside.

I. 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, as AstraZeneca always does. 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.

Other textual clues reinforce that Section 340B's silence on contract pharmacies was deliberate. The must-offer provision does not mention contract or agency arrangements, even though other parts of the statute mention them expressly. Indeed, the very next provision of the Veterans Health Care Act, which created the 340B program, dealt specifically with contract pharmacy purchases. And the lack of on-point language in Section 340B is all the more pronounced when viewed through traditional canons of construction: A particularly clear statement is necessary when an agency wants to displace common law rights; to settle major questions of vast economic significance; or to assert newly discovered authority. Here, HRSA attempts to do all three.

The Government's contrary argument assumes its own conclusion: The Government starts with the assumption that the 340B statute obligates manufacturers to deliver discounted drugs to contract pharmacies, then says nothing "limits" or "qualifies" this obligation. But the Government never

justifies the assumption in the first place—and never even identifies the statutory provision that creates this supposed obligation.

Rather than engage with the text, the Government appeals to policy concerns and supposed statutory purpose. But these arguments are no substitute for textual analysis, and they fail on their own terms. Congress prevented manufacturers from imposing onerous conditions on 340B sales by requiring them to make bona fide "offers" to covered entities; the Government does not dispute that AstraZeneca does so. The Government is also wrong that a literal interpretation of Section 340B would have rendered the statute a "dead letter" when it was enacted in 1992, given that relatively few covered entities had inhouse pharmacies at that time. The covered entities with inhouse pharmacies, who were providing drugs for free or at below cost to their financially needy patients, were precisely the entities whom Congress enacted the 340B program to help. And HRSA itself, in its 1996 Guidance, endorsed a limitation of one contract pharmacy relationship per covered entity; clearly HRSA did not think that limitation rendered the statute a dead letter.

II. The May 17 Letter should also be set aside, independent of its inconsistency with the 340B statute, because it resulted from an arbitrary and capricious agency process. As Judge Stark explained, the letter is based on the "flawed" legal premise that Section 340B unambiguously forbids AstraZeneca's policy. JA 43. In addition, the agency has never explained the switch in position reflected in the May 17 Letter: Starting in 1996—and for most of the 340B program's lifespan—HRSA's guidance supported covered entities entering into only a single contract pharmacy arrangement. AstraZeneca's policy adopts that same limitation, which the agency now says the statute "direct[ly]" forbids. JA 157. An agency process that fails to acknowledge (much less explain) such a dramatic shift does not reflect "reasoned decision-making."

ARGUMENT

I. AstraZeneca's Policy Does Not Violate Section 340B

The agency action at issue in this case, HRSA's May 17 Letter, accuses AstraZeneca's contract pharmacy policy of being "in direct violation" of Section 340B. JA 157-58. That is incorrect, because nothing in the statute precludes AstraZeneca's policy. Contrary to the Government's statement of the issues (at 3-4), the question for this Court is *not* whether Section 340B "allow[s]" AstraZeneca to change its policy with respect to contract pharmacies. Unlike HRSA—which is a "creature[] of statute" that "possess[es] only the authority that Congress has provided," *NFIB v. Dep't of Labor*, 142 S. Ct. 661, 665 (2022) (per curiam)—AstraZeneca is not a governmental actor and is not required to identify affirmative statutory authority for its actions. Instead, the question is whether the statute *forbids* AstraZeneca from restricting 340B sales to contract pharmacies. As Judge Stark correctly held (twice), it does not.

A. The Statute Does Not Require AstraZeneca to Provide Discounts for Drugs Delivered to Contract Pharmacies

Statutory text, context, history, and applicable canons of interpretation all make clear that Section 340B does not require AstraZeneca to sell discounted 340B drugs to unlimited contract pharmacies.

1. The text of Section 340B does not require manufacturers to sell discounted drugs to contract pharmacies

As Judge Stark noted, "the text of 42 U.S.C. § 256b(a) never mentions pharmacies, which is a 'strong indication that the statute does not compel any particular outcome with respect to covered entities' use of pharmacies.'" JA 42 (quoting JA 20); *see* JA 20 (Section 340B is "silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs"). That conclusion accords with the views of *every single court* to consider the question. *See Sanofi-Aventis U.S., LLC v. HHS*, 570 F. Supp. 3d 129, 193 (D.N.J. Nov. 5, 2021) ("By its terms, § 340B is silent on what role (if any) contract pharmacies play in Congress' discount drug scheme."); *Novartis Pharms. Corp. v. Espinosa*, Nos. 21-cv-1479, 1686, 2021 WL 5161783, at *6 (D.D.C. Nov. 5, 2021) ("silent") *Eli Lilly & Co. v. HHS*, No. 1:21-cv-81, 2021 WL 5039566, at *17 (S.D. Ind. Oct. 29, 2021) ("silent"). Indeed, even the Government's own amici acknowledge that "the 340B statute is silent with respect to contract pharmacies." AHA Amicus Br. at 6. Congress's silence is sufficient to resolve the statutory question here, because HHS and HRSA "literally ha[ve] no power" to impose contract pharmacy obligations on manufacturers "unless and until Congress confers [such] power upon [them]." *City of Philadelphia*, 916 F.3d at 284.

a. The central obligation that Section 340B imposes on participating manufacturers is the "must-offer" requirement: Manufacturers must "offer each covered entity covered outpatient drugs" at discounted prices to "covered entit[ies]." 42 U.S.C. § 256b(a)(1). 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).[10] 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 complies with this requirement: AstraZeneca makes its products available for purchase by covered entities at discounted prices—in any amount, without limitation. But the must-offer provision does not compel manufacturers to deliver 340B-

[10] *See*, *e.g.*, *Offer*, Am. Heritage Dictionary of the English Language 1255 (3d ed. 1992) ("To present for acceptance or rejection" and "To present for sale"); *accord Offer*, Random House Webster's Coll. Dictionary 939 (1992).

discounted drugs (or otherwise make them available) 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.'" JA 20.

