United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued October 24, 2022 Decided May 21, 2024

No. 21-5299

NOVARTIS PHARMACEUTICALS CORPORATION,
APPELLEE

v.

CAROLE JOHNSON, IN HER OFFICIAL CAPACITY AS ADMINISTRATOR, HEALTH RESOURCES AND SERVICE ADMINISTRATION AND XAVIER BECERRA, IN HIS OFFICIAL CAPACITY AS SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
APPELLANTS

Consolidated with 21-5304

Appeals from the United States District Court
for the District of Columbia
(No. 1:21-cv-01479)
(No. 1:21-cv-01686)

Daniel J. Aguilar, Attorney, U.S. Department of Justice, argued the cause for appellants. With him on the briefs were *Brian M. Boynton*, Principal Deputy Assistant Attorney

General, *Sarah E. Harrington*, Deputy Assistant Attorney General, and *Alisa B. Klein*, Attorney.

William B. Schultz and *Margaret M. Dotzel* were on the brief for *amici curiae* American Hospital Association, et al. in support of appellants.

William Tong, Attorney General, Office of the Attorney General for the State of Connecticut, *Clare Kindall*, Solicitor General at the time the brief was filed, *Leslie Rutledge*, Attorney General, Office of the Attorney General for the State of Arkansas, *Philip J. Weiser*, Attorney General, Office of the Attorney General for the State of Colorado, *Kathleen Jennings*, Attorney General, Office of the Attorney General for the State of Delaware, *Karl A. Racine*, Attorney General, Office of the Attorney General for the District of Columbia, *Holly T. Shikada*, Attorney General, Office of the Attorney General for the State of Hawaii, *Kwame Raoul*, Attorney General, Office of the Attorney General for the State of Illinois, *Derek Schmidt*, Attorney General, Office of the Attorney General for the State of Kansas, *Jeff Landry*, Attorney General, Office of the Attorney General for the State of Louisiana, *Aaron M. Frey*, Attorney General, Office of the Attorney General for the State of Maine, *Brian E. Frosh*, Attorney General, Office of the Attorney General for the State of Maryland, *Maura Healey*, Attorney General, Office of the Attorney General for the Commonwealth of Massachusetts, *Dana Nessel*, Attorney General, Office of the Attorney General for the State of Michigan, *Keith Ellison*, Attorney General, Office of the Attorney General for the State of Minnesota, *Lynn Fitch*, Attorney General, Office of the Attorney General for the State of Mississippi, *Douglas J. Peterson*, Attorney General, Office of the Attorney General for the State of Nebraska, *Aaron D. Ford*, Attorney General, Office of the Attorney General for the State of Nevada, *Matthew J. Platkin*, Attorney General, Office

of the Attorney General for the State of New Jersey, *Hector Balderas*, Attorney General, Office of the Attorney General for the State of New Mexico, *Joshua H. Stein*, Attorney General, Office of the Attorney General for the State of North Carolina, *Ellen F. Rosenblum*, Attorney General, Office of the Attorney General for the State of Oregon, *Josh Shapiro*, Attorney General, Office of the Attorney General for the Commonwealth of Pennsylvania, *Peter F. Neronha*, Attorney General, Office of the Attorney General for the State of Rhode Island, *Sean D. Reyes*, Attorney General, Office of the Attorney General for the State of Utah, *Thomas J. Donovan, Jr.*, Attorney General at the time the brief was filed, Office of the Attorney General for the State of Vermont, were on the brief for *amici curiae* States of Connecticut, et al. in support of appellants. *Robert L. Marconi*, Assistant Attorney General, Office of the Attorney General for the State of Connecticut entered an appearance.

Matthew Sidney Freedus and *Ronald S. Connelly* were on the brief for *amici curiae* National Association of Community Health Centers and Ryan White Clinics for 340B Access in support of appellants.

Catherine E. Stetson argued the cause for appellee Novartis Pharmaceuticals Corporation. With her on the brief were *Susan M. Cook, Danielle Desaulniers Stempel,* and *Dana A. Raphael.*

Philip J. Perry argued the cause for appellee United Therapeutics Corporation. With him on the brief were *Andrew D. Prins, Gregory B. in den Berken,* and *Joseph E. Begun.*

William J. Trunk was on the brief for *amicus curiae* Pharmaceutical Research and Manufacturers of America in support of appellees.

