UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SERVIER PHARMACEUTICALS LLC,

Plaintiff,

v.

XAVIER BECERRA,
et al.,

Defendants.

Civil Action No. 24-2664 (RDM)

MEMORANDUM OPINION

Plaintiff Servier Pharmaceuticals LLC ("Servier") brings this action challenging the determination by the Centers for Medicare and Medicaid Services ("CMS") that Servier does not qualify as a "specified small manufacturer" for purposes of the Manufacturer Discount Program introduced in the Inflation Reduction Act of 2022. That program requires drug manufacturers to offer covered drugs to Medicare Part D beneficiaries at discounted prices starting in 2025. Those manufacturers that qualify as "specified small manufactures," however, are eligible for a phase-in program that implements a manufacturer's discount obligations gradually over seven years, rather than imposing the full statutory discount rate on January 1, 2025. The parties present competing interpretations of the statutory criteria for determining whether a manufacturer qualifies as a "specified small manufacturer." On Servier's reading of the statute, it qualifies; on CMS's reading, it does not.

Although prior to the Supreme Court's recent decision in *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244 (2024), resolution of the parties' dispute would have required application of the two-part standard set forth in *Chevron, U.S.A., Inc. v. Natural Resources*

Defense Council, Inc., 467 U.S. 837 (1984), under current law, the Court must decide just one question: fairly construed using the traditional tools of statutory interpretation, what is the *best* construction of the less-than-pellucid statutory text that governs the parties' dispute. Applying that standard, the Court is persuaded that CMS correctly concluded that Servier does not qualify as a "specified small manufacturer."

The Court will, accordingly, **DENY** Plaintiff's motion for summary judgment and will **GRANT** Defendants' cross-motion for summary judgment.

I. BACKGROUND

A. Statutory and Regulatory Background

The Medicare program provides healthcare for the elderly and disabled. *See* 42 U.S.C. § 1395 *et seq*. It is administered by CMS, a component of the U.S. Department of Health and Human Services. *See Johnson v. Becerra*, 668 F. Supp. 3d 14, 17 (D.D.C. 2023). Medicare has four parts. Parts A and B of the program make up the traditional Medicare system under which CMS reimburses healthcare providers for services rendered to Medicare beneficiaries. 42 U.S.C §§ 1395c, 1395j. Parts C and D, in contrast, permit individuals to receive their Medicare benefits through private insurers. Part C, also known as the Medicare Advantage program, permits Medicare beneficiaries to enroll in private health insurance plans. *Id.* § 1395w-21(a)(1). Finally, Part D, which is the part at issue here, offers an additional, voluntary program that subsidizes prescription drug insurance coverage for beneficiaries enrolled in traditional or Part C plans. *Id.* § 1395w-101(a)(1).

1. *Medicare Part D's Benefit Design*

Medicare Part D was introduced in 2003 as part of the Medicare Prescription Drug, Improvement, and Modernization Act (the "Medicare Modernization Act"), Pub. L. No. 108-173, 117 Stat. 2066 (2003). "Under Part D, qualified Medicare beneficiaries may enroll in a

variety of Part D plans, administered by private insurance companies, that contract with CMS to provide coverage for drugs that have been identified by the Medicare statute as 'covered part D drugs.'" *Brew v. Burwell*, 263 F. Supp. 3d 431, 433 (W.D.N.Y. 2017).

a. The Medicare Modernization Act's Original Framework (2003)

The Medicare Modernization Act established a framework to allocate the cost of covered drugs among beneficiaries, insurance companies, and drug manufacturers. That framework, which has evolved in significant respects since Part D was first implemented, has included various cost allocation formulas that have applied to different payment "layers" and various statutory amounts that set the boundaries between the layers. Originally, there were four layers to a "standard prescription drug coverage" plan.[1] *See* 42 U.S.C. §1395w-102(b) (2003). Under the first layer, the deductible layer, the beneficiary was responsible for paying the full cost of drugs until she incurred costs equal to the statutory deductible, which was set at $250 for 2006 and increased in subsequent years.[2] *See id.* § 1395w-102(b)(2) (2003). The second layer, referred to as the "coverage" layer, applied to expenditures made after the beneficiary reached the deductible amount. Under that layer, the insurance company paid 75% of the "negotiated price" of covered drugs, and the beneficiary was responsible for paying the remaining amount

[1] Insurers can also offer "alternative prescription drug coverage" with a different benefit design, so long as the Secretary approves the plan as compliant with a host of requirements designed to ensure that the alternative plan is at least as generous to beneficiaries as the standard plan. 42 U.S.C. § 1395w-102(c).

[2] The statute provided for an "annual percentage increase" to the deductible, initial coverage limit, and annual out-of-pocket threshold that was tied to the "average per capita aggregate expenditures for covered part D drugs in the United States for part D eligible individuals, as determined by the Secretary." 42 U.S.C. § 13952-102(b)(6).