Section 340B's failure to mention contract pharmacies is particularly noteworthy given the precision with which the statute identifies 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 difficult to imagine that 'Congress enumerated 15 types of covered entities with [such] a high degree of precision' and then intended to impliedly sweep in sales implicating contract pharmacies." JA 42 (quoting JA 22).

b. In the since-withdrawn Advisory Opinion, HHS located manufacturers' supposed obligation to provide discounts for drugs delivered to contract pharmacies in Section 340B's first sentence, which states:

> 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 277. The Opinion declared it "difficult to envision a less ambiguous phrase," which it interpreted as imposing on manufacturers an obligation—one that 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 278.

In the May 17 Letter, however, the agency abandoned reliance on the purchased-by language. *See* JA 41 n.5 ("The Violation Letter says nothing about the 'purchased by' language."). Accordingly, any reliance on that language now to justify the letter would contravene the "well established" rule "that an agency's action must be upheld, if at all, on the basis articulated by the agency itself." *Facchiano Constr. Co. v. U.S. Dep't of Lab.*, 987 F.2d 206, 215 (3d Cir. 1993) (citing *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947)).

In any event, as Judge Stark explained, the purchased-by language "simply cannot bear the weight that the government place[d] on it." JA 21. By providing that "[*t*]*he Secretary shall* enter into an agreement with each manufacturer" governing "the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity," the purchased-by language imposes obligations *on the Secretary*, not on manufacturers. 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." JA 20.

To illustrate, consider a hypothetical statute providing: "An employer must pay a salesperson who works on commission at least 10% of the value of merchandise *purchased by* a customer." The obvious meaning of this provision would be to impose obligations *on the employer* in compensating its salespeople. The provision would not impose *any* obligations on a salesperson—much less obligations on the salesperson vis-à-vis the customer. Still less would it obligate the salesperson to transfer the merchandise via any particular distribution mechanism, such as by transferring it to unnamed third parties at a separate location. Yet that is precisely the kind of upside-down

textual interpretation that would be required to accept the reasoning in the since-withdrawn Advisory Opinion.

2. Statutory context confirms that Section 340B does not require manufacturers to facilitate delivery to contract pharmacies

Giving the text its plain meaning suffices to answer the relevant question: Section 340B requires only that manufacturers "offer" drugs at discounted prices to covered entities; it does not require manufacturers to transfer statutorily discounted drugs to an unlimited number of contract pharmacies. But several additional aspects of the statutory scheme reinforce this understanding.

a. 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 omission 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 to covered entities only.

The considered nature of that choice becomes even clearer in the broader statutory context. Congress enacted the 340B program in Section 602 of the Veterans Health Care Act of 1992 (VHCA), Pub. L. 102-585, 106 Stat. 4943, 4967-71. And *in the very next section of the VHCA*, Section 603, Congress dealt expressly 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." JA 23.

Another part of Section 340B itself reinforces that conclusion, moreover, by providing for the establishment of a "prime vendor program under which covered entities may *enter into contracts with prime vendors for the*

distribution of covered outpatient drugs." 42 U.S.C. § 256b(a)(8) (emphasis added). This subsection has precisely the sort of explicit distribution language that subsection (a)(1) lacks. It is implausible that Congress would have taken such care to *expressly permit* "distribution" contracts with "vendor[s]" in some aspects of the statutory scheme, only to *implicitly mandate* an expansive distribution system of 340B drugs through contract pharmacies.

b. Several traditional canons of construction reinforce that a statutory obligation cannot be inferred from Section 340B's silence regarding contract pharmacy sales.

Displacing common law rights. When legislation displaces common law rights, a statute must "speak directly" to the question. *United States v. Texas*, 507 U.S. 529, 534 (1993). Because manufacturers have a common law right to sell their products at market prices and distribute them as they see fit, Congress must "enact *exceedingly clear language*" if it wishes to authorize agency officials to intrude on such a "fundamental element[] of property ownership." *Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2489 (2021) (emphasis added). That canon has increased potency here because, while Congress displaced manufacturers' common law rights with respect to one

specific aspect of their drug sales—price—it did *not* alter their common law rights to select a distribution method.

Major questions doctrine. The Supreme Court has recently and repeatedly made clear that "when authorizing an agency to exercise powers of vast economic and political significance," Congress not only must speak, but it must "speak clearly." *NFIB*, 142 S. Ct. at 665 (quoting *Ala. Ass'n of Realtors*, 141 S. Ct. at 2489); *see West Virginia v. EPA*, 597 U.S. ___, slip op. at 19-20 (2022). Here, HRSA claims the authority to establish and administer a complex system for the distribution of drugs under the Nation's second-largest prescription drug program; on the Government's own account (at 18-19), that system generates *billions* of dollars annually in revenue for covered entities (as well as billions for for-profit pharmacies). That is precisely the kind of power that Congress cannot confer *sub silentio*.