Paul J. Zidlicky and *Eric D. McArthur* were on the brief for *amicus curiae* Kalderos, Inc. in support of appellees.

William A. Sarraille was on the brief for *amicus curiae* Johnson & Johnson Health Care Systems, Inc in support of appellee United Therapeutics Corporation.

Before: KATSAS, RAO, and CHILDS, *Circuit Judges*.

Opinion for the Court by *Circuit Judge* KATSAS.

KATSAS, *Circuit Judge*: Section 340B of the Public Health Service Act requires drug manufacturers to sell certain drugs at discounted prices to select healthcare providers. To facilitate the distribution of these drugs, the providers often contract with outside pharmacies. According to drug manufacturers, these partnerships have left the section 340B program vulnerable to abuse—at great cost to the manufacturers. In response, the manufacturers have imposed their own contractual terms on providers, such as limits on the number of pharmacies to which they will make shipments. The government contends that these restrictions violate the statute. The district court held that section 340B does not prohibit manufacturers from limiting the distribution of discounted drugs by contract. We agree.

I

A

As a condition of participating in Medicare Part B and Medicaid, section 340B requires drug manufacturers to sell certain drugs to covered entities at bargain prices. Covered entities—such as healthcare providers serving low-income patients—benefit through insurance reimbursements that exceed the marked-down cost of the drugs.

Congress enacted section 340B in 1992 amendments to the Public Health Service Act. Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967–71. In March 2010, the Affordable Care Act expanded the list of covered entities eligible to participate in the program and added several new provisions aimed at improving compliance with program requirements. Pub. L. No. 111-148, tit. VII, §§ 7101–02, 124 Stat. 119, 821–27.

Section 340B requires manufacturers to enter into standard agreements with the Secretary of Health and Human Services "under which the amount required to be paid … to the manufacturer for covered outpatient drugs … purchased by a covered entity … does not exceed an amount" known as the "ceiling price." 42 U.S.C. § 256b(a)(1). As amended by the Affordable Care Act, section 340B further provides that each standard agreement "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." *Id.* The ceiling price is fixed by a statutory formula strikingly generous to purchasers. *See id.* § 256b(a)(2); *see also id.* § 1396r-8(c). In some instances, it can be as low as a penny per unit. *See* 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1211 (Jan. 5, 2017).

Since 1992, Congress has limited the section 340B program in three important ways. First, the statute defines "covered entity" to mean only healthcare providers that fit within narrow categories such as black lung clinics, rural referral centers, and hospitals that primarily serve low-income patients. 42 U.S.C. § 256b(a)(4). Second, the statute prohibits "diversion," which occurs when covered entities "resell or otherwise transfer the drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B). Third, the statute prohibits

covered entities from receiving the section 340B discount on drugs also subject to a Medicaid rebate. *Id.* § 256b(a)(5)(A)(i).

Section 340B provides for audits of covered entities to ensure program compliance. The Secretary or manufacturers may initiate an audit. 42 U.S.C. § 256b(a)(5)(C). If the Secretary finds that a covered entity engaged in diversion or accepted duplicate discounts, the manufacturer may recover damages from the covered entity in administrative proceedings. *Id.* § 256b(a)(5)(D). The Secretary also may impose further penalties for intentional or systematic diversion. *Id.* § 256b(d)(2)(B)(v).

The Secretary lacks rulemaking authority over the section 340B program. Nonetheless, the Health Resources and Services Administration, which administers the program for the Secretary, has issued guidance documents interpreting and implementing the scheme. Three of them address the distribution of drugs from manufacturers to covered entities.

1994 Guidance. HRSA's initial guidance stated that a covered entity may use a "purchasing agent." Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,113 (May 13, 1994). According to the guidance, manufacturers may ship discounted drugs to this agent, which then must ship them to the covered entity for dispensing to patients. *See id.* HRSA opined that manufacturers may not "single out covered entities" for "restrictive conditions" such as "minimum purchase amounts." *Id.* But it said that manufacturers, in their contracts with covered entities, may "include provisions that address customary business practice, request standard information, or include other appropriate contract provisions." *Id.* at 25,114.