due. *See id.* §§ 1395w-102(b)(2), 1395w-102(b)(3) (2003).[3] The coverage layer applied until total outlays on drugs for that beneficiary (including amounts spent by the beneficiary to reach the deductible) reached the "initial coverage limit," which was set at $2,250 for 2006 and increased in subsequent years. *Id.* The third layer, referred to as the "coverage gap" layer or the "donut hole," applied to expenditures in excess of the initial coverage limit. Under the coverage gap layer, in the absence of any secondary coverage or additional CMS cost-sharing subsidies,[4] the beneficiary was required to pay the full cost of drugs until her out-of-pocket costs reached an "annual out-of-pocket threshold." *See* CMS, *Medicare Coverage Gap Discount Program Beginning 2011: Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance* 11 (May 21, 2010), https://perma.cc/244C-RY7X. The fourth and final layer was referred to as the "catastrophic" layer, and it applied once the annual out-of-pocket threshold (set at $3,600 for 2006 and adjusted thereafter) was met. *See* 42 U.S.C. § 1395w-102(b)(4) (2003). Under that layer, the beneficiary paid 5% of the cost of the drug or a set copay ($2 for generics and $5 for branded drugs), the insurance company paid 15%, and the government covered the remaining 80%. *See* Congressional Budget Office, *Paying for Drugs in Medicare Part D Under Current Law and Under Proposals to Redesign the Program* 6 (2021), https://perma.cc/K7B8-4SVN.

[3] The "negotiated price" includes any "negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include[s] any dispensing fees for such drugs." 42 U.S.C. § 1395w-102(d)(1)(B).

[4] One such subsidy is for low-income individuals. *See* 42 U.S.C. § 1395w-114 (2003). Individuals who qualified for that subsidy were not required to pay out of pocket during the coverage gap. Rather, their insurance plan paid and was then reimbursed by CMS. *Id.* § 1395w-114(a)(1)(C), (2)(C) (2003).

b. The ACA and the Manufacturer Coverage Gap Discount Program (2010)

The Patient Protection and Affordable Care Act ("ACA") of 2010, Pub. L. No. 111-148, 124 Stat. 119, modified the Medicare Modernization Act's original framework to "close" the "donut hole" through the newly created Manufacturer Coverage Gap Discount Program, *id.* § 3301, 124 Stat. 461–68, *codified at* 42 U.S.C. § 1395w-114a. That program required brand-name drug manufacturers with drugs covered under Medicare Part D to enter into written agreements—referred to as "Coverage Gap Discount Program agreements" or "CGDP agreements"—with the Secretary to provide those drugs at a discount of 50% of the negotiated price to beneficiaries subject to the coverage gap. *See* 42 U.S.C. §§ 1395w-114a(b), (g)(4), 1395w-153(a) (2010). In 2018, Congress increased the manufacturer discount obligation under the coverage gap layer to 70%. *See id.* § 1395w-114a(g)(4)(A) (2018); 42 C.F.R. § 423.2305. It also required insurance plans to cover 5% of the cost of brand-name drugs, which left beneficiaries to pay 25%, making the beneficiaries' share in the "coverage gap" layer the same as their share under the coverage layer and effectively closing that gap from the perspective of a beneficiary. *See* Congressional Research Service, *Medicare Part D Prescription Drug Benefit* 23 (2018), https://perma.cc/DWD6-F5NU. The ACA gradually eliminated the coverage gap with respect to generic drugs as well. Starting in 2011, insurance plans were required to cover 7% of the cost of generic drugs in the coverage gap. 42 U.S.C. § 1395w-102(b)(2)(C)(ii). That percentage increased in increments of 7% from 2011 until 2020, when the insurance plan's share reached 75%. *Id.*

There was, however, one important exception: manufacturers were not required to offer a discount on drugs dispensed to beneficiaries who received low-income subsidies. *See id.* § 1395w-114a(g)(1)(C). Those individuals already received coverage under the coverage gap layer in the form of government subsidies. Even more notably, during this period the

manufacturer discount obligation applied only to the coverage gap phase. Manufacturers were not obligated under the ACA to provide any discounts to the negotiated drug price under the initial coverage or the catastrophic coverage layers.

c. The IRA and the Manufacturer Discount Program (2022)

That all changed with the Inflation Reduction Act of 2022 ("IRA"), Pub. L. No. 117-169, 136 Stat. 1818, which made three significant changes to Plan D's benefit design:

First, the IRA eliminated the coverage gap layer starting in 2025 by removing the "initial coverage limit." *See* 42 U.S.C. § 1395w-102(b)(3) (including such limits only for "year[s] preceding 2025"). The coverage layer thus stretched from the statutory deductible all the way up to the annual out-of-pocket threshold, thereby eliminating the coverage gap layer from the statutory scheme.

Second, the IRA altered the design of the catastrophic layer: Starting in 2024, beneficiaries were no longer responsible for paying anything at all under the catastrophic layer. Instead, insurance plans covered 20% of drug costs and the government subsidized the other 80% (at least for 2024, *see infra*). *See id.* §§ 1395w-102(b)(4)(A)(i)(II), 1395w-115(b)(1)(A). In 2025, moreover, the annual out-of-pocket threshold that forms the lower boundary of catastrophic layer (which was $8,000 for 2024) dropped to $2,000.[5] *Id.* § 1395w-

[5] This drop is not quite as dramatic as it appears. Despite its name, the annual out-of-pocket threshold used to take into account both out-of-pocket expenditures *and* the value of manufacturer discounts on brand-name drugs in the coverage gap layer. That means that "Part D beneficiaries who purchased only brand-name drugs in 2024 will have spent about $3,300 out of their own pockets" by the time they hit the $8,000 threshold. *See* Juliette Cubanski & Tricia Neuman, *Changes to Medicare Part D in 2024 and 2025 Under the Inflation Reduction Act and How Enrollees Will Benefit*, KFF.org (2023), https://perma.cc/XPP4-NRE3. In contrast, beneficiaries who purchased generic drugs may have spent more than that because those drugs are not eligible for manufacturer discounts. Starting in 2025, however, the out-of-pocket threshold no longer takes into account manufacturer discounts. *See* 42 U.S.C. § 1395w-102(b)(4)(E) (only "[f]or each of years 2011 through 2024" will incurred costs "include the

102(b)(4)(B)(i)(VII). As these changes go into effect, beneficiaries will not bear any portion of the cost of covered drugs once they have incurred $2,000 in out-of-pocket expenses.