Newly discovered agency authority. "When an agency claims to discover in a long-extant statute an unheralded power to regulate a 'significant portion of the American economy,'" courts "typically greet its announcement with a measure of skepticism." *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014); *accord NFIB*, 142 S. Ct. at 666. Here, HRSA's assertion of authority to regulate contract pharmacy arrangements is more than a newfound

"discover[y]" of previously "unheralded" authority; the assertion affirmatively contradicts the agency's long history of *disclaiming* any such authority.

Throughout the 340B program's history, HRSA has consistently maintained that it lacks power under the statute to impose contract pharmacy obligations on manufacturers. In 1996, HRSA stated that Section 340B is "silent as to permissible drug distribution systems," and it offered "program guidance" on the use of contract pharmacies only in view of that statutory "gap[]." 61 Fed. Reg. at 43,549-50. HRSA adhered to that position for years.[11] In July 2020, for instance, HRSA wrote "that although the agency 'strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements,'" it lacked "authority to enforce" any such requirement. *Am. Hosp. Ass'n v. HHS*, No. 4:20-cv-08806, 2021 WL 616323, at *3 (N.D. Cal. Feb. 17, 2021) (quoting HRSA). The next day, HRSA told a reporter that "[t]he 2010 guidance . . . is not legally enforceable," such that HRSA cannot "compel[]" manufacturers "to provide 340B discounts on drugs dispensed by contract pharmacies." Tom Mirga, *HRSA Says its 340B*

---

[11] *See* Michelle Stein, *HRSA Urges Pharma To Continue 340B Discounts At Contract Pharmacies*, Pa. Office of Rural Health (Aug. 2020) (HRSA's Director of Communications: "HRSA is unable to develop enforceable policy" with respect to contract pharmacies), https://bit.ly/3wnHDZz.

Contract Pharmacy Guidance Is Not Legally Enforceable, 340B Report (July 9, 2020).[12] Indeed, as late as December 2020, HRSA stated that it does not issue audit findings for covered entities "for a failure to oversee 340B Program compliance at contract pharmacies through internal audits and other measures as set forth in guidance because *the 340B statute does not address contract pharmacy use*." U.S. Gov't Accountability Office, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance With 340B Requirements*, GAO-21-107, at 15-16 (emphasis added).[13]

Only on December 30, 2020, when it issued the Advisory Opinion, did the agency suddenly claim to discover statutory authority to "require[]" manufacturers to facilitate contract pharmacy sales. JA 283. As Judge Stark explained, the 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." JA 14 (emphases omitted). That the agency itself never before understood its Section 340B authority to sweep so broadly is a "powerful indication" that the agency's new construction is wrong. *FTC v. Bunte Bros.*, 312 U.S. 349, 351 (1941); *see id.* at 352 ("[T]he want of

[12] https://bit.ly/3PCMyze.

[13] https://www.gao.gov/assets/gao-21-107.pdf.

assertion of power by those who presumably would be alert to exercise it" is "significant in determining whether such power was actually conferred.").

B. The Government's Contrary Arguments Are Unpersuasive

The Government argues (at 33) that Section 340B is "straightforward" in requiring drug manufacturers to deliver discounted drugs to contract pharmacies. But its argument ignores the statutory text almost entirely, relying instead on supposed "[p]ractical considerations" and a one-sided assessment of the statute's purpose. Gov't Br. at 35-36 (citations omitted).

The Supreme Court recently rejected exactly this type of argument in another case involving HHS's interpretation of the 340B statute. The agency argued there that Congress "could not have intended" a literal reading, which would force the agency to "'overpay'" for certain drugs. *Am. Hosp. Ass'n v. Becerra*, 596 U.S. ___, slip op. at 12 (2022). The Supreme Court disagreed. If a faithful application of the statute "is bad policy or is working in unintended ways," the Court explained, "HHS can ask Congress to change the law." *Id.* at 13. Policy questions always have at least two sides, moreover, and "the 340B story may be more complicated than HHS portrays it. In all events, this Court is not the forum to resolve that policy debate." *Id.* So too here.

1. The Government fails to identify a statutory obligation that prohibits AstraZeneca's policy

The Government identifies no words in the 340B Statute that could conceivably be interpreted as requiring manufacturers to provide discounted drugs to contract pharmacies. Indeed, it does not even try. That omission is particularly notable because the Government has not argued that its interpretation of the statute is entitled to deference. To the contrary, the Government specifically disclaims *Chevron* deference, *see* Gov't Supp. Br. at 31, and it does not ask for *Skidmore* deference either.

In its briefs before this Court, the Government has not even explained *which sentence* in the 340B statute it believes imposes contract pharmacy obligations on manufacturers. Over the course of this dispute, the Government has cast about for relevant statutory language. In the now-vacated Advisory Opinion, the agency relied on the "purchased by" language, asserting that so long as the drugs were "purchased by" a covered entity, manufacturers had to deliver those drugs without restrictions. JA 277-78. But in the May 17 Letter, HRSA contended instead that the "must-offer" provision prohibited AstraZeneca's contract pharmacy policy; as Judge Stark noted, the letter "sa[id] nothing about the 'purchased by' language." JA 41 n.5, 157-58. Even now, the Government's amici cannot agree which is the relevant provision.