1996 Guidance. This guidance acknowledged that section 340B "is silent as to permissible drug distribution systems," but it nonetheless sought to fill "gaps in the legislation" and thereby "move the program forward." Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,549–50 (Aug. 23, 1996). HRSA recognized that many covered entities use outside pharmacies to distribute drugs to their patients. *Id.* at 43,550. To accommodate them, HRSA stated that a covered entity without an in-house pharmacy may contract with a single outside pharmacy to dispense drugs at a single location. *Id.* at 43,555. A commentor suggested that covered entities "should be permitted to contract with more than one" pharmacy, *id.* at 43,551, but HRSA maintained the "limitation of one pharmacy contractor per entity," *id.* at 43,555. And it stressed that a covered entity, in directing shipments to its contract pharmacy, must retain title to the drugs and thus "be responsible" for any diversion or duplicate discounts. *Id.* at 43,553.

2010 Guidance. Fourteen years later, HRSA swerved. It opined that covered entities may contract with an unlimited number of outside pharmacies and may do so regardless of whether the entities have in-house pharmacies. Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,272–73 (Mar. 5, 2010). The agency reasoned that contract pharmacies enable covered entities to "create wider patient access by having more inclusive arrangements in their communities." *Id.* at 10,273. HRSA reiterated its view that each covered entity must maintain title to and responsibility for the drugs, *id.* at 10,277, and must "maintain auditable records sufficient to demonstrate continued compliance with 340B requirements," *id.* at 10,274.

The 2010 Guidance prompted a significant expansion in the section 340B program. According to the Government

Accountability Office, the number of covered entities participating in the program increased from about 9,700 to 13,000 between 2010 and 2019. GAO Report No. 20-212, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement, at 2 (2020). Yet over the same period, the number of contract pharmacies participating in the program increased from about 1,300 to 23,000. *Id.* By 2017, the country's largest chain pharmacies—such as Walgreens and CVS—accounted for most of this market. GAO Report No. 18-480, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, at 21 (2018). Covered purchases have similarly expanded. One analyst estimates that they jumped from roughly $6.9 billion in 2012 to $24.3 billion by 2018. A. Fein, *Exclusive: 340B Program Purchases Reach $24.3 Billion—7%+ of the Pharma Market—as Hospitals' Charity Care Flatlines*, Drug Channels (May 14, 2019).

The mechanism for distributing covered drugs also has evolved. While some contract pharmacies maintain separate inventories of section 340B drugs, most fill prescriptions from inventories that intermingle discounted and non-discounted drugs. Only after dispensing the drugs do these pharmacies attempt to discern whether individual customers were patients of covered entities—in other words, whether individual prescriptions were eligible for the discount. Many pharmacies outsource this determination to third-party administrators, who often receive a larger fee for every prescription deemed eligible for the discount. Once the pharmacy or the administrator categorizes a certain number of prescriptions as eligible, the pharmacy places an order to replenish its section 340B purchases. The covered entity, the pharmacy, and the third-party administrator often divvy up the spread between the discounted price and the higher insurance reimbursement rate.

Each of these actors thus has a financial incentive to catalog as many prescriptions as possible as eligible for the discount.

Manufacturers have argued that these arrangements lead to unlawful diversion and duplicate discounts. For support, they point to potential abuses noted in a report by the Inspector General of HHS. *See* S. Wright, Off. of the Inspector Gen., OEI-05-13-00431, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program 9–15 (2014). As to diversion, the concern is that pharmacies rely on manipulable algorithms to code whether prescriptions warrant the discount. For example, suppose a physician practices at a covered entity and somewhere else. The physician writes a prescription for a patient of his private practice. Yet the contract pharmacy, connecting the physician to the covered entity, classifies the prescription as eligible for the discount. *See id.* at 10. As for duplicate discounts, the Inspector General found that some contract pharmacies do not track and exclude 340B-eligible prescriptions from Medicaid rebate claims, leading to impermissible duplication. *See id.* at 13.

B

Novartis Pharmaceuticals Corporation and United Therapeutics Corporation sell drugs subject to the section 340B discount. In 2020, both companies began to limit the number and kinds of contract pharmacies to which they would ship orders. For covered entities that are hospitals, Novartis planned to work only with contract pharmacies located within 40 miles of the hospital. United Therapeutics planned to work only with contract pharmacies previously used by the covered entity to distribute section 340B drugs during the first three quarters of 2020. Or, if a covered entity neither used a contract pharmacy during that period nor had an in-house pharmacy, United Therapeutics would agree to deliver section 340B

orders to a single contract pharmacy designated by the entity. Additionally, it planned to require covered entities to provide "claims data associated with all 340B contract pharmacy orders" to a third-party platform, to facilitate efforts to police diversion and duplicate discounts. J.A. 803. Around the same time, other manufacturers adopted similar restrictions.