Third, and most importantly for present purposes, the IRA replaced the Manufacturer Coverage Gap Discount Program with the "Manufacturer Discount Program ("MDP")." *Id.* § 1395w-114c. Under the old Manufacturer Coverage Gap Discount Program, drug manufacturers were required to provide discounts of 70%—but only for purposes of the coverage gap layer, which Congress eliminated starting in 2025. But the elimination of the coverage gap does not mean that drug manufacturers are off the hook. Under the new Manufacturer Discount Program, drug manufacturers are now required to offer smaller discounts under the two remaining coverage layers: a 10% discount for purposes of the initial coverage layer and a 20% discount for purposes of the catastrophic coverage layer. *Id.* § 1395w-114c(g)(4)(A).

2. *Manufacturers Eligible for Phasing in the Manufacturer Discount Program*

Congress provided, however, that two categories of manufacturers are eligible for a phase-in of the MDP discounts that gradually increases their discount obligations between 2025 and 2031, rather than immediately imposing the full 10% and 20% discount requirements in 2025. These categories are referred to in the statute as "specified manufacturers" and "specified small manufacturers." *Id.* § 1395w-114c(g)(4)(B), (C). Unfortunately, those terms are not only similar but also not particularly accurate descriptions of the respective categories: a *specified* manufacturer is determined primarily by reference to the relative size of its sales (the Part D expenditures for all of its drugs must have been relatively small), whereas a specified *small*

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negotiated price" of a drug "regardless of whether part of such costs were paid by a manufacturer" under the Medicare Coverage Gap Discount Program).

manufacturer is distinguished by its specialization (the Part D expenditures for any one of its drugs must have predominated over Part D expenditures for all of its others drugs).

Those two categories are relevant here because CMS determined that Servier was a *specified* manufacturer but not a specified *small* manufacturer. Servier disputes the latter determination and argues that, had CMS correctly applied the statute, it would have concluded that Servier qualifies as a specified *small* manufacturer as well. The parties' dispute, accordingly, focuses on these statutory definitions.

a. Specified Manufacturers

"Specified manufacturers" qualify for a phase-in of their MDP discount obligations for "applicable drugs" marketed as of August 16, 2022, but only for drugs dispensed to beneficiaries eligible for low-income subsidies. 42 U.S.C. § 1395w-114c(g)(4)(B)(i).

Under the IRA, to qualify as a "specified manufacturer," a manufacturer must satisfy three criteria: First, it must have had a Coverage Gap Discount Program agreement in effect with CMS for 2021. *Id.* § 1395w-114c(g)(4)(B)(ii)(I)(aa). Second, the value of the manufacturer's Part D drug sales in 2021 must have constituted less than 1% of total 2021 Part D expenditures. *Id.* § 1395w-114c(g)(4)(B)(ii)(I)(bb). Third, the value of the manufacturer's Part B expenditures in 2021 must have constituted less than 1% of total 2021 Part B expenditures. *Id.* § 1395w-114c(g)(4)(B)(ii)(I)(cc). The parties agree that Servier satisfies all three of these criteria and therefore qualifies as a "specified manufacturer" eligible for the phase-in period with respect to drugs purchased by beneficiaries who receive low-income subsidies.

b. Specified Small Manufacturers

The parties disagree, however, as to whether Servier is a "specified small manufacturer." Specified small manufacturers also qualify for a phase-in of their MDP discount obligations for covered drugs marketed as of August 16, 2022. Unlike the phase-in for "specified

manufactures," however, this additional phase-in applies only to specified drugs (those that constitute at least 80% of total Part D expenditures for that manufacturer). For that drug, however, the manufacturer is entitled to the phase-in for *all* applicable Plan D beneficiaries, regardless of income. *Id.* § 1395w-114c(g)(4)(C). The IRA defines a "specified small manufacturer" as follows:

> (ii) Specified small manufacturer
>
> (I) In general
>
> In this subparagraph, subject to subclause (III), the term "specified small manufacturer" means a manufacturer of an applicable drug for which, in 2021—
>
> (aa) the manufacturer is a specified manufacturer (as defined in subparagraph (B)(ii)); and
>
> (bb) the total expenditures under part D for any one of the specified small manufacturer drugs of the manufacturer that are covered by the agreement or agreements under section 1395w-114a of this title of such manufacturer for such year and covered under this part during such year are equal to or more than 80 percent of the total expenditures under this part for all specified small manufacturer drugs of the manufacturer that are covered by such agreement or agreements for such year and covered under this part during such year.

Id. § 1395w-114c(g)(4)(C)(ii)(I).[6] The statute then defines "specified small manufacturer drugs" to mean, "with respect to a specified small manufacturer, for 2021, an applicable drug that is produced, prepared, propagated, compounded, converted, or processed by the manufacturer." *Id.* § 1395w-114c(g)(4)(C)(ii)(II)(aa). Moreover, the cross-referenced section 1395w-114a, as discussed above, is the section that governs the Manufacturer Coverage Gap Discount Program,

[6] There are two limitations on this definition that the parties agree are not at issue in this case. *See id.* § 1395w-114c(g)(4)(C)(ii)(II)(bb) (regarding corporate affiliates within a single controlled group), (III) (regarding specified small manufacturers acquired after 2021).

and so the "agreement or agreements under section 1395w-114a" are Coverage Gap Discount Program agreements.