Compare NACHC Amicus at 10-11 (focusing on "shall-offer" provision), *with* AHA Amicus at 11 (describing "purchased by" as the "key statutory text").

a. To the extent the Government offers any textual argument at all, it simply begs the question (presumes its own conclusion): The Government begins from the *assumption* that the statute requires manufacturers to deliver discount drugs to contract pharmacies, and then argues that nothing "limit[s]" or "eliminate[s]" that requirement. *See, e.g.*, Gov't Br. at 3-4, 33-36. But the Government never justifies its central assumption.[14]

As the Supreme Court has explained, this approach to statutory interpretation is "exactly backwards." *Christensen v. Harris County*, 529 U.S. 576, 588 (2000). In *Christensen*, the Department of Labor issued an opinion letter interpreting the Fair Labor Standards Act to prohibit employers from compelling employees to use their accrued time off (instead of receiving monetary compensation). *Id.* at 580-81. An employer nevertheless adopted a

[14] The Government also begs the question when it accuses drug manufacturers: of "impos[ing] . . . restriction[s]" on covered entities' statutory right (Gov't Br. at 31); of "imposing their own conditions" (*id.* at 35); of "add[ing] provisos" to the statute (*id.* at 34); of "add[ing] on . . . conditions" (*id.* at 37); of "'usurp[ing]' Congress's directive" (*id.* at 38); and of "engag[ing] in self-help" (*id.* at 41). All of those accusations start from the unjustified premise that a statutory obligation exists in the first place.

contrary policy and its employees sued, contending that "the FLSA prohibits such a policy." *Id.* at 578. The Government sided with the employees, arguing that because "neither the statute nor the regulations *permit* an employer to require an employee to use accrued compensatory time," employers were therefore *prohibited* from doing so. *Id.* at 588.

The Supreme Court rejected that position. When a "statute is silent on [an] issue," the Court explained, it is not possible to "prove that [a regulated party] has violated" a statutory command. *Id.* at 585. Thus, "unless the FLSA *prohibits* [an employer] from adopting its policy, [its employees] cannot show that [the policy] has violated the FLSA." *Id.* at 588 (emphasis in original). The clear holding: Agencies may not infer that statutory silence "implicitly prohibits" a private party from engaging in otherwise lawful conduct. *Id.* at 582. Yet that is precisely what HRSA has done here.

b. The Government's heavy reliance on *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), reflects the same logical flaw. Citing *Bostock*, the Government argues that manufacturers cannot add "provisos" to their 340B sales because "'there is no such thing as a canon of donut holes.'" Gov't Br. at 34 (quoting *Bostock*, 140 S. Ct. at 1747). But *Bostock* in fact proves the opposite of the Government's point.

Bostock concerned Title VII's prohibition against "an employer" who "discriminate[s] against any individual . . . because of such individual's . . . sex," 42 U.S.C. § 2000e-2(a)(1), and considered whether that prohibition covers discrimination against gay or transgender employees. In determining "the ordinary public meaning of [this] command," the Court read the "key" phrase "'because of' sex" to "incorporate[] the simple and traditional standard of but-for causation." 140 S. Ct. at 1738-39 (quotation marks omitted). Under that standard, the Court explained, "it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual based on sex." *Id.* at 1741. The Court thus gave "Title VII's broad language" its full reach, declining to recognize a "tacit exception" to the "general statutory rule." *Id.* at 1747.

Bostock thus confirms that when courts want to know whether a statute requires certain conduct, they must follow "what [the statute] says about it." *Id.* at 1739. There was no question in *Bostock* that Title VII contained an express provision forbidding an employer from discriminating "'because of' sex." *Id.* at 1740. The only question was "the breadth of [that] legislative command." *Id.* at 1749 (cleaned up). Here, by contrast, no "requirement" to deliver 340B-priced drugs to contract pharmacies "is contained in the statute."

JA 24. AstraZeneca does not ask for "exceptions to a broad rule" that covers contract pharmacy sales. Gov't Br. at 34 (citation omitted). The 340B statute simply does not articulate any such "broad rule."

Bostock undermines the Government's argument in other ways as well. *Bostock* reaffirms that: (a) courts should adhere to "the law as written," rather than "disregard its plain terms based on some extratextual consideration," *id.* at 1749; (b) "if Congress had wanted to address [subject] matters in [a statute], it would have referenced them specifically," *id.* at 1746; and (c) courts should not "abandon the statutory text" in favor of an "appeal to assumptions and policy," *id.* at 1749. Those same principles are pertinent here, as reflected in Judge Stark's decisions. *See* JA 3 ("The Court's role . . . is to set aside any personal views it may hold on these matters" and to focus on the "text of the 340B statute"); JA 22 ("If Congress intended to include agents within the definition of 'covered entity,' it evidently knew how to do so."); JA 26 ("that kind of policymaking is for Congress, not this Court").

c. The Government argues (at 37-38) that a literal interpretation of Section 340B must be wrong, because it would allow manufacturers to impose onerous conditions on sales to covered entities so long as the statute did not expressly preclude them. For instance, manufacturers could require covered

entities to "purchase the manufacturer's drugs whenever possible, and never a competitor's," because "[t]here is nothing in the 340B statute that explicitly prohibits such a unilateral condition." *Id.* at 37. Thus, according to the Government (at 38), honoring the language of the statute would "defy common sense" and "defeat Congress's stated objectives" of ensuring covered entities' access to discounted drugs. The Government's argument fails on multiple levels.