In response, HHS issued an advisory opinion stating that section 340B requires manufacturers to deliver covered drugs to any contract pharmacies with which a covered entity chooses to partner. The agency reasoned that drugs shipped to any contract pharmacy are still "purchased by" the covered entity and thus within the plain language of the statute, regardless of "how the covered entity chooses to distribute" the drugs. J.A. 382. HHS used vivid language to make its point that a covered entity may choose any number of delivery locations: It said that the "situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant" to the manufacturers' statutory obligations. *Id.* at 383.

The District Court for the District of Delaware held that the advisory opinion was arbitrary, in part because section 340B does not unambiguously prohibit manufacturers from imposing distribution conditions. *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 58–62 (D. Del. 2021). Two days later, while that court was still considering what relief to afford, HHS withdrew the opinion.

In the meantime, HRSA sent enforcement letters to Novartis, United Therapeutics, and other large drug manufacturers. In these letters, HRSA asserted that the statutory duty to offer drugs to covered entities at or below the ceiling price "is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs." J.A. 65 (Novartis letter) ("Nothing in the 340B statute

grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities."); *accord id.* at 596 (United Therapeutics letter). The agency ordered the companies to honor all contract-pharmacy relationships and to credit covered entities for overcharges.

Novartis and United Therapeutics filed separate lawsuits under the Administrative Procedure Act. The companies sought vacatur of the enforcement letters, declaratory judgments that the disputed conditions are lawful, and injunctions barring future enforcement. On summary judgment, the district court rejected the government's position that section 340B categorically prohibits manufacturers from imposing contractual conditions on how its products may be distributed. *Novartis Pharms. Corp. v. Espinosa*, 2021 WL 5161783, at *5–8 (D.D.C. Nov. 5, 2021). The court thus set aside the enforcement letters, and it declared that the disputed conditions do not violate section 340B "under the positions advanced in the Violation Letters and developed in this litigation." *Id.* at *9. The court reserved for future cases the question whether the conditions might be unlawful under some other theory, so it declined to enjoin future enforcement. *Id.*

II

Familiar standards of review govern this case. Under the APA, the district court was tasked with determining whether HRSA's enforcement letters were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). We must do the same. *Jicarilla Apache Nation v. DOI*, 613 F.3d 1112, 1118 (D.C. Cir. 2010).

The Secretary lacks rulemaking authority over the section 340B program. Two initial points follow. First, we must consider whether the disputed conditions violate section 340B

itself, not whether they violate agency guidance lacking the force of law. Second, we cannot defer to HRSA's interpretation of section 340B under *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837 (1984), and its progeny. *See United States v. Mead Corp.*, 533 U.S. 218, 229–31 (2001); *Christensen v. Harris Cnty.*, 529 U.S. 576, 586–87 (2000). Instead, we may follow the agency's interpretation of the statute only to the extent it has the "power to persuade." *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944).

This appeal turns on whether drug manufacturers may impose contractual conditions on how their products are distributed to covered entities. The parties present stark alternatives. According to HRSA, manufacturers may impose no such conditions. Covered entities thus may insist on delivery to an unlimited number of contract pharmacies, regardless of their planetary or other location. For their part, the manufacturers assert a nearly unfettered ability to impose conditions. Among other things, they suggest that they could (but choose not to) ship drugs only to the covered entities themselves, thus removing contract pharmacies from the picture entirely. Fortunately, we need only consider the specific conditions addressed in the enforcement letters under review. And we begin with the sweeping rationale asserted in those letters.

III

We reject HRSA's position that section 340B prohibits drug manufacturers from imposing any conditions on the distribution of discounted drugs to covered entities.