Thus, to qualify as a "specified small manufacturer" a manufacturer must satisfy two criteria: First, it must have qualified as a "specified manufacturer" for 2021. Second, the total Part D expenditures for any one of the drugs that it produced, prepared, propagated, compounded, converted or processed for 2021, which was covered in 2021 by its Coverage Gap Discount Program agreement, must equal or exceed 80% of the total Part D expenditures for drugs produced, prepared, propagated, compounded, converted or processed by that manufacturer for 2021, which were covered by such an agreement or agreements.

3. *CMS Guidance on Specified Small Manufacturers*

Congress directed CMS to implement the MDP "by program instruction or other forms of guidance." IRA § 11201(f), 136 Stat. 1818, 1892. Consistent with that instruction, CMS issued its Medicare Part D Manufacturer Discount Program Final Guidance (the "Final Guidance") on November 17, 2023. Dkt. 18-1 at 3–59. CMS also issued an accompanying memorandum entitled "Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers" (the "Methodology Memorandum"), which is cross-referenced throughout the Final Guidance. Dkt. 18-1 at 61–68.

CMS's Final Guidance reiterates that, for purposes of the IRA, a "specified small manufacturer" must satisfy two criteria for 2021. First, the manufacturer must qualify as a "specified manufacturer." Second, "[t]he total expenditures under Part D for any one of [that manufacturer's] specified small manufacturer drugs (as described in section 130 of this guidance) covered under a Coverage Gap Discount Program agreement(s) for 2021 and covered under Part D in 2021 are equal to or greater than 80 percent of the total expenditures for all its specified small manufacturer drugs covered under Part D in 2021." Dkt. 18-1 at 30. Section

130, in turn, tracks the statutory definition and provides that "specified small manufacturer drug means, for 2021, any applicable drug that is produced, prepared, propagated, compounded, converted, or processed by a specified small manufacturer." Dkt. 18-1 at 58.

The Final Guidance further explains that CMS will "identify which manufacturers qualify" as "specified manufacturers" and/or "specified small manufacturers" "by analyzing Medicare Part B claims data, Part D [Prescription Drug Event] data, and ownership information submitted by manufacturers." Dkt. 18-1 at 30. For "a detailed description of the methodology CMS will use to identify manufacturers eligible for phase-ins," including information about "data sources and calculations," the Final Guidance refers to the Methodology Memorandum. Dkt. 18-1 at 30–31.

As relevant here, the Methodology Memorandum explains how CMS will determine whether a "specified manufacturer" also qualifies as a "specified small manufacturer"—*i.e.*, whether "the [specified] manufacturer's total expenditures for one specified [small manufacturer] drug are equal to or greater than 80 percent of the total expenditures for all of its specified [small manufacturer] drugs covered under Part D in 2021." Dkt. 18-1 at 66. The relevant analysis includes three steps: First, CMS groups different strengths and dosages of a drug[7] together to form "one specified small manufacturer drug." Dkt. 18-1 at 66. Second, CMS calculates the Part D total expenditures for each aggregated "specified small manufacturer drug." *Id.* Third, CMS calculates each such drug's percent share of the Part D total expenditures for that

[7] CMS groups different strengths and dosages of a drug together if they have "the same active moiety and the same holder of the New Drug Application." Dkt. 18-1 at 66. For biological products, CMS looks at whether the products have "the same active ingredient and the same holder of the Biologic Licensing Application." *Id.* Fixed combination drugs with combinations of active moieties or active ingredients will be aggregated based on whether they have a "distinct combination" of active ingredients. *Id.*

manufacturer to determine whether any "single specified drug" had 2021 expenditures equal to or greater than 80% of the total Part D expenditures for the "specified small manufacturer." *Id.* at 67.

Servier does not take issue with this three-step approach but, rather, challenges the way that CMS attributes drugs to a particular manufacturer. The Methodology Memorandum describes CMS's method of attribution as follows:

> CMS will attribute Part D expenditures for a drug, including authorized generic drugs and repackaged and relabeled drugs, to a specified manufacturer based on the [National Drug Code(s)] for the drug, as reported on [Prescription Drug Event] records. Specifically, CMS will match the labeler code extracted from the first 5 digits of each [National Drug Code] to the manufacturer.

Dkt. 18-1 at 66.

A National Drug Code is "a numeric code" that identifies the "labeler, product, and package size and type" of a particular "finished drug product or unfinished drug." 21 C.F.R. § 207.33(a). It has three parts: a "labeler code," a "product code," and a "package code." *Id.* § 207.33(b)(1)(i)–(iii). The labeler code is a unique four- or five-digit sequence "assigned by the [Food and Drug Administration ("FDA")]" to "[e]ach person who engages in manufacturing, repacking, relabeling, or private label distribution of a drug subject to listing." *Id.* § 207.33(b)(1)(i), (c)(1). The product and package codes, on the other hand, are proposed by "[e]ach manufacturer, repacker, or relabeler," who "must propose" to the FDA a unique National Drug Code "for each package size and type of drug that it manufacturers, repacks, or relabels for commercial distribution." *Id.* § 207.33(d)(1)(i). Thus, the labels that appear on packages of the same size and type of drug manufactured, repackaged, or relabeled by the same company would

all have the same National Drug Code, but a package of that same drug of a different size or type would have its own National Drug Code.[8]