First, an offer subject to a condition like the one the Government hypothesizes would not satisfy Section 340B's "must-offer" requirement. As another district judge explained, the "must-offer" provision means that manufacturers must make "meaningful, bona fide offers" to covered entities. *Novartis Pharms.*, 2021 WL 5161783, at *6. For that reason, a manufacturer cannot condition its offer on the covered entity's commitment to purchase the manufacturer's drugs over competing products.

But this requirement does not help the Government here. AstraZeneca's policy allows covered entities to buy 340B drugs without limit and also allows covered entities that lack an in-house pharmacy to have such drugs distributed through a single contract pharmacy. That plainly constitutes a bona fide "offer," and the Government does not argue otherwise.

Second, insofar as Section 340B can be read as requiring manufacturers to deal with covered entities on the same terms as they deal with commercial purchasers, *cf.* 42 U.S.C. § 256b(a)(1) (manufacturers must offer 340B drugs to covered entities "if such drug is made available to any other purchaser at any price"), that still would not help the Government. Here, there is *no* evidence that AstraZeneca has treated commercial sales more favorably than sales to covered entities. And in fact it has not: There is no distribution model that AstraZeneca allows for commercial purchasers but does not allow for covered entities. To the contrary, AstraZeneca treats covered entities *more favorably*, because only covered entities that lack an in-house pharmacy are allowed to use the contract pharmacy distribution model. Otherwise, drugs are "made available" to both groups on the same terms. *Id.*

2. *The Government's purpose-based and policy arguments are unavailing*

Lacking support in the text, the Government relies heavily on purpose-based and policy arguments. Of course, "even the most formidable argument concerning the statute's purpose [can]not overcome . . . the statute's text." *Kloeckner v. Solis*, 568 U.S. 41, 55 n.4 (2012); *see Bostock*, 140 S. Ct. at 1749 ("[I]t is ultimately the provisions of th[e] legislative commands rather than the principal concerns of our legislators by which we are governed.") (quotation

marks omitted). Instead, the "best evidence of Congress's intent is the statutory text." *NFIB v. Sebelius*, 567 U.S. 519, 544 (2012). But even if the Court were inclined to consider these atextual arguments, they cannot support the weight the Government places on them.

a. Legislative history does not support the Government's proposed contract pharmacy requirement

The Government raises two arguments based on the legislative history. Even where legislative history is definitive, it "cannot cloud clear text." *Clean Air Council v. U.S. Steel Corp.*, 4 F.4th 204, 210 (3d Cir. 2021). But the Government's arguments are unpersuasive on their own terms.

First, the Government argues (at 29-30) that Congress considered but "declined to enact" legislation that would have "confined [340B] price discounts to covered entities that dispense drugs through in-house pharmacies," from which the Government infers that Congress must have wanted to leave covered entities free to use contract pharmacies. Even if the Court were inclined to rely on legislative history, "failed legislative proposals are a particularly dangerous ground on which to rest an interpretation of a prior statute," *Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 187 (1994) (quotation marks omitted), because a "bill can be proposed for any number of reasons, and it can be rejected for just as many

others," *Solid Waste Agency of N. Cook Cnty. v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 170 (2001). Regardless, the failed legislative proposal supports *AstraZeneca's* interpretation of the statute, not the Government's.

Congress considered 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). "Congress chose not to include pharmacy services in the version of the bill that it ultimately passed," however, and so it deleted the italicized language. JA 23; *see* JA 42-43. Congress's decision not to authorize discounts for drugs provided through "on-site [contract] pharmacy services" thus shows that Section 340B's silence about *off-site* contract pharmacies—a far greater leap—was no mere oversight.

The Government attempts to draw an inference from Congress's omission from the final bill of the phrases "'and dispensed by'" and "'on-site,'" arguing (at 36) that these omissions somehow prove Congress wanted to liberate covered entities from any "limit on the mechanism for dispensing drugs." 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." JA 43 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).

Second, the Government argues that Congress must have mandated contract pharmacy sales because it intended for the 340B program to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Gov't Br. at 5 (quoting H.R. Rep. No. 102-384, pt. 2, at 12 (1992)). But when that sentence is read in full, it 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. 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, if anything the House Report *refutes* the notion that Congress wanted to facilitate contract pharmacy sales: The immediately preceding

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 is precisely how the current contract pharmacy system generates most of its revenue. *See* pp. 12-14, *supra*.

b. The Government's other purpose-based arguments lack merit

1. The Government invokes the "predicate acts" canon, asserting that the 340B "statutory scheme must be construed to ensure that 'everything necessary to making it effectual, or requisite to attaining the end, is implied.'" Gov't Br. at 34-35 (quoting Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 192-93 (2012)). But the Government omits critical language from its quoted source, which says: "*whenever a power is given by a statute*, everything necessary to making it effectual or requisite to attaining the end is implied." *Reading Law* at 192-93 (quoting James Kent, *Commentaries on American Law* *464 (Charles M. Barnes ed., 13th ed. 1884)) (emphasis added). Thus again, the Government's argument simply begs the question—*assuming* that the power to require recognition of contract pharmacy arrangements has been "given by statute" in the first place.