A

In pertinent part, section 340B requires manufacturers to "offer each covered entity covered outpatient drugs for

purchase" at or below a specified ceiling "price." 42 U.S.C. § 256b(a)(1). To construe this text, we look to the ordinary meaning of its key terms. *HollyFrontier Cheyenne Refin., LLC v. Renewable Fuels Ass'n*, 141 S. Ct. 2172, 2176 (2021). *Offer* means "[t]o present for acceptance or rejection." *American Heritage Dictionary of the English Language* 1255 (3d ed. 1992); *accord Black's Law Dictionary* 1304 (11th ed. 2019). *Purchase* means "[t]o obtain in exchange for money or its equivalent; buy." *American Heritage Dictionary of the English Language*, *supra*, at 1470; *accord Black's Law Dictionary*, *supra*, at 1491. And *price* means "[t]he amount … of money … asked for or given in exchange for something else." *American Heritage Dictionary of the English Language*, *supra*, at 1437; *accord Black's Law Dictionary*, *supra*, at 1439. Putting these terms together, section 340B merely requires manufacturers to propose to sell covered drugs to covered entities at or below a specified monetary amount. Section 340B is thus silent about delivery conditions, which HRSA itself once acknowledged. *See* 1996 Guidance, 61 Fed. Reg. at 43,549–50. As explained below, we think that this silence preserves—rather than abrogates—the ability of sellers to impose at least some delivery conditions.

To begin, in construing the term *offer*, we must consider its meaning in the law of contracts. *See Molzof v. United States*, 502 U.S. 301, 305–06 (1992); A. Scalia & B. Garner, *Reading Law: The Interpretation of Legal Texts* 320–21 (2012). And background contract principles establish that an "offer"—like any ensuing contract—may contain both price and non-price terms. *See, e.g.*, 1 *Corbin on Contracts* § 1.11 (2023) (defining "offer" as "an expression by one [bargaining] party of assent to certain definite terms" provided that the other party will "express assent to the same terms"); *see also* Restatement (Second) of Contracts § 24 cmt. a (Am. L. Inst. 1981). Indeed, an offer often must contain some terms beyond the mere price

to be definite enough to bind the contracting parties. *See*, *e.g.*, Restatement (Second) of Contracts, *supra*, § 33 cmt. a; 1 *Williston on Contracts* § 4:22 (4th ed. 2023). And non-price terms typically include provisions about the place or manner of delivery. *See*, *e.g.*, U.C.C. §§ 2-307, 2-308, 2-503 (Am. L. Inst. & Unif. L. Comm'n 2022); 18 *Williston on Contracts*, *supra*, § 52:4. As a general matter, including such terms is fully consistent with making an "offer" at a specified "price."

Moreover, statutory silence implies that private parties may act freely, as the Supreme Court explained in *Christensen*. That case presented a question whether the Fair Labor Standards Act prohibited employers from imposing certain contractual conditions on employees. The government argued that because the statute did not expressly "*permit*" employers to impose the disputed conditions, they could not do so. 529 U.S. at 588. The Court said that position was "exactly backwards." *Id.* In its view, the dispositive question was whether the FLSA prohibited the conditions at issue, *see id.*, and statutory silence did not impliedly prohibit otherwise lawful conduct, *id.* at 582–83. The same principle governs here: Statutory silence implies that manufacturers *may* impose distribution conditions by contract, not that they are prohibited from doing so.

On balance, agency guidance reinforces our conclusion. For almost three decades—between section 340B's enactment in 1992 and the advisory opinion in 2020—HRSA construed the statute to allow manufacturers to insist on at least some reasonable conditions. The 1994 Guidance stated that manufacturers, in their contracts with covered entities, may "include provisions that address customary business practice, request standard information, or include other appropriate contract provisions." 59 Fed. Reg. at 25,114. The 1996 Guidance stated that manufacturers may limit distribution to

one contract pharmacy per covered entity; indeed, it purported to prohibit any more widespread distribution absent further administrative action. 61 Fed. Reg. at 43,555. And even the 2010 Guidance, which purported to abandon that limit, did not foreclose the possibility of other commercially reasonable distribution conditions. We recognize that this guidance was issued before Congress amended section 340B to require drug manufacturers to "offer" covered drugs "for purchase" by covered entities at or below a specified "price." Pub. L. No. 111-148, tit. VII, § 7102, 124 Stat. at 827. But for present purposes, that requirement is not meaningfully different from the parallel requirement, imposed by section 340B from its enactment, that the "price" manufacturers may charge for drugs "purchased by a covered entity" may not exceed specified amounts. *See* Pub. L. No. 102-585, § 602, 106 Stat. at 4967.

