United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued December 18, 2025 Decided August 18, 2026

No. 25-5054

SERVIER PHARMACEUTICALS LLC,
APPELLANT

v.

ROBERT F. KENNEDY, JR., IN HIS OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES AND MEHMET OZ, IN HIS OFFICIAL CAPACITY AS ADMINISTRATOR FOR THE CENTERS FOR MEDICARE AND MEDICAID SERVICES,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:24-cv-02664)

William Perdue argued the cause for appellant. With him on the briefs were *Kolya Glick* and *Clare Saunders*.

Sean R. Janda, Attorney, U.S. Department of Justice, argued the cause for appellees. With him on the brief were *Brett A. Shumate*, Assistant Attorney General, *Michael S. Raab*, Attorney, and *James F. Segroves*, Attorney, U.S. Department of Health and Human Services.

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

Opinion for the Court filed by *Circuit Judge* MILLETT.

MILLETT, *Circuit Judge*: To combat high drug prices, Congress enacted the Medicare Manufacturer Discount Program in 2022. The Program requires drug manufacturers to discount the price of certain drugs covered by Medicare Part D starting in 2025. But Congress allowed two types of drug manufacturers to phase in their discount obligations over several additional years: "specified manufacturers" and "specified small manufacturers[.]" 42 U.S.C. § 1395w-114c(g)(4)(B)–(C). At a high level, a specified manufacturer is a manufacturer whose "total expenditures"—that is, sales—under Part D are below a particular threshold. A specified manufacturer qualifies as a "specified small manufacturer" if 80% or more of its sales under Part D came from a single drug. In both instances, qualification depends on data drawn from one year: 2021.

In April 2021, Servier Pharmaceuticals LLC acquired a drug called Tibsovo from Agios Pharmaceuticals, along with the stock of the drug that Agios had already manufactured. This pre-existing stock was dispensed to Part D patients through the end of the year. Servier later switched over to selling new tablets that it manufactured, but those new tablets were not dispensed to a Part D patient until February 2022. Servier did not sell any other drug to a Part D patient in the United States in 2021.

When Servier requested to phase in its discount obligations in the Medicare Manufacturer Discount Program, the Centers for Medicare & Medicaid Services ("CMS") designated it a specified manufacturer. The agency acknowledged that Servier had manufactured some Tibsovo in

2021, but found that none of those tablets were sold under Part D that year. As a result, Servier's "total expenditures" for 2021 were $0, making it a specified manufacturer. But since, necessarily, no single drug made up 80% or more of those non-existent sales, CMS determined that Servier was not a specified small manufacturer.

Servier sued the Secretary of Health and Human Services and the Administrator for CMS, contending that the law required CMS to credit it with the 2021 sales of the Tibsovo tablets that Agios made.

The district court granted summary judgment for the government, and we affirm. For each manufacturer, the "total expenditures" for a specified small manufacturer drug are calculated based on the units of that drug that the manufacturer actually "produced, prepared, propagated, compounded, converted, or processed[.]" 42 U.S.C. § 1395w-114c(g)(4)(C)(ii)(I)–(II). Servier has not shown that it undertook any of those activities with respect to any Part D sales of Tibsovo tablets in 2021, and so CMS correctly found that Servier does not qualify as a specified small manufacturer.

I

A

Medicare is a federal program administered by the Centers for Medicare & Medicaid Services, which is part of the Department of Health and Human Services. *See* 42 U.S.C. §§ 1395–1395*mmm*. Medicare provides health insurance coverage for people aged 65 or older, people with certain disabilities, and people with end-stage renal disease. *See id.* §§ 1395c, 1395j, 1395w-21(a), 1395w-101(a).

Medicare has four parts. Parts A through C allow people to enroll in health insurance programs provided by the government or by private insurance companies. Part D, at issue here, is an opt-in program offering prescription drug coverage to Medicare enrollees. *See Cares Community Health v. HHS*, 944 F.3d 950, 954 (D.C. Cir. 2019); *Action All. of Senior Citizens v. Sebelius*, 607 F.3d 860, 861 (D.C. Cir. 2010).

When Medicare Part D was first enacted in 2003, drug costs were shared between the patient, the government, and each patient's private insurer. *See* 42 U.S.C. § 1395w-102(b) (2003). The government provided subsidies to low-income patients, *see id.* § 1395w-114(a), but the remaining coverage gap still posed a financial challenge to many patients.

Congress began to address that gap in 2010. As part of the Affordable Care Act, Congress required insurance companies to increase their coverage. *See generally* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010). Congress also required drug manufacturers to sign agreements with CMS under which the manufacturers would discount certain drugs as part of the newly formed Coverage Gap Discount Program. *Id.* at 461–468.

Unsatisfied with the results, Congress set out once again to address high drug prices in the Inflation Reduction Act of 2022. *See* Pub. L. No. 117-169, 136 Stat. 1818, 1833–1905; S. REP. No. 116-120, at 1 (2019) (considering bill "to lower prescription drug prices in the Medicare * * * program[]"). Congress did so in part by replacing the Coverage Gap Discount Program with the Manufacturer Discount Program ("Program"). *See* 136 Stat. at 1880–1892. This Program requires drug manufacturers to provide discounts for drugs once patients reach an out-of-pocket threshold. *See id.*; S. REP. No. 116-120, at 15.

The Program took effect in 2025, but Congress allowed two categories of manufacturers—"specified manufacturers" and "specified small manufacturers"—to phase in their discount obligations over time by providing only a 1% discount in 2025, and ramping up to the full 10% or 20% discount in stages over the next several years. 42 U.S.C. § 1395w-114c(b)(1)(A), (g)(4)(B)–(C).