Moreover, the predicate acts canon "must be applied with caution, lest the tail of what is implied wag the dog of what is expressly conferred." *Reading Law* at 193. In particular, any "implication" accepted under the canon "must be a necessary, not a conjectural or argumentative one." *Id.* (quoting *Field v. People ex rel. McClernand*, 3 Ill. 79, 83 (1839)). The Government fails to heed that warning: Its predicate acts argument rests on an unsupported theory of what the statute is designed to do, and therefore what it means for the 340B statute to be "effectual."

Indeed, the Government's premise is not merely argumentative; it is incorrect. As explained, Congress enacted Section 340B to ensure that covered entities do not pay too much for drugs that they provide to their financially needy patients. *See* pp. 6-7, 47, *supra*. AstraZeneca's interpretation is fully consistent with that congressional goal. The agency's interpretation—that manufacturers must provide 340B drugs in any manner, to any third-party, at any place that a covered entity wants—reflects the very different goal of maximizing revenue for covered entities. "But the point of the [340B program] is not" to allow covered entities to generate "the most money possible." *Becerra v. Empire Health Found.*, 597 U.S. ___, slip op. at 18 (2022).

2. The Government argues that, under AstraZeneca's interpretation, "Section 340B would have been a dead letter . . . from the very moment of its enactment." Gov't Br. at 35 (quotation marks omitted). According to the Government (at 35), most covered entities lacked in-house pharmacies at that time, and so if drug manufacturers "refused to provide the discounted price to all of the covered entities that relied on [outside pharmacies]," those covered entities would have been excluded from the 340B program. The Government's "dead letter" argument fails on multiple levels.

First, the fact that only a small percentage of covered entities had in-house pharmacies when Section 340B was enacted in 1992 does not mean the law was a "dead letter." The covered entities using in-house pharmacies at that time were precisely the covered entities that Congress was concerned about: Those were the covered entities who were "experienc[ing] price increases" for drugs they provided to their "low-income and uninsured patients" for free or at below cost, so Congress wanted to give those entities "access to price reductions." H.R. Rep. at 10, 12. Section 340B accomplished that worthy goal, which hardly "defies rationality or renders the statute nonsensical and superfluous." *Riccio v. Sentry Credit, Inc.*, 954 F.3d 582, 588 (3d Cir. 2020) (en banc) (citation omitted).

Second, the Government offers no evidence to support its assertion that covered entities commonly used contract pharmacies at the time of the 340B statute's enactment—much less that Congress thought they were a *necessary* part of the statutory scheme. *See* Gov't Br. at 36 (asserting that "Congress knew of these pharmacy arrangements," but offering no evidence that such arrangements were prevalent). Indeed, neither contract pharmacies nor purchasing agents are mentioned even once in the House and Senate Committee reports on Section 340B.

Third, early agency guidance contradicts the Government's current position that HRSA believed covered entities were using contract pharmacies under the 340B program. In 1994, the agency advised that a covered entity could use "a purchasing agent without forfeiting its right to" 340B pricing, but insisted that all 340B drugs must still be "distribut[ed] to the entity" itself before being dispensed to patients. 59 Fed. Reg. at 25,113. That requirement, which is inconsistent with contract pharmacy use, would be nonsensical if contract pharmacies were always essential to the program's design.

Even when HRSA issued its first non-binding guidance about contract pharmacies in 1996, it made clear that they had not yet been a part of the 340B program. The agency thus explained that, "[d]uring the early period of

program implementation, it *became apparent* that only a very small number of the 11,500 covered entities used in-house pharmacies." 61 Fed. Reg. at 43,550 (emphasis added). That this fact "became apparent" to HRSA years *after* the program began contradicts the Government's assertion (at 36) that Congress "knew" about contract pharmacy use from the program's inception. And, of course, even after HRSA signaled its approval of contract pharmacy use for the first time in 1996, such approval was subject to a "limitation of one pharmacy contractor per entity," 61 Fed. Reg. at 43,555—exactly the same as AstraZeneca's policy today. Apparently HRSA did not think that limiting covered entities to a single contract pharmacy would render Section 340B a "dead letter."

3. Finally, the Government makes numerous assertions (at 43-44) about how AstraZeneca's interpretation undermines the 340B program *as it operates today*. Those assertions obviously shed no light on the meaning of words enacted in 1992. And regardless, the Government's characterization of modern-day practice is inaccurate.

Every covered entity can participate in the 340B program under AstraZeneca's policy. Each covered entity can obtain discounted drugs—either directly through its own in-house dispensing pharmacy or, if the covered

entity does not have an on-site pharmacy, via a single contract pharmacy of the covered entity's choice. That is how the program operated for most of its lifespan: HRSA itself limited covered entities to a single contract pharmacy in its 1996 Guidance. And even two decades later, the agency observed that "contract pharmacy arrangements are not common in the 340B Program. The overwhelming majority (82 percent) of covered entities do not contract with pharmacies." HRSA, *Contract Pharmacy Oversight* (Feb. 6, 2014).[15]

In addition, the Government's accusation (Suppl. Gov't Br. 3-5) that AstraZeneca's policy restricts patient access to necessary medications is simply false. AstraZeneca's policy does not limit whether and where a patient can fill her prescription. Patients always have the right to acquire AstraZeneca's drugs at *any* pharmacy of their choice; and, regardless of where a patient fills the prescription, the copay remains the same, and the patient's insurer covers the same amount. *See* 61 Fed. Reg. at 43,555 ("If the patient does not elect to use the contracted service, the patient may obtain the prescription from the covered entity and then obtain the drug(s) from the pharmacy provider of his or her choice."). AstraZeneca's policy prevents for-

[15] https://bit.ly/3OiAqT3.

profit pharmacies from securing drugs at discounted prices, and then dispensing those drugs to subsequent customers, regardless whether they are actually covered entity patients.