HRSA's current position also would produce absurd consequences. Consider United Therapeutics, which manufactures "specialty" drugs requiring an unusual degree of instruction and support. J.A. 540. To ensure patient safety—and reduce its own exposure to tort liability—the company makes these drugs available only through specialized pharmacies or healthcare providers. If that kind of restriction violated section 340B, the company would be compelled to distribute these drugs in a potentially dangerous manner. Or consider hypotheticals posited by Novartis: Suppose one covered entity insists on delivery in red boxes to minimize its processing costs and another insists on delivery at night when hospitals are least busy. Of course, we would enforce statutory text requiring such conditions. But we cannot plausibly interpret statutory silence to subject manufacturers to whatever delivery conditions any covered entity might find most convenient.

Finally, the Third Circuit has also rejected HRSA's current position. In *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696 (3d Cir. 2023), that court held that because section 340B is "silent about delivery," HRSA erred in concluding that the statute "requires drug makers to deliver drugs to an unlimited number of contract pharmacies." *Id.* at 703 (cleaned up). As explained above, we agree entirely.

B

HRSA resists this conclusion on five grounds. First, it invokes the proposition that there is no "such thing as a 'canon of donut holes.'" *Bostock v. Clayton Cnty.*, 140 S. Ct. 1731, 1747 (2020). In other words, if a "general statutory rule" applies by its terms, Congress's "failure to speak directly" to a covered case does not suggest a "tacit exception." *Id.* But no "general statutory rule" applies here. The requirement to "offer" drugs at a certain "price" does not prohibit distribution conditions, much less require the offeror to accede to any distribution terms demanded by the offeree.

Second, HRSA invokes the statutory audit and dispute-resolution mechanisms. But they serve to ensure compliance with the various obligations that section 340B imposes. They do not speak to the scope of those underlying obligations, such as what a manufacturer must do to make the requisite "offer" at the requisite "price." HRSA reasons that this enforcement scheme is carefully calibrated, which tends to suggest that it is exclusive. *See, e.g.*, *Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 209 (2002). Perhaps so, but that at most shows that section 340B establishes the precise metes and bounds of audits and administrative adjudications. It does not suggest that contractual limits on distribution are unlawful.

Third, HRSA cites legislative history. It notes that Congress, in enacting section 340B, rejected a proposal that

would have limited discounts to drugs dispensed through the "on-site pharmacy services" of covered entities. S. Rep. No. 102-259, at 2 (1992). But failures to enact legislation "are not reliable indicators of congressional intent." *Mead Corp. v. Tilley*, 490 U.S. 714, 723 (1989) (citing *Trailmobile Co. v. Whirls*, 331 U.S. 40, 61 (1947)). And particularly so here, given the sweeping nature of the proposed amendment, which would have categorically prohibited the use of any contract pharmacies. The rejection of that amendment, even if deemed significant, hardly suggests that Congress opted for the opposite extreme of categorically requiring manufacturers to deal with an unlimited number of contract pharmacies.

Fourth, HRSA invokes what Justice Scalia dubbed the "predicate-act canon," which reads into statutes "everything necessary" to make them "effectual." *Reading Law*, *supra*, at 192–93 (cleaned up). Likewise, the agency invokes cases disfavoring constructions that "would frustrate Congress' manifest purpose," *United States v. Hayes*, 555 U.S. 415, 426–27 (2009); make a statute "devoid of reason and effect," *Great-West Life*, 534 U.S. at 217–18; or make a statute "self-defeating," *Quarles v. United States*, 139 S. Ct. 1872, 1879 (2019). But in applying the predicate-act canon, courts must exercise caution "lest the tail of what is implied wag the dog of what is expressly conferred." *Reading Law*, *supra*, at 193. And "no legislation pursues its purposes at all costs." *Rodriguez v. United States*, 480 U.S. 522, 525–26 (1987) (per curiam). Under the section 340B scheme, therefore, wider distribution is not necessarily better. And the more limited distribution mechanisms used for nearly two decades, from 1992 to 2010, hardly rendered the scheme self-defeating or ineffectual. HRSA's generalized appeal to statutory purpose thus provides no basis for expanding section 340B beyond the most natural reading of its terms.