Central to this appeal is the boundary between those two categories. In broad strokes, a *specified manufacturer* is a drug manufacturer that had low total sales under Part D in 2021, whereas a *specified small manufacturer* is a specified manufacturer that was also highly specialized in 2021, meaning that its Part D sales predominantly came from one drug. In other words, Congress provided a ramp-up period for (i) small manufacturers and (ii) small and highly specialized manufacturers that allows them both to ease into the discount obligation gradually.[1]

To be a *specified* manufacturer, an entity must satisfy three criteria: (1) It must have had an existing agreement with CMS under the old Coverage Gap Discount Program in 2021; (2) its Part D sales in 2021 must be less than 1% of the industry-wide total; and (3) its Part B sales in 2021 also must be less than 1% of the industry-wide total. 42 U.S.C. § 1395w-114c(g)(4)(B)(ii)(I).

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[1] While the statute speaks in terms of a manufacturer's "expenditures" for a drug, *see* 42 U.S.C. § 1395w-114c(g)(4)(C)(ii), that term refers to the Part D plan's costs of providing the drug to a patient, *id.* §§ 1395w-114c(g)(4)(D), 1395w-115(b)(3). So, from Servier's perspective, the term loosely refers to its sales to Part D patients. We frequently use the simpler term "sales" in this opinion.

Then, to be a *specified small* manufacturer, a specified manufacturer also must (1) manufacture a covered Part D drug in 2021, (2) for which the total sales under Part D for any one of its specified small manufacturer drugs are (3) "equal to or more than 80 percent of the total [sales] under [Part D] for all specified small manufacturer drugs of the manufacturer[.]" 42 U.S.C. § 1395w-114c(g)(4)(C)(ii)(I). Put more simply, 80% or more of a specified manufacturer's Part D sales of "specified small manufacturer drugs" in 2021 must come from one of those drugs.

That last term, "specified small manufacturer drug[,]" has its own statutory definition:

> with respect to a specified small manufacturer, for 2021, an applicable drug that is *produced, prepared, propagated, compounded, converted, or processed by the manufacturer*.

42 U.S.C. § 1395w-114c(g)(4)(C)(ii)(II)(aa) (emphasis added). The term "applicable drug[,]" for present purposes, simply means a drug covered under Part D. *Id.* § 1395w-114c(g)(2).

Because specified-manufacturer status and specified-small-manufacturer status are assessed entirely by reference to a manufacturer's drug sales in the year 2021—the year before the law was passed—no manufacturer could take any action to affect its status under the new Program.

The two statuses come with different benefits. In very broad strokes, specified manufacturers may phase in their discount obligations only for the units dispensed to low-income Part D patients, *see* 42 U.S.C. § 1395w-114c(g)(4)(B)(i), whereas specified small manufacturers get to phase in their

discount obligations across *all* applicable Plan D patients, regardless of income, *see id.* § 1395w-114c(g)(4)(C)(i).

B

The Inflation Reduction Act of 2022 authorized the Secretary of Health and Human Services to implement its provisions (including the Program) "by program instruction or other forms of program guidance." 136 Stat. at 1892. Accordingly, CMS issued Program guidance in the form of two documents in November 2023: *Medicare Part D Manufacturer Discount Program Final Guidance* (Nov. 17, 2023) ("Final Guidance"), J.A. 28–84; and *Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers* (Nov. 17, 2023) ("Methodology Memorandum"), J.A. 85–93.

1

The Final Guidance generally restates the statutory provisions and definitions. But it also elaborates on their meaning in a few instances. For one, the Final Guidance says that the term "manufacturer" includes "entities otherwise engaged in repackaging or changing the container, wrapper, or labeling of any applicable drug in furtherance of the distribution of [that] drug from the original place of manufacture" to the final entity that sells or delivers the drug to the patient. J.A. 83.

For another, the Final Guidance explains that CMS will use several sources of information to determine which manufacturers are eligible for phase-ins. J.A. 55. Those data sources include "Part D [prescription dispensing] data[] and ownership information submitted by manufacturers." J.A. 55. The Final Guidance also refers the reader to the Methodology

Memorandum for a description of the methodology, data sources, and calculations that CMS will use to identify specified manufacturers and specified small manufacturers. J.A. 55–56.

Lastly, the Final Guidance delineates a review process for entities deemed ineligible for phase-ins. Dissatisfied entities can request a "recalculation" of the decision by sending an email to CMS that "clearly identif[ies] the * * * labeler code(s) relevant to the request, describe[s] the issue(s) forming the basis of the request for recalculation, and include[s] or describe[s] any relevant supporting information." J.A. 57. CMS's recalculation decision is "final and binding[.]" J.A. 57.

2

The Methodology Memorandum outlines the three steps that CMS will take to determine if a "specified manufacturer" is also a "specified small manufacturer." *First*, CMS selects a specified small manufacturer drug of that entity, grouping together multiple strengths and dosages of the drug to the extent they exist. J.A. 91. *Second*, CMS calculates the entity's Part D sales for that drug in 2021. J.A. 91–92. *Third*, CMS divides the entity's Part D sales for that drug by its Part D sales across all of its specified small manufacturer drugs in 2021. J.A. 92. CMS then repeats this process for each specified small manufacturer drug of that entity. If the sales of any drug are "equal to or greater than 80 percent" of that manufacturer's total sales, then the entity qualifies as a specified small manufacturer. J.A. 92.

The Methodology Memorandum also explains that "CMS will attribute Part D [sales] for a drug * * * to a specified manufacturer" by relying on each drug's National Drug Code(s). J.A. 91.

A National Drug Code is "a numeric code" that identifies the "labeler, product, and package size and type" of each drug product. 21 C.F.R. § 207.33(a). As relevant here, the first four to six digits of each code make up the "labeler code." *Id.* § 207.33(b)(1)(i). That code is a unique identifier that the Food and Drug Administration ("FDA") assigns to "[e]ach person who engages in manufacturing, repacking, relabeling, or private label distribution of a drug[.]" *Id.* § 207.33(c)(1); *see also id.* § 207.33(d).