As the Methodology Memorandum further explains, CMS gathers the National Drug Codes of disbursed Part D drugs from Prescription Drug Event records, which Part D insurers (or others) must submit to CMS "[f]or each dispensing event"—that is, every time a drug covered by Part D is dispensed to a beneficiary. Department of Health and Human Services, *Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)* 9 (Apr. 27, 2006), https://perma.cc/VD29-SSVB. Each Prescription Drug Event record includes the National Drug Code of the dispensed drug in addition to 36 other required data elements, which also include the date the prescription was filled and the amount paid for the drug. *See id.* at 9, 11–17. Relying on this process, CMS used the National Drug Code labeler codes reported in Prescription Drug Event records from 2021 to attribute Part D drug expenditures to particular manufacturers.

B. Factual Background

That brings us to the events giving rise to the present dispute. Servier is an "oncology company dedicated to addressing rare [cancers] and patient populations with unmet needs" that "entered" the United States in 2018. Dkt. 18-1 at 86. At the start of 2021, Servier had a U.S. roster of two drugs: Asparlas and Oncaspar. *Id* at 86–87. It is undisputed that no Part D expenditures were incurred in 2021 for either Asparlas or Oncaspar. Dkt. 8-1 at 13; Dkt. 13-1 at 19; *see also* Dkt. 18-1 at 90.

[8] "The National Drug Code (NDC) number is requested but not required to appear on all drug labels and in all drug labeling, including the label of any prescription drug container furnished to a consumer." 21 C.F.R. § 201.2.

At issue in this case is Servier's third drug, Tibsovo. Prior to April 2021, Agios Pharmaceuticals ("Agios") owned the approved New Drug Application ("NDA") for Tibsovo, and it manufactured and sold the drug under its own FDA-approved labeler code. On April 1, 2021, however, Servier "acquired the oncology business of Agios," including the existing stock of Tibsovo and the approved NDA.[9] Dkt. 18-1 at 87. As relevant here, Servier sold Tibsovo "labeled with the Agios labeler code (NDC: 71334-01-001) from April 1, 2021 to February 13, 2022," and that labeler code "remained on Agios' Coverage Gap Discount Program ('CGDP') agreement" during that period of time "because the CGDP requires manufacturers to 'reimburse all applicable discounts provided by Part D sponsors on behalf of the Manufacturers for all applicable drugs having [National Drug Codes] with the Manufacturer's FDA-assigned labeler code(s).'" *Id.* (emphasis omitted).

It was not until after February 13, 2022, that "Servier sold TIBSOVO under its own labeler code." *Id.* Moreover, although "Servier took over responsibility for the manufacturing of TIBSOVO" immediately after the acquisition, it did not release any "finished product to [its] supply chain with [its own] labeler code [until] October 2021," and that product was not "sold in the U.S." until February 14, 2022. *Id.* The FDA's drug database confirms that the "start marketing date" for Servier-manufactured Tibsovo (NDC: 72694-617-60) was October 19, 2021. *See* FDA, National Drug Code Directory, https://perma.cc/PS9Z-GD9K. Significantly, all

[9] According to Servier, Agios also transferred "ownership" of the Tibsovo National Drug Code ("NDC"). Dkt. 18-1 at 87. When asked at oral argument what it means to transfer ownership of an NDC, however, counsel retreated from this position, explaining that it is the approved ND*A*—which provides the right to market the drug—that transfers in the course of a single-product acquisition and not the predecessor company's NDC. Dkt. 21 at 33–34 (Tr. Oral Arg.); *see also* Dkt. 18-1 at 89. The record further reflects that Servier obtained its own NDC for Tibsovo in 2021 and that Servier used that distinct NDC for the stocks of Tibsovo that Servier produced (with the assistance of its contractor), released into the supply chain in October 2021, and first sold in the United States on February 14, 2022. *Id.* at 87.

Tibsovo dispensed to Part D beneficiaries in 2021 was manufactured by Agios (or, more precisely, by Agios's contract manufacturer) prior to Servier's acquisition of Tibsovo, was labeled with Agios's labeler code, and was covered under Agios's Coverage Gap Discount Program agreement. In short, "no Part D expenditures in 2021" were incurred "for any Tibsovo manufactured by Servier." Dkt. 13-1 at 22. Part D expenditures were incurred, however, for Tibsovo manufactured by Agios, the existing stock of which was acquired by Servier on April 1, 2021, and which Servier subsequently distributed. Finally, at the time that Servier distributed the Agios-manufactured quantities of Tibsovo, Servier was manufacturing its own quantities of the drug, although that stock was not sold in the United States until after February 13, 2022.