Fifth, HRSA relies on its own extreme hypotheticals. Suppose a manufacturer refuses to ship to any contract pharmacy, demands to deliver drugs at its own facility, or requires that a covered entity pick up its orders one pill at a time. The short answer is that no such conditions are before us in this case. The longer answer is that section 340B does require drug manufacturers to make an "offer," and even the manufacturers concede that this means at least a bona fide offer. Moreover, assessing the bona fides of an offer perhaps can take into account the historical context of section 340B, including the widespread use of contract pharmacies when that provision was enacted. Furthermore, some conditions may be onerous enough to effectively increase the contract "price," thus perhaps nudging it above the statutory ceiling. We are confident that the courts can sensibly adjudicate questions like these if they should arise in other cases. For now, we conclude only that HRSA's concern about unreasonable conditions fails to justify its atextual and ahistorical position that manufacturers may impose no distribution conditions at all.

IV

We turn now to the specific conditions at issue here. In the enforcement letters and before the district court, HRSA advanced a single, sweeping rationale for targeting the conditions favored by Novartis and United Therapeutics—its view that section 340B prohibits manufacturers from imposing *any* conditions on the delivery of covered drugs to covered entities. The district court rejected that position and then stopped, reserving for future cases the question whether the conditions at issue might be vulnerable based on some narrower challenge by the agency. 2021 WL 5161783, at *9.

HRSA urges us to go farther, to provide as much certainty as possible in our resolution of this case. That is an important

reason for proceeding, and several other considerations reinforce it. For one thing, on the legal questions presented, we review the district court's views *de novo* and the agency's views only under *Skidmore*. So we need not center our analysis around the conclusions or rationale of another decisionmaker. Moreover, HRSA does not seek to further develop any predicate facts or to further explain its position as to the specific conditions under review. Precisely the opposite: At oral argument, we repeatedly asked the agency if it wanted that opportunity, either on remand or in future proceedings. In response, HRSA repeatedly urged us to decide the lawfulness of the disputed conditions on their face, in this case and on the present record. Finally, the answers are readily apparent.

Start with United Therapeutics. For each covered entity, the company is willing to work with at least one contract pharmacy designated or previously used by the entity. In ordinary usage, nobody would say that this policy undermines the bona fides of any "offer" or increases the contract "price." Moreover, this policy conforms to business practices that governed section 340B sales during much of the program's history. And until 2010, the agency itself took the position that a manufacturer not only could, but *must*, refuse to work with more than one contract pharmacy per covered entity. As for United Therapeutics' further requirement that contract pharmacies provide claims data for contract-pharmacy orders, the 1994 Guidance itself opined that drug manufacturers may require "standard information" from covered entities. 59 Fed. Reg. 25,114. Likewise, the 2010 Guidance opines that covered entities must "maintain auditable records sufficient to demonstrate continued compliance with 340B requirements." 75 Fed. Reg. at 10,274. And the only record evidence on this point indicates that the burden of providing the claims data is "minimal." J.A. 577. We recognize that this evidence appears in the district-court record but not the administrative record.

However, HRSA afforded no formal adjudicatory process before issuing the enforcement letters; it seeks no remand to further develop a record before some administrative adjudicator; and it urges us to address the condition on the record currently before us.

When this case was briefed and argued, Novartis sought to work only with contract pharmacies within 40 miles of covered entities that were hospitals. We need not pass upon that condition because Novartis has since abandoned it. Now, Novartis intends to deliver section 340B drugs to a covered entity's in-house pharmacy or to a single contract pharmacy designated by the covered entity. For reasons explained, that restriction neither precludes Novartis from making a bona fide "offer" nor increases its contract "price." The restriction is also consistent with historic practices under the section 340B program. It is indistinguishable from the parallel provision adopted by United Therapeutics. And it is indistinguishable from the distribution conditions upheld by the Third Circuit in *Sanofi Aventis*. *See* 58 F.4th at 701, 706.

V

In sum, we hold that section 340B does not categorically prohibit manufacturers from imposing conditions on the distribution of covered drugs to covered entities. We further hold that the conditions at issue here do not violate section 340B on their face. We do not foreclose the possibility that other, more onerous conditions might violate the statute. Likewise, we do not foreclose the possibility that these conditions may violate section 340B as applied in particular circumstances—if, for example, HRSA could show that a specific covered entity for some reason could not supply the claims information demanded by United Therapeutics. The district court correctly set aside the enforcement letters under

review, while reserving the possibility of future enforcement under theories of liability narrower than the one pressed here.

Affirmed.