C

1

Servier Pharmaceuticals LLC entered the market in 2018. J.A. 111. At the start of 2021, Servier marketed only two drugs in the United States, Asparlas and Oncaspar. J.A. 111–112. Neither drug had any Part D sales in 2021. J.A. 114.

In April 2021, Servier acquired Agios Pharmaceuticals' oncology division. J.A. 112. As part of this transaction, Servier obtained ownership of the New Drug Application ("NDA") for a cancer-treating drug called Tibsovo, the legal rights and responsibilities for Tibsovo, and the existing stock of Tibsovo tablets previously made by Agios and that bore Agios's labeler code. J.A. 112; J.A. 122.

Servier soon began making Tibsovo tablets with its own labeler code on them. In the meantime, Servier continued to sell its supply of Agios tablets to, as relevant here, Part D patients. J.A. 112. While Servier released some tablets bearing its own labeler code in late 2021, none of them were sold to Part D patients until 2022, after the end of the statutory reference period. J.A. 112; *see* J.A. 128–129.

2

Servier applied for special designation under the Manufacturer Discount Program. Because Servier's other two drugs resulted in no Part D expenditures in 2021, the success of its application turned on whether Tibsovo's expenditures would be attributed to Servier rather than to Agios. If so, 100% of its Part D expenditures in 2021 would come from one drug, qualifying Servier as a specified small manufacturer. If not, Servier would still qualify as a specified manufacturer by dint of its low total expenditures, but would have to begin paying discounts right away on the drugs dispensed to non-low-income patients.

In April 2024, CMS informed Servier that it qualified as a "specified manufacturer," but not as a specified small manufacturer. J.A. 108.

Servier filed a recalculation request with CMS, arguing that Tibsovo qualifies as "a specified small manufacturer drug of Servier" because "Servier owned Tibsovo, including [its] New Drug Application[,]" and "acquired responsibility for manufacturing Tibsovo" in April 2021. J.A. 111 (formatting modified). Servier acknowledged that Tibsovo bore Agios's labeler code and remained on Agios's Coverage Gap Discount agreement throughout 2021. J.A. 112. But that was irrelevant, according to Servier, because it had "accepted responsibility for coverage gap discounts for Tibsovo and fully reimbursed Agios for such discounts post-acquisition." J.A. 114 (formatting modified).

CMS denied the recalculation request. It explained that its data showed that all Tibsovo tablets dispensed in 2021 bore Agios's labeler code, which remained on Agios's Coverage

Gap Discount Program agreement. J.A. 119. In contrast, the "Part D expenditures for Servier's labeler code * * * were $0.00 in 2021." J.A. 119. CMS added that Servier "first marketed [Tibsovo] under its FDA-assigned labeler code *after* 2021" and, accordingly, "in 2021, Tibsovo was not attributable to Servier, as determined by the labeler code." J.A. 119 (formatting modified).

3

Servier sued Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services, and Mehmet Oz, in his official capacity as Administrator for CMS, in September 2024, seeking a declaratory judgment that Servier qualifies as a specified small manufacturer. After the parties cross-moved for summary judgment, the district court granted the governmental defendants' motion and denied Servier's. *See Servier Pharms. LLC v. Becerra*, No. 24-cv-2664, 2025 WL 27352, at *1 (D.D.C. Jan. 3, 2025).

The district court held that CMS's denial of specified-small-manufacturer status was lawful because Servier failed to satisfy two independent statutory requirements. *Servier*, 2025 WL 27352, at *10–17. First, the court read 42 U.S.C. § 1395w-114c to attribute a drug's expenditures only to the entity or entities that manufactured, or created, the units of the drug that were sold under Part D in 2021. *Id.* at *11–14. On that basis, the district court agreed with CMS that Tibsovo was Agios's "specified small manufacturer drug"—not Servier's—because all the Tibsovo sold under Part D in 2021 "came from the existing stock of the drug that Agios had manufactured and that Servier acquired[.]" *Id.* at *10. Second, the district court concluded that Servier failed to satisfy the requirement for Tibsovo to be listed on Servier's 2021 Coverage Gap Discount Program agreement rather than Agios's. *Id.* at *11–12, *15.

The district court then rejected Servier's arbitrary and capricious challenges. The court explained that CMS did not err by using labeler codes to identify a drug's manufacturer. *Servier*, 2025 WL 27352, at *17–18. It reasoned that Servier's objection to CMS's use of this data was really a gripe with CMS's statutory interpretation—a question of law that rose and fell with Servier's contrary-to-law arguments. *Id.* The court then held that CMS had adequately explained its decision, and that a remand would be pointless in any event because there would be nothing left for CMS to do since the court had decided what the statute meant. *Id.* at *18–19.

Servier timely appealed.

II

The district court had jurisdiction under 28 U.S.C. § 1331. We have jurisdiction under 28 U.S.C. § 1291.

Under the Administrative Procedure Act ("APA"), we will set aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]" 5 U.S.C. § 706(2)(A). When the district court reviews agency action under the APA, this court reviews the district court's decision *de novo*. *Cigar Ass'n of America v. FDA*, 964 F.3d 56, 61 (D.C. Cir. 2020). We likewise evaluate an agency's interpretation of a statute without deference to the district court or the agency. *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2262, 2266 (2024).

On appeal, Servier contends that CMS erroneously denied it specified-small-manufacturer status based on a misinterpretation of 42 U.S.C. § 1395w-114c's provision for attributing Medicare drug sales. Servier also argues that

CMS's decision was arbitrary and capricious because the agency relied on a flawed data source, failed to adequately explain its reasoning, and treated similarly situated parties differently.

We agree with the district court that CMS properly determined that Servier was not a specified small manufacturer. That is because Servier did not actually "produce[], prepare[], propagate[], compound[], convert[], or process[]" any units of Tibsovo sold under Part D in 2021. 42 U.S.C. § 1395w-114c(g)(4)(C)(ii)(II). Given that ruling, we need not decide whether Servier satisfied the other statutory requirements to be a specified small manufacturer.