C. Procedural Background

The present dispute turns on whether CMS properly determined that Servier qualified as a "specified manufacturer" but not a "specified small manufacturer" for purposes of phase-in eligibility. CMS communicated that determination to Servier on April 4, 2024. Dkt. 18-1 at 83. After CMS notified Servier that it had concluded that Servier qualified as a "specified manufacturer" but not a "specified small manufacturer," the company sought recalculation pursuant to procedures set forth in CMS's Final Guidance.[10] Servier argued that CMS's determination "was based on a misunderstanding regarding the ownership of Tibsovo." Dkt. 18-1 at 86. According to Servier, Tibsovo "qualifies as a specified drug and a specified small

[10] In its Final Guidance, CMS "provide[d] a mechanism for manufacturers that wish to request a recalculation of their phase-in eligibility determination." Dkt. 18-1 at 32. A manufacturer who wants to take advantage of that mechanism "must file the request with CMS no later than 30 calendar days from the date" it received the determination. *Id.* "After consideration of the issues raised, CMS will decide whether to perform the recalculation, and will issue a written decision to the manufacturer . . . that will include CMS' decision about whether to perform the requested recalculation and, if such recalculation is performed, the resulting eligibility determination." *Id.* That decision "is final and binding." *Id.*

manufacturer drug of Servier under the statute and CMS guidance" because "Servier owned TIBSOVO, including the TIBSOVO [National Drug Code] and New Drug Application" and "responsibility for manufacturing TIBSOVO" as of April 1, 2021. *Id.* It also argued that "[w]hile TIBSOVO was technically included on Agios' CGDP agreement throughout 2021, . . . Servier accepted responsibility for coverage gap discounts for TIBSOVO and fully reimbursed Agios for such discounts post-acquisition." *Id.* at 89. In other words, Agios had entered into an CGDP agreement with CMS requiring Agios to reimburse all applicable discounts provided by Part D sponsors on its behalf in 2021, and Servier agreed, in turn, to reimburse Agios for the amounts that Agios would owe for Tibsovo under that CGDP agreement for the period following the acquisition on April 1, 2021. *See* Dkt. 21 at 15 (Tr. Oral Arg.) ("Servier bore the full responsibility of reimbursing [Agios for] those rebates over the final nine months of" 2021). Finally, Servier argued that "[o]nce TIBSOVO is considered, Servier satisfies the requirements for a specified small manufacturer." Dkt. 18-1 at 89. Servier's other drugs had no Part D expenditures in 2021, and thus any 2021 Tibsovo Part D expenditures attributed to Servier would constitute 100% of Servier's Part D expenditures, easily satisfying the 80% threshold to qualify as a "specified small manufacturer."

CMS was unpersuaded. It concluded that "the concerns identified in [Servier's recalculation] request" did not raise "a calculation error in phase-in eligibility for Servier and" thus did not warrant "a recalculation of [the agency's] determination of phase-in eligibility." Dkt. 18-1 at 94. CMS explained:

> You assert that, because Servier acquired assets for a drug, TIBSOVO, from another manufacturer on April 1, 2021, CMS should have used 2021 data for that drug to make its phase-in eligibility determination for Servier. However, the labeler code for TIBSOVO (71334) remained under the divesting manufacturer's Coverage Gap Discount Program agreement in 2021. CMS determined manufacturer phase-in eligibility using expenditure date in

> accordance with the statute, the Final Guidance, and the Methodology [Memorandum]. As stated in the Methodology [Memorandum] (see section A, step 2, and section C, step 2), CMS used all final action, non-delete Prescription Drug Event (PDE) records . . . for all applicable drugs dispensed in Benefit Year 2021 that are attributable to each manufacturer, as determined by the labeler code extracted from the [National Drug Code] to identify each manufacturer's Part D expenditures. . . . Consistent with the Methodology [Memorandum], CMS determined the Part D expenditures for Servier's labeler code, 72694, were $0.00 in 2021. While there may have been Part D expenditures in 2021 for a drug, TIBSOVO, that Servier first marketed under its FDA-assigned labeler code after 2021, that is not relevant to Servier's eligibility determination because, in 2021, TIBSOVO was not attributable to Servier, as determined by the labeler code. Therefore, such expenditures cannot be attributed to Servier.

Id. at 94. CMS further observed that "the concerns [Servier] raise[d] about the agency's consideration of Servier's 2021 Part D expenditures does not suggest an error in the calculation in the phase-in eligibility determination for Servier, but rather constitutes an objection to the Discount Program policies established in the statute, the Final Guidance, and the Methodology [Memorandum]." *Id.* CMS, accordingly, concluded that, although Servier qualified as a "specified manufacturer," it did not qualify as a "specified small manufacturer" for purposes of the phase-in. *Id.* at 95.

Upon receiving the denial of its recalculation request, Servier informed CMS that it was "considering its legal/litigation options," and it "request[ed] a short call to discuss the issue." Dkt. 18-1 at 97. CMS declined. *Id.* A week later, Servier brought this action against CMS, seeking "a declaratory judgment that it qualifies as a specified small manufacturer and is entitled to benefit from the phase-in provisions as well as preliminary and permanent injunctive relief preventing the Secretary from enforcing his contrary determination." Dkt. 1 at 1.

The parties proposed to resolve their dispute by filing expedited cross-motions for summary judgment "that would hopefully allow the Court to issue a ruling before the phase-in period commences on January 1, 2025." Dkt. 7 at 2. Subsequently, the parties informed the Court that they hoped to obtain a decision by early January 2025, but that, although the MDP

would take effect on January 1, 2025, Servier will have thirty-eight days to pay any relevant rebates after receiving an invoice from CMS's third-party administrator. Dkt. 21 at 55–56, 65 (Tr. Oral Arg.). Pursuant to the parties' proposal, Servier moved for summary judgment on October 1, 2024, Dkt. 8, and CMS cross-moved for summary judgment on October 29, 2024, Dkt. 13. The Court heard oral argument on December 13, 2024. *See* Min. Entry (Dec. 13, 2024).