AstraZeneca takes the Government's policy concerns seriously. AstraZeneca is committed to patient access and to ensuring that every covered entity can obtain AstraZeneca's products at 340B prices. Insofar as AstraZeneca's policy has financial repercussions for covered entities that have come to rely on arbitrage revenue generated through unlimited contract pharmacies, AstraZeneca will continue to work with those entities to mitigate any loss of access pursuant to AstraZeneca's patient assistance and support programs. But "this Court is not the forum to resolve" those policy concerns. *Am. Hosp. Ass'n*, 596 U.S. at ___, slip op. at 13.

II. HRSA's May 17 Letter Is Arbitrary and Capricious

"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." *Michigan v. EPA*, 576 U.S. 743, 750 (2015) (citation omitted). Even where the agency's position is consistent with the governing statute, therefore, "agency action is lawful only" if it constitutes an exercise of "reasoned decisionmaking." *Id.* (quotation marks omitted).

The May 17 Letter is *not* consistent with Section 340B, for the reasons just discussed. But even if it were, the letter would still have to be set aside: HRSA failed to engage in reasoned decision-making in multiple respects. Those errors provide "independent ground[s]" for vacating the letter as arbitrary and capricious. *Bell Atlantic Tel. Cos. v. FCC*, 206 F.3d 1, 8 (D.C. Cir. 2000).

A. The May 17 Letter Is Based on the Incorrect Premise that Congress Compelled HRSA's Position on Contract Pharmacies

1. When an agency acts based on the incorrect belief "that [its] interpretation is compelled by Congress," courts do not merely "withhold . . . deference." *Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006) (quoting *PDK Labs. Inc. v. DEA*, 362 F.3d 786, 798 (D.C. Cir. 2004)). Rather, they must "vacate[]" the agency action and

"remand for [the agency] to interpret the statutory language" free from that incorrect belief. *Id.*

As Judge Stark explained, the May 17 Letter (like the Advisory Opinion before it) "is based on the 'unjustified assumption' that Congress imposed [the agency's] interpretation as a statutory requirement." JA 25 (quoting *Am. Lung Ass'n v. EPA*, 985 F.3d 914, 944 (D.C. Cir. 2021)); *see* JA 39. The letter asserts that a manufacturer's contract pharmacy obligations flow "direct[ly]" from Section 340B's must-offer provision; that "[n]othing in the 340B statute" limits or qualifies that obligation; and that "[t]he 340B statute does not permit" any other approach, such as the one adopted by AstraZeneca. JA 157-58.

Therefore, unless this Court agrees with HRSA that its position on contract pharmacy sales is "compelled by Congress," the May 17 Letter must be vacated. *PDK Labs.*, 362 F.3d at 798. As Judge Stark explained, "[i]t does not matter that the [May 17] Letter does not describe the statute as 'unambiguous' because the [letter] still evinces an understanding that its conclusion is driven by a clear statutory command with respect to drug manufacturers' obligations." JA 43. Since that understanding is legally "flawed," the letter must be "vacated and set aside." *Id.*

2. The Government incorrectly accuses Judge Stark (Gov't Supp. Br. at 9) of "a basic misunderstanding of administrative-law principles." According to the Government (*id.* at 9-10), because HRSA makes "no claim of *Chevron* deference," any error in its reasoning was irrelevant; even if the May 17 Letter was premised on the legally erroneous view that Section 340B unambiguously forbids AstraZeneca's policy, vacating the letter was not an appropriate remedy. Rather, if Judge Stark "perceived an ambiguity" in the statute—contrary to the agency's view—the Government says (*id.* at 10) "it was [his] responsibility to resolve that ambiguity by employing all available tools of statutory interpretation."

But the principle that agency decision-making must be free from legal misapprehension is a fundamental requirement of *all* "agency action" under the Administrative Procedure Act. 5 U.S.C. § 706(2). Whether or not an agency's decisions are entitled to *Chevron* deference, they must still be rational—that is, not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 706(2)(A). Thus in *PDK Laboratories*, the D.C. Circuit vacated agency action that had been based on the agency's mistaken belief that the statute "plainly meant what the [agency] assumed"—even though the agency "neither invoke[d] *Chevron* nor ask[ed]

[the court] to give any special deference to the Deputy Administrator's judgment about the meaning of the provision." 362 F.3d at 794. The same result is warranted here.

In any event, Judge Stark *did* "employ[] all available tools of statutory interpretation," Gov't Supp. Br. at 10, and he determined that the relevant statutory "clues . . . militate *against* the view" taken by HRSA. JA 22 (emphasis added). Among other "key points," Judge Stark considered "the text of 42 U.S.C. § 256b(a)," the fact that a neighboring subsection "explicitly refers to certain affiliates of covered entities," the fact that "'Congress enumerated 15 types of covered entities with a high degree of precision,'" and the "legislative history." JA 42 (quoting JA 22); *see* JA 22-23 (considering "another part of the VHCA" that "refers specifically" to contract purchases); JA 23 (considering "a provision in a different health care statute" that "explicitly covers" authorized purchasing agents). The Government's abbreviated account of Judge Stark's rulings, *see* Supp. Br. at 6-7, thus badly short-changes his reasoning. But his actual opinions were thorough and persuasive.