Finally, we reject Servier's arbitrary and capricious challenges, some of which simply repackage its failed contrary to law challenges, and the rest of which are misplaced.

III

Because all agree that Servier's drugs Asparlas and Oncaspar did not result in any Part D sales in 2021, specified-small-manufacturer status turns entirely on whether the statute counts any amount of Tibsovo sold under Part D in 2021 as part of Servier's "total expenditures"—that is, its sales. *See* Resp. Br. 11; J.A. 114 (Servier Recalculation Request).

Servier asserts that the statute required CMS to credit it with Tibsovo's Part D sales in 2021 for two reasons.

First, Servier argues that the statutory calculation of "total expenditures" must be made by reference to ownership and manufacture of a drug product (*e.g.*, Tibsovo) as a whole, and not with reference to the individual tablets actually sold into Part D and who manufactured them. That would mean that, by

owning and manufacturing *any* amount of Tibsovo in 2021, Servier could claim Tibsovo as one of its "specified small manufacturer drugs" and count Tibsovo's 2021 sales as part of its "total expenditures" regardless of whether a single one of those tablets was actually dispensed under Part D in 2021.

Second, and alternatively, Servier contends that, even if total expenditures is measured on a Part-D tablet-by-tablet basis, Servier was a "manufacturer" of those Part D tablets because it owned the NDA for Tibsovo, performed quality-control checks, and updated the label for its purchased stock of Tibsovo tablets.

Neither of those arguments holds up given the plain statutory text, the facts found by CMS, and Servier's forfeiture of its arguments pertaining to its quality-control and label-updating actions.

A

1

CMS properly determined that Servier was not a specified small manufacturer by examining whether it manufactured any tablets sold to Part D patients in 2021, rather than by assessing Tibsovo sales as a whole. Servier's argument to the contrary has three key steps: (1) Servier created some Tibsovo tablets in 2021; (2) which makes Servier a "manufacturer" of Tibsovo *as a product*, and Tibsovo a "specified small manufacturer drug" of Servier's; and (3) the "total expenditures" for Tibsovo *as a product*—regardless of who manufactured which tablet—exceeded 80% of the total sales for all of Servier's qualifying Part D products combined. Servier Opening Br. 25, 27–28, 33. In Servier's view, it is irrelevant that none of the tablets it manufactured actually generated any 2021 Part D sales.

Servier's mixing and matching of select pieces of statutory text favors what helps it and ignores what does not. We reject that bespoke reading, for four reasons.

First, Servier's product-wide reading is incompatible with the full statutory text that defines a specified small manufacturer as "a manufacturer of an applicable drug for which, in 2021":

> the total expenditures under part D for any one of the specified small manufacturer drugs of the manufacturer * * * are equal to or more than 80 percent of the total expenditures under [Part D] for all specified small manufacturer drugs of the manufacturer[.]

42 U.S.C. § 1395w-114c(g)(4)(C)(ii)(I).

"[S]pecified small manufacturer drug[,]" in turn, is defined as a Part D drug "that is produced, prepared, propagated, compounded, converted, or processed by the manufacturer" in 2021. 42 U.S.C. § 1395w-114c(g)(4)(C)(ii)(II)(aa).

Putting those two definitions together, Congress said directly that the "total expenditures"—that is, sales—used to qualify an entity as a specified small manufacturer are (1) the 2021 Part D expenditures *for* (2) the drug stock that was "produced, prepared, propagated, compounded, converted or processed" *by* that business. This court must give effect to all of Congress's words, including its prepositions identifying who must do what with respect to the drug sold to Part D patients in 2021. *Cf. Telecommunications Research & Action Ctr. v. FCC*, 801 F.2d 501, 517–518 (D.C. Cir. 1986) (finding decisive Congress's use of the preposition "under" instead of

"by"). While Servier wants to look only at the drug itself, it forgets that Congress was creating a *manufacturer*-specific exception. Unsurprisingly, then, Congress directed CMS to focus on the manufacturer of the drug—that is, the producer, preparer, propagator, compounder, converter, or processor of those tablets dispensed to Part D patients.

Given that text, Servier's legal title to the Tibsovo drug product is beside the point. What matters is that the Tibsovo tablets that made their way into Medicare Part D sales in 2021 were not produced, prepared, propagated, compounded, converted or processed *by* Servier.

Second, the statutory structure confirms that reading. When Congress created the Manufacturer Discount Program in 2022, Section 1395w-114c already contained the catch-all term "applicable drug[.]" 42 U.S.C. § 1305w-114c(g)(2). The statute repeatedly uses that term as a default to refer to the drugs involved in the Program. *See, e.g.*, *id.* § 1305w-114c(b) ("An agreement under this section shall require the manufacturer to provide * * * discounted prices for applicable drugs of the manufacturer" dispensed on or after January 1, 2025.).

Notably, when Congress prescribed how to calculate the "total expenditures" for a given manufacturer, it departed from that established terminology. 42 U.S.C. § 1395w-114c(g)(4)(C)(ii)(I)(bb). Congress introduced a new and more specific term—"specified small manufacturer drug"—and defined it as "an applicable drug *that is produced, prepared, propagated, compounded, converted, or processed by the manufacturer*." *Id.* § 1395w-114c(g)(4)(C)(ii)(II)(aa) (emphasis added). Congress then directed CMS to calculate the total expenditures under Part D in 2021 for each of the "specified small manufacturer drugs" of each manufacturer, *id.*

§ 1395w-114c(g)(4)(C)(ii)(I)(bb), not each of the "applicable drugs" of that manufacturer. In other words, the total expenditures must come from the drug or portion of a drug that the business actually "produced, prepared, propagated, compounded, converted, or processed."