II. LEGAL STANDARD

Servier brings this action under the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 *et seq*. Under the APA, a reviewing court shall "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "[W]hen a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal." *Rempfer v. Sharfstein*, 583 F.3d 860, 865 (D.C. Cir. 2009) (alteration omitted) (quoting *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001)). In other words, "[t]he entire case on review is a question of law." *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993).

The general standard for summary judgment set forth in Rule 56 of the Federal Rules of Civil Procedure does not apply to a review of agency action. But summary judgment nonetheless "serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006) (citing *Richards v. INS*, 554 F.2d 1173, 1177 & n.28 (D.C. Cir. 1977)). The Court will grant summary judgment to the agency if it did not "violate[ ] the Administrative Procedure Act by taking action that is

'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Forsyth Mem'l Hosp., Inc. v. Sebelius*, 639 F.3d 534, 537 (D.C. Cir. 2011) (quoting 5 U.S.C. § 706(2)). Although this review is "fundamentally deferential," *Fox v. Clinton*, 684 F.3d 67, 75 (D.C. Cir. 2012), the APA nonetheless requires not only that "an agency's decreed result be within the scope of its lawful authority" but also that "the process by which it reaches that result . . . be logical and rational," *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 374 (1998).

In resolving questions of statutory interpretation, the Court "must exercise [its] independent judgment in deciding whether [the] agency acted within its statutory authority, as the APA requires." *Loper Bright Enters.*, 144 S. Ct. at 2273. That undertaking requires the Court to employ "the traditional tools of statutory construction" to reach a *de novo* determination about the meaning of the statute. *Id.* at 2268; *see also Pac. Gas & Elec. Co. v. FERC*, 113 F.4th 943, 947 (D.C. Cir. 2024). In contrast, "review under the 'arbitrary and capricious' standard is narrow." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Under this standard, the Court must avoid substituting its "judgment for that of the agency," but must nonetheless ensure that the agency has "examine[d] the relevant data and [has] articulate[d] a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Id.* (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)). "Normally, an agency rule would be arbitrary and capricious 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.*

III. ANALYSIS

Servier challenges CMS's determination that it does not qualify as a "specified small manufacturer" under two prongs of the APA. First, Servier maintains that CMS's determination is contrary to law and that, notwithstanding CMS's conclusion, it satisfies each of the statutory criteria for eligibility. Second, Servier argues that CMS's determination was arbitrary and capricious (1) because CMS considered only information it knew was incomplete or flawed, and (2) because in responding to Servier's recalculation request, CMS failed adequately to explain why it relied exclusively on the labeler code—and declined to rely on Servier's evidence of actual ownership—in attributing post-April 1, 2021 Part D expenditures for Tibsovo to Agios, rather than Servier. In response, CMS defends its reading of the statute, and it asserts that it relied on accurate information and adequately explained its reasons for rejecting Servier's request for recalculation.

A. Contrary to Law

Servier's principal argument takes issue with CMS's reading of the MDP statute. The parties agree that Servier satisfies the first criterion for 2021—that is, it qualifies as a "specified manufacturer." 42 U.S.C. § 1395w-114c(g)(4)(C)(ii)(I)(aa). They disagree, however, about whether it satisfies the second criterion, which asks whether total Part D expenditures "for any one of the specified small manufacturer drugs of the manufacturer that are covered by the [CGDP] agreement or agreements . . . of such manufacturer for" 2021 represented at least 80% "of the total [Part D] expenditures for all specified small manufacturer drugs of the manufacturer that are covered by such agreement or agreements for [2021]." *Id.* § 1395w-114c(g)(4)(C)(ii)(I)(bb).

On CMS's reading, expenditures are attributable only to the manufacturer of the stock of the drug that was dispensed in 2021, and Servier thus does not meet the second criterion because "there were no Part D expenditures in 2021 for any drugs manufactured by Servier." Dkt. 13-1 at 21. By Servier's own admission, the Tibsovo that Servier sold in 2021 came from the existing stock of the drug that Agios had manufactured and that Servier acquired in April 2021 as part of Servier's acquisition of Agios's oncology business. *Id.* at 21–22. Although Servier did manufacture additional quantities of Tibsovo in 2021, that stock was not sold to consumers until after February 13, 2022. *Id.* And even though CMS has construed "the term 'manufacturer' to include 'entities otherwise engaged in repackaging or changing the container, wrapper, or labeling of any applicable drug in furtherance of the distribution of the applicable drug from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer,'" *id.* at 23 (quoting AR55), "Servier does not claim that it engaged in any of those acts in connection with the Tibsovo drug product dispensed to Part D beneficiaries in 2021," *id.* Finally, according to CMS, even if Servier were correct that drug "ownership" was sufficient to satisfy the statutory requirement (and CMS disputes that premise), Servier's argument would nonetheless fail because Servier has not shown—and cannot show—that the Tibsovo that was dispensed to Part D beneficiaries in 2021 was introduced to the supply chain by Servier (using the existing stock that it acquired in April 2021), rather than by Agios (prior to the acquisition). *Id.* Because the labeler code for all Tibsovo dispensed in 2021 identified Agios as the manufacturer (and included no reference to Servier), it is impossible to determine whether any Tibsovo dispensed in 2021 came from the existing stock that Servier acquired. *Id.*

On Servier's reading, in contrast, none of this matters. Addressing the statutory criteria as discrete and disconnected elements, Servier argues that it undisputably "manufactured"