B. HRSA Erred in Relying on False Claims of Consistency

Another black-letter requirement of "reasoned" decision-making is that, when an agency changes its mind, the agency "must at least display awareness that it is changing position and show that there are good reasons for the new policy." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016) (citation omitted); *see FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (agency must "display awareness that it is changing position" and cannot "depart from a prior policy *sub silentio*") (emphasis omitted).

The May 17 Letter asserts that "HRSA has made plain, *consistently since the issuance of its 1996 contract pharmacy guidance*, that the 340B statute requires manufacturers to honor . . . purchases [of covered outpatient drugs] regardless of the dispensing mechanism." JA 157 (emphasis added). That claimed consistency is demonstrably false. As Judge Stark explained, "the agency's position has not been consistent over the past 25 years." JA 44. Among the many shifts, he pointed to the following:

- The May 17 letter "focuses on the 'shall offer' requirement," whereas the 1996 and 2010 guidance "were issued before [that] requirement was enacted," JA 44;

- The 1996 and 2010 Guidance "were directed to covered entities," whereas the May 17 Letter "is directed to a specific drug manufacturer," *id.*;
- The 1996 and 2010 Guidance "attempted to fill statutory gaps," whereas the May 17 Letter "seeks to enforce a requirement allegedly contained in the statute," *id.*; and
- "AstraZeneca's new policy regarding 340B drugs would have ***complied*** with the parameters set out in the 1996 Guidance," while the May 17 Letter "determines that AstraZeneca's new policy does ***not*** comport with the agency's current understanding of the 340B statute," JA 44-45 (emphasis in original).

See JA 45 (providing a summary "table of differences among all the relevant documents"). These inconsistencies belie the Government's assertions (Supp. Br. at 11) that the agency has behaved "consistently."

Finally, the Government is wrong to assert (Supp. Br. at 12) that HRSA has sufficiently explained the agency's "evolution . . . regarding the number of contract pharmacies." To be sure, as the Government notes, when HRSA shifted from a endorsing one contract pharmacy arrangement in 1996, to endorsing unlimited contract pharmacy arrangements in 2010, the agency "explained" that it wanted to broaden the 340B program. *Id.* And since both the 1996 Guidance and the 2010 Guidance were "nonbinding," the Government

states, that policy explanation was "satisfactory" enough. *Id.* at 11-12 (quotation marks omitted).[16]

But the agency has never explained its switch to its *current* position—including in the May 17 Letter that is being challenged in this litigation—that AstraZeneca's contract pharmacy policy is "in direct violation of the 340B statute." JA 157. That about-face is based on a new interpretation of the statute's text, and it remains completely unexplained. How did HRSA go from approving a "limitation of one pharmacy contractor per entity" in 1996, 61 Fed. Reg. 43,549-01 at 43,550, to its current position that Section 340B forbids any attempt "to restrict the number of contract pharmacies that a covered entity may use," Gov't Supp. Br. at 10? As Judge Stark noted, the agency has never provided "any credible explanation" for that switch, and its "failure" even "to

[16] The Government asserts (Supp. Br. at 10) that "HHS has consistently stated that its guidance on the [contract pharmacy] issue was nonbinding." But in the district court, the agency *repeatedly* invoked the 2010 Guidance as a reason why AstraZeneca's policy was unlawful—including asking the court to "afford deference [to it] under *Skidmore*" if the court perceived any "ambiguity in the 340B statute." Gov't 2d S.J. Br. at 23, *AstraZeneca v. Becerra*, No. 21-17 (July 23, 2021), ECF 93; *see, e.g.*, Gov't 1st S.J. Br. at 12, *AstraZeneca*, *supra* (May 5, 2021), ECF 56 ("To the extent that HHS expects 'immediate compliance,' . . . such expectation was created by the 2010 Guidance"). On appeal, the Government has finally abandoned any request for deference to the agency.

acknowledge that the agency's position has shifted over time provides an independent basis for the Court" to vacate the May 17 Letter. JA 49.

CONCLUSION

For the foregoing reasons, the district court's judgment should be affirmed.

Dated: July 21, 2022

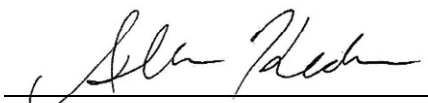
Allon Kedem
Jeffrey L. Handwerker
Sally L. Pei
Stephen K. Wirth
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Ave., NW
Washington, DC 20001-3743
Tel.: +1 202.942.5000
Fax: +1 202.942.5999
allon.kedem@arnoldporter.com

Counsel for AstraZeneca Pharmaceuticals LP

CERTIFICATE OF SERVICE

I hereby certify that on July 21, 2022, I electronically filed the foregoing document with the United States Court of Appeals for the Federal 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.

Dated: July 21, 2022



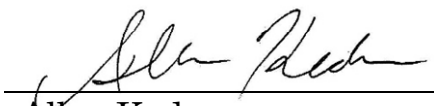
Allon Kedem

CERTIFICATE OF COMPLIANCE

1. The foregoing brief complies with the type-volume limitations of Fed. R. App. P. 32(a) because the brief contains 12,356 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

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

Dated: July 21, 2022



Allon Kedem