If Congress, like Servier, deemed who manufactured the relevant Part D tablets irrelevant, Congress would have stuck with the preexisting term "applicable drugs"—or omitted any reference to manufacturing and manufacturers altogether. Servier's approach, in other words, asks us to read Congress's calibrated definition of a "specified small manufacturer drug" out of the statute. This court, however, must assume Congress meant the words it said—all of them. *See Pulsifer v. United States*, 144 S. Ct. 718, 731–732 (2024) ("When a statutory construction thus renders an entire subparagraph meaningless, * * * the canon against surplusage applies with special force.") (formatting modified).

Third, and relatedly, the whole reason Congress adopted a manufacturer-focused definition of the relevant drug expenditures is that the Manufacturer Discount Program is—as the name says—all about manufacturers. *See* 42 U.S.C. § 1395w-114c(a) ("The Secretary shall establish a *manufacturer* discount program" under which "the Secretary shall enter into agreements * * * with *manufacturers*[.]") (emphases added); *id.* § 1395w-114c (repeatedly referring to "a manufacturer"; "the manufacturer"; and "such manufacturer"). As the government notes, "[t]he statute uses the word *manufacturer* over a dozen times[.]" Resp. Br. 27 (formatting modified). Congress's repetition of this term reflects its focus on manufacturing as an essential characteristic of entities that are covered by the Program and that may further qualify for phase-in eligibility. Congress chose not to extend its program and phase-in exceptions to those like Servier who merely own

another manufacturer's product or who manufacture only tablets that never entered into the Part D program in 2021.

Fourth, this straightforward reading comports with the broader statutory scheme. *See Mullin v. Doe*, 146 S. Ct. 2121, 2136 (2026) ("We evaluate the provision at issue with a view to its place in the overall statutory scheme, not just in a single subsection.") (formatting modified); *Dubin v. United States*, 143 S. Ct. 1557, 1566 (2023) ("A statute's meaning does not always turn solely on the broadest imaginable definitions of its component words. Instead, linguistic and statutory context also matter.") (formatting modified) (internal citation omitted).

In redesigning Medicare Part D in 2022, Congress sought to "lower prescription drug prices" by requiring manufacturers to discount certain drugs. S. REP. NO. 116-120, at 1. At the same time, Congress recognized that enforcing the immediate payment of discounts could unduly burden small and specialized drug manufacturers within the Part D program, and so allowed those manufacturers—and only those manufacturers—to phase in their discount obligations. *See* 42 U.S.C. § 1395w-114c(g)(4)(C) (titled "Phase-in for specified small manufacturers"); 136 Stat. at 1885. Reading "specified small manufacturer drug" to focus on the identity of the actual manufacturer of the Part D tablets effectuates Congress's purpose of identifying those who created the drugs that were actually used in the Part D program in 2021. Congress, after all, defined "total expenditures" based on sales of a drug within Part D, and not broadly to all patients.

Servier's proposal, by contrast, is contextually implausible. Here, Tibsovo resulted in $89 million of Part D expenditures in 2021, $66 million of which came after Servier acquired Tibsovo in April 2021. Yet Servier suggests that CMS should attribute the full $89 million in sales to Servier.

See Servier Opening Br. 28, 35; Servier Reply Br. 7, 9. Crediting Servier with even those expenditures that predate its acquisition of Tibsovo and that come from Tibsovo tablets with which Servier had no manufacturing involvement whatsoever makes no sense in a statute that is focused on differentiating manufacturers by size and level of diversification.

At other times in its briefing, Servier says CMS should have attributed only "$66 million out of the $89 million" to Servier. Servier Reply Br. 2. But Servier had nothing to do with the actual manufacturing of the tablets tied to that $66 million. Servier's inconsistency underscores that neither of its approaches maps onto the statutory text or design.

2

Servier's remaining arguments do not move the needle.

First, Servier argues that, if Congress had wanted a tablet-by-tablet analysis, Congress could have instructed CMS to calculate "the total expenditures under part D *for units of* any one of the specified small manufacturer drugs of the manufacturer[.]" Servier Opening Br. 30.

That Congress may have had alternative ways of articulating its manufacturer-specific focus does not change the clarity of the words Congress did employ, as confirmed by statutory context. After all, Congress could have implemented Servier's proposed reading by directing CMS to calculate "total expenditures" for each drug "as a whole," or each drug "marketed by a pharmaceutical company." But doing so would have required abandoning entirely the definition's focus on the small and non-diversified manufacturers Congress was helping. At the end of the day, this court's job is to interpret the text Congress wrote using settled tools of statutory

construction. Having done so, a game of competing "what ifs" will not change the answer.

Second, Servier points out that the statute treats the different forms (such as the different dosages) of a drug as one, and contends that "total expenditures" must also refer to all expenditures for Tibsovo as one drug. *See* Servier Opening Br. 27; 42 U.S.C. § 1395w-114c(g)(2)(A)(i).

But aggregating drug forms is very different than aggregating manufacturers and owners. The former fits with Congress's goal of identifying small manufacturers and those with non-diverse portfolios. The statutory inquiry, after all, is manufacturer-specific, not drug-specific. *See* 42 U.S.C. § 1395w-114c(g)(2)(A), (g)(4)(B)(ii)(I), (g)(4)(C)(ii)(I) (beginning the inquiry by asking whether an entity is "a manufacturer of an applicable drug"); *id.* § 1395w-114c(g)(4)(C)(ii) (referring to that entity as "the manufacturer" or "such manufacturer").

Third, Servier directs this court to a provision that forbids one manufacturer from retaining its specified-small-manufacturer status "if [it] is acquired after 2021 by another manufacturer that is not a specified small manufacturer," 42 U.S.C. § 1395w-114c(g)(4)(C)(ii)(III). *See* Servier Opening Br. 46. Servier argues that the absence of an identical provision for acquisitions occurring in 2021 implies that there is no restriction on transfers of status within that year.

That hardly gets Servier where it wants to go. Servier, after all, does not argue that the portion of Agios it acquired qualified for and should have retained small-specified-manufacturer status. Nor does Servier develop any argument that Agios's specified-small-manufacturer status (if any)

would have transferred automatically to Servier upon acquisition. Certainly nothing in the text suggests that.

That does not mean that acquisitions that occurred in 2021 are always irrelevant. Under the statutory text, their import will depend on what actions the acquiring entity took in 2021 with regard to the actual manufacture of the acquired drug and its Part D sales.

Fourth, Servier points out that adopting its reading would not create perverse incentives for manufacturers that do not qualify as small to try to game the system by acquiring other drugs or entities because qualification for the exception is timebound to events in 2021. *See* Servier Opening Br. 34–35. That may be. But this court's job is to hew to Congress's text, not to freelance one-off exceptions under a no-harm, no-foul theory of statutory construction.

B

Taking a different tack, Servier argues that it was, as a matter of law, the manufacturer of the Tibsovo tablets sold under Part D in 2021 because it (i) owned Tibsovo's NDA, (ii) performed quality control of Tibsovo tablets created by Agios, and (iii) updated Tibsovo's labeling. Servier Opening Br. 36–48. Servier offers to submit evidence on remand of these activities, along with evidence that it, in fact, created at least one Tibsovo tablet sold under Part D in 2021. *Id.* at 16–17, 41, 53 n.3; Servier Reply Br. 31–32 & n.1. A number of these arguments are forfeited, and those that are not run headlong into contrary statutory text.

1

Servier argues that its mere ownership of Tibsovo's NDA means that it "propagated" the drug because "no other manufacturer * * * could introduce Tibsovo into interstate commerce without Servier's permission." Servier Opening Br. 36–37, 41. Servier emphasizes that, as the NDA holder, it assumed all "rights and responsibilities" for Tibsovo. *Id.* at 36–41.

While the government contends that this argument was not preserved below, the record shows otherwise. *See, e.g.*, J.A. 111 (Servier arguing to CMS that it had "misunderst[ood]" Servier's "ownership of Tibsovo" and that Servier "acquired responsibility" for manufacturing Tibsovo in April 2021); Servier Mot. for Summ. J. at 13, ECF No. 8-1 (arguing that "Servier owned Tibsovo beginning on April 1, 2021"); Mot. Hr'g Tr. 11:9–12:23, ECF No. 21 (arguing that "all that has to be * * * determined is who owns the economic interest [when] expenditures occurred, who was the holder of the NDA?"). The district court, in fact, ruled on the issue and rejected Servier's arguments based on the ordinary meaning of "propagate" and the *noscitur a sociis* canon of statutory construction. *Servier*, 2025 WL 27352, at *17.

Having won the forfeiture battle, Servier nonetheless loses the interpretive war.

a

First, the ordinary meaning of "propagate" has to do with an increase in number or amount. *See, e.g.*, *Propagate*, WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1817 (3d ed. 2002) ("to cause to continue or increase by natural reproduction"; "to cause to spread out and affect a greater

number or greater area"; "to reproduce or accomplish incidence of elsewhere"); *Propagate*, OXFORD ENGLISH DICTIONARY (3d ed. revised 2007) ("to cause * * * to reproduce or multiply"; "to produce (a new individual) by natural processes *from* a parent stock, seed, etc.").

Servier's focus on the legal rights it possesses or the legal obstacles it removed bears no resemblance to propagate's ordinary meaning. Nothing about Servier's mere ownership of Tibsovo's NDA caused the stock of *previously manufactured* Tibsovo tablets that it purchased to "increase" in number.

Second, Section 1395w-114c specifies how a manufacturer can propagate a drug: "either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or [both]." 42 U.S.C. § 1395w-114c(g)(5). That language refers to the physical creation of the drug, not to paper title or legal oversight.

Third, the "neighboring words" confirm that Congress meant what it said. *Learning Res., Inc. v. Trump*, 146 S. Ct. 628, 643 (2026); *see Dubin*, 143 S. Ct. at 1570 (A term "should be read in a similar manner to its companions."). Here, the words accompanying "propagate" all encompass means of physically creating or reproducing the drug itself. "Produce" means "to cause to have existence or to happen"; "to give being, form, or shape to" or to "make" or "manufacture[.]" MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 991 (11th ed. 2020). "Prepare" means "to put together" or to "compound[.]" *Id.* at 980. "Compound" means "to put together (parts) so as to form a whole[,]" to "combine[,]" or "to form by combining parts[.]" *Id.* at 255. "Convert" means "to alter the physical or chemical nature or properties of esp[ecially] in manufacturing[.]" *Id.* at 273. Finally, "process" means "to

subject to a special process or treatment (as in the course of manufacture * * *)[.]" *Id.*

All of those meanings give effect to Congress's textual focus on who physically created and manufactured the pills provided to Part D patients. None of them share Servier's focus on post-manufacture ownership or legal authority. *Cf. United States v. Fields*, 53 F.4th 1027, 1049 (6th Cir. 2022) ("When used in connection with a word like * * * 'drug,' the words in [21 U.S.C. § 802(15)]"—"production, preparation, propagation, compounding, or processing"—"connote * * * the creation of a final product from component ingredients[.]"); *id.* at 1049 n.14 (collecting definitions).

Fourth, when Congress wants to cast a wider net, it knows how to do so. The Drug Price Negotiation Program was enacted on the same day and in the same Public Law as the Manufacturer Discount Program. *See* 136 Stat. at 1833–1854. In the Drug Price Program, Congress defined "manufacturer" by incorporating a statutory definition that is identical to the Manufacturer Discount Program's definition *except* that Congress added entities engaged "in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products" to the former definition. 42 U.S.C. § 1320f(c)(1) (referencing 42 U.S.C. § 1395w-3a(c)(6)(A), which references 42 U.S.C. § 1396r-8(k)(5)). That definition is no doubt more to Servier's liking. But it is not the definition Congress chose for the Manufacturer Discount Program at issue here.[2]

[2] For that same reason, Servier's reliance on the broader definition of manufacturer in CMS's guidance under the Drug Price Negotiation Program is beside the point. *See* Servier Opening Br. 43; *see also Loper Bright*, 144 S. Ct. at 2273. Similarly irrelevant is a Medicaid Drug Rebate Program regulation interpreting the Drug

b

Servier's counterarguments do not change the outcome.

First, Servier contends that the statute's exclusion of "wholesale distributor[s]" and "retail pharmac[ies]" from the definition of "manufacturer," 42 U.S.C. § 1395w-114c(g)(5), means that Congress understood the term "manufacturer" to be broad enough to incorporate those entities, Servier Opening Br. 41–42. Not at all. Congress's choice to be extra clear as to some entities does not change the ordinary meaning of the underlying definition, especially when context and structure so resoundingly confirm Congress's meaning, as they do here. *See Atlantic Richfield Co. v. Christian*, 140 S. Ct. 1335, 1350 n.5 (2020) (Congress may "employ[] a belt and suspenders approach" to carry out its aims.).

Second, Servier points to a regulation promulgated by CMS as part of the Medicaid Drug Rebate Program as reading "manufacturer" to include the NDA owner. Servier Opening Br. 43–44. That regulation is of no help to Servier. For one, it interprets a materially different statutory definition of manufacturer. *See* 42 U.S.C. § 1396r-8(k)(5). For another, it provides only that, for "authorized *generic* products, the term 'manufacturer' will also include the *original* holder of the NDA." 42 C.F.R. § 447.502 (emphases added). Tibsovo is not a generic.

Price Program's broader definition of manufacturer. *See* Servier Opening Br. 43–44 (citing 42 U.S.C. § 1396r-8(k)(5); 42 C.F.R. § 447.502).

2

Next, Servier offers to provide evidence that it "performed manufacturing activities" for some of the Tibsovo stock that was dispensed in the Part D program in 2021. Servier Opening Br. 53 n.3; Servier Reply Br. 31–32 & n.1.

Servier does not explain what it means by "manufacturing activities." If Servier is referring to its possession of legal rights or wielding of legal responsibilities for Tibsovo, that evidence would be irrelevant.

To the extent Servier is arguing instead that it in fact created tablets dispensed under Part D in 2021, Servier told CMS the opposite. J.A. 112 ("Servier continued to sell TIBSOVO labeled with the Agios labeler code * * * from April 1, 2021 to February 13, 2022, *after which* Servier sold TIBSOVO under its own labeler code.") (emphasis added); *see id.* ("TIBSOVO was still being sold by Servier * * * with Agios' labeler code from April 1, 2021, through the end of 2021[.] * * * Servier first released finished product to [the] Servier supply chain with the Servier labeler code beginning in October 2021, and such product was first sold in the U.S. on February 14, 2022.").

Servier also told the district court the opposite. *See* J.A. 128 (Q: "But [Servier] didn't sell any of the drug that itself manufactured in 2021; correct?" A: "No. * * * [W]hen Servier acquired ownership of the drug, it also acquired existing inventory of TIBSOVO that it sold into the marketplace over the remaining nine months of 2021."); *see also* Servier Mot. for Summ. J. at 15 (stating that "the Tibsovo it sold in 2021 displayed the legacy codes from" Agios, and that Servier "sold that acquired inventory" in 2021). Servier's representations led the district court to find as undisputed fact

that Servier-manufactured Tibsovo was "first sold in the United States on February 14, 2022." *Servier*, 2025 WL 27352, at *7 n.9; *see also id.* at *10, *12, *13 (similar).

It is too late for Servier to change its factual story now. *Cf. District of Columbia v. Air Fla., Inc.*, 750 F.2d 1077, 1084 (D.C. Cir. 1984) ("[I]ssues and legal theories not asserted at the District Court level ordinarily will not be heard on appeal.").

Servier's effort to get around forfeiture by pointing to CMS's binding guidance for a "recalculation request"—a request for reconsideration of CMS's denial of specified-small-manufacturer status—fails. The guidance is explicit that manufacturers may request a recalculation by "describ[ing] the issue(s) forming the basis of the request for recalculation, and includ[ing] or describ[ing] *any* relevant supporting information." J.A. 57 (emphasis added).

Servier then argues that issue exhaustion is non-jurisdictional in this case, and so it was not required to exhaust this factual assertion in the informal agency proceeding. *See* Servier Reply Br. 13–20. Maybe. But the argument is still forfeited for failure to raise the issue—in fact, for having argued the opposite—in district court.

3

Servier has forfeited its remaining arguments that it manufactured the tablets of Tibsovo dispensed under Part D in 2021 by performing quality control of, and updating the label for, those tablets.

First, Servier cursorily asserts in one sentence that it "prepared" and "processed" Tibsovo by engaging in "quality control" of Tibsovo tablets created by Agios before they were

bottled and distributed. Servier Opening Br. 40–41. But whenever Servier brought up quality control before the agency or the district court, it was in support of a different argument—that Servier had manufactured Tibsovo because it bore "ownership responsibilities" for the quality control and safety of the drug. Mot. Hr'g Tr. 60:7–11; *see also*, *e.g.*, J.A. 112 (arguing in recalculation request that Servier "took over the manufacture and quality control" of Tibsovo after the acquisition); Mot. Hr'g Tr. 59:19–60:11 (same); Servier Opp. to CMS Cross-Mot. for Summ. J. at 9, ECF No. 15 (same). Its effort to repackage that argument here is forfeited.

Second, the same forfeiture problem dooms Servier's other factual argument that it "prepared" and "processed" Tibsovo because it obtained FDA approval for a new indication (a new use) of Tibsovo and updated its label accordingly. Servier Opening Br. 16–17. Servier points out that the Final Guidance treats entities that relabel or repackage products as manufacturers. *See* J.A. 83 (defining "manufacturer" to include "entities otherwise engaged in repackaging or changing the container, wrapper, or labeling of any applicable drug * * *").

But Servier never informed the agency or the district court that it had updated Tibsovo's label, nor argued that there was any legal significance to this fact. *See* J.A. 111–115; (Servier Recalculation Request); J.A. 122–123 (email to CMS). *See generally* Servier Mot. for Summ. J.; Servier Opp. to CMS Cross-Mot. for Summ. J. The district court relied on that omission: "Servier did not relabel or repackage Agios's stock of Tibsovo[.]" *Servier*, 2025 WL 27352, at *16.

* * * * *

In sum, CMS properly determined that Servier was not a specified small manufacturer under the Manufacturer Discount Drug Program because Servier has not shown that it "produced, prepared, propagated, compounded, converted, or processed" any units of Tibsovo dispensed to a Part D patient in 2021. 42 U.S.C. § 1395w-114c(g)(4)(C)(ii)(I)–(II).

IV

We turn next to Servier's arguments that CMS's use of labeler codes to identify the "manufacturer" of a drug was arbitrary and capricious. Servier is incorrect.

This court's scope of review under the arbitrary and capricious standard is "narrow[,]" and we cannot "substitute [our] judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). We set aside agency action only if "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.* The agency "must examine the relevant data and articulate a satisfactory explanation for its action[.]" *Id.*

A

Servier accuses CMS of both relying on flawed data and failing to explain the decision to use only labeler codes as a proxy for the "manufacturer" of a drug. Servier Opening Br. 48–54. Servier points out that (1) the statute does not mention the term "labeler code," (2) the Guidance said that CMS would consider "'ownership information submitted by

manufacturers[,]'" and (3) CMS has determined in other related programs that a "manufacturer" includes an NDA holder. *Id.* at 48–51 (quoting J.A. 55).

By way of reminder, a drug's labeler code is a unique identifier that the FDA assigns to "[e]ach person who engages in manufacturing, repacking, relabeling, or private label distribution of a drug[.]" 21 C.F.R. § 207.33(c)(1).

Turning to the merits, Servier makes no argument as to why labeler-code data is ill-suited to the task of identifying the manufacturer. Quite the opposite. Servier agrees that "labeler codes may accurately reflect the statutory 'manufacturer' of the drug in question in most cases[.]" Servier Opening Br. 50; *see also id.* at 30 (acknowledging that the use of labeler codes would be accurate in any case without a mid-year change in ownership). As it must since that is a key purpose of the labeler code. *See* 21 C.F.R. § 207.33(c)(1) ("Each person who engages in manufacturing[] * * * of a drug * * * must apply for [a National Drug Code] labeler code[.]").

Servier's real beef is with CMS's explanation of its decision to stick with labeler-code data despite the change in ownership from Agios to Servier. That objection fails because ownership is not relevant to the specified-small-manufacturer status that Servier seeks. *See* Sections III.A, III.B.1, *supra*. *See generally* 5 U.S.C. § 706 (In reviewing agency action under the arbitrary and capricious standard, we take "due account * * * of the rule of prejudicial error."). Because this court has decided what the statute means as a matter of law, there is no more explanation for the agency to give. *See Loper Bright*, 144 S. Ct. at 2273; *cf. Centro de Trabajadores Unidos v. Bessent*, 167 F.4th 1218, 1237 (D.C. Cir. 2026) ("Once the court determines the meaning of [a statute], there is no reason to seek an agency's explanation as to why it may have changed its view

on the meaning of the statute. The court's judgment is the final word.").

Servier insists that its arbitrary-and-capricious challenge is not a "purely legal challenge." Servier Opening Br. 51. But Servier fails to identify any factual issue that the agency had in front of it and left unresolved. *See* Servier Opening Br. 51–53, 53 n.3 (referencing only forfeited factual issues).

B

Lastly, Servier accuses CMS of acting arbitrarily and capriciously by failing to consider "that labeler codes do not indicate the physical makers of drugs, which often are produced by contract manufacturing organizations and distributed by private label distributors." Servier Opening Br. 54–55 (emphasis omitted). Servier also argues that CMS treated it differently from a similarly situated party, Agios, because the two companies stand in the same relation to Tibsovo: Both engaged contract manufacturing organizations to produce tablets of Tibsovo in 2021, yet only Agios can count Tibsovo sales towards its total expenditures for specified-small-manufacturer purposes. Servier Opening Br. at 56–57.

As to the former argument, it was entirely reasonable for CMS to attribute Tibsovo tablets created at Agios's direction to Agios because that direction is an intrinsic part of the manufacturing process. After all, it is "common practice in the drug industry to contract out the performance of certain manufacturing operations" to contractors. *See* 21 C.F.R. § 201.1(d). Attribution of those contractors' actions to their principal comports with ordinary conceptions of agency law. *See Saba v. Compagnie Nationale Air France*, 78 F.3d 664, 670 n.6 (D.C. Cir. 1996) ("[T]he acts of an agent * * * can be attributed to its principal[.]"); *McKesson Corp. v. Islamic*

Republic of Iran, 52 F.3d 346, 351 (D.C. Cir. 1995) (Whether "Iran exercised sufficient control over Pak Dairy to create a relationship of principal to agent" determines whether Pak Dairy's actions "were attributable to Iran.") (formatting modified); RESTATEMENT (THIRD) OF AGENCY LAW, ch. 2 intro. note (Oct. 2024 update) (describing the "bases on which the common law of agency attributes the legal consequences of one person's action to another person").

As to the latter argument, CMS did not treat like entities differently. The agency consistently attributed Tibsovo tablets created at Agios's direction to Agios, and Tibsovo tablets created at Servier's direction to Servier. Servier's problem arises not from any asymmetrical treatment, but rather from the timing of its manufacture and sale of Tibsovo into the Part D program. Agios-manufactured Tibsovo was dispensed under Part D in 2021—the timeframe that counts—while Servier-manufactured Tibsovo was not.

V

For the foregoing reasons, we affirm the district court's grant of summary judgment for Robert F. Kennedy, Jr., as Secretary of Health and Human Services, and Mehmet Oz, as Administrator for CMS.

So ordered.