Tibsovo in 2021; that Part D expenditures for Tibsovo constituted "at least 80% of the total expenditures for Servier's Part D drugs in 2021;" and that "Tibsovo was covered by a Coverage Cap Discount Program agreement in 2021" (even if it was Agios, and not Servier, that entered that agreement with CMS). Dkt. 15 at 6. According to Servier, the information contained in the labeler code is not dispositive in the present context because Servier "acquired full ownership interests in Tibsovo in April 2021" and because sales of Tibsovo "for the remainder of 2021 accounted for more than 80% of expenditures on Servier's drugs under Part D for the year." *Id.* at 7. What matters, Servier continues, is that it owned all interests in Tibsovo, including the interest in the approved NDA for the drug, starting in April 2021, and that Tibsovo was dispensed to Part D beneficiaries throughout 2021, including after Servier's acquisition. Finally, Servier takes issue with what it characterizes as CMS's "tablet-tracing argument," according to which expenditures for a particular stock of product is traced back to the manufacturer of that product. *Id.* Under Servier's contrary reading, "[t]he statute merely requires that Servier manufactured Tibsovo in 2021 and that the Part D expenditures for the drug for that year comprised more than 80% of total expenditures [for] Servier's Part D drugs." *Id.* The statute does not require a manufacturer or CMS to trace particular stocks of the drug at issue from the actual manufacturer to the relevant Part D expenditure.

1.

The Court starts, as it must, with the statutory text. *See Barnhart v. Sigmon Coal Co., Inc.*, 534 U.S. 438, 450 (2002). Here, the controlling statutory text includes two requirements. CMS must first decide whether the manufacturer qualifies as a "specified manufacturer." For present purposes, both parties agree that Servier satisfies that requirement. The parties' dispute,

instead, focuses on the second requirement. For that requirement, a "specified manufacturer" qualifies as a "specified small manufacturer" if and only if in 2021:

> the total expenditures under part D for any one of the specified small manufacturer drugs of the manufacturer that are covered by the agreement or agreements under section 1395w-114a of this title of such manufacturer for such year and covered under this part during such year are equal to or more than 80 percent of the total expenditures under this part for all specified small manufacturer drugs of the manufacturer that are covered by such agreement or agreements for such year and covered under this part during such year.

42 U.S.C. § 1395w-114c(g)(4)(C)(ii)(I)(bb). The phrase "specified small manufacturer drugs" is defined, in turn, to mean, "with respect to a specified small manufacturer, for 2021, an applicable drug that is produced, prepared, propagated, compounded, converted, or processed by the manufacturer." *Id.* § 1395w-114c(g)(4)(C)(ii)(II)(aa). And an "agreement . . . under section 1395w-114a" refers to an agreement between the manufacturer and CMS for 2021 pursuant to the Medicare Coverage Gap Discount Program—that is, a CGDP agreement—under which the manufacturer agreed "to provide applicable beneficiaries access to discounted prices for applicable drugs of the manufacturer," *id.* § 1395w-114a(b)(1)(A) (2018), and agreed to provide reimbursement in "an amount equal to the difference between . . . the negotiated price of the applicable drug [and] the discounted price of the applicable drug," *id.* § 1395w-114a(c)(1)(A)(iv). Finally, "such year" refers to 2021, and "this part" refers to Part D.

Putting these pieces together, the relevant statutory language takes the following—reconstituted—form:

> In 2021 . . . the total expenditures under part D for any one of the [1] specified small manufacturer drugs [defined to mean: *for 2021, an applicable drug that is produced, prepared, propagated, compounded, converted, or processed by the manufacturer*] [2] of the manufacturer [3] that are covered by a *Coverage Gap Discount Program* agreement or agreements of such manufacturer for *2021* and [4] covered under *Part D* during *2021* [5] are equal to or more than 80 percent of the total expenditures under *Part D* for all specified small manufacturer drugs [defined to mean: "*for 2021, an applicable drug that is produced, prepared, propagated, compounded, converted, or processed by the manufacturer*] of the

> manufacturer that are covered by such agreement or agreements for *2021* and covered under *Part D* during *2021*.

The parties agree that no expenditures were incurred under Part D in 2021 for any drug other than Tibsovo, and so if any Tibsovo expenditures can be attributed to Servier they will account for more than 80% of Servier's total expenditures under Part D ([5]). At least for present purposes, moreover, CMS does not dispute that the phrase "of the manufacturer" is best read to connote ownership—that is, a drug for which the NDA is owned by the relevant manufacturer. As a result, the relevant, reconstituted statutory language can be simplified as follows: Servier qualifies as a "specified small manufacturer" if and only if, in 2021, the Medicare program incurred expenditures under Part D for a drug [1] that Servier produced, prepared, propagated, compounded, converted, or processed for 2021, [2] which was owned by Servier, [3] which was covered by a CGDP agreement of Servier for 2021, and [4] which was covered under Part D during 2021.

Understood in this light, two barriers frustrate Servier's argument. First, as Servier concedes, all of the Tibsovo that was dispensed in 2021 (and, accordingly, all of the Tibsovo that resulted in Part D expenditures) was "produced, prepared, propagated, compounded, converted, or processed" by Agios or its contractor, and not by Servier or its contractor. Dkt. 18-1 at 87. Although Servier manufactured its own stock of Tibsovo in 2021, none of that stock was dispensed until after February 13, 2022. Second, the Tibsovo that was dispensed in 2021 was covered by Agios's CGDP agreement with CMS, and not by a CGDP agreement to which Servier was a party. *Id.* Indeed, it was for this reason that Servier entered into a separate agreement with Agios to reimburse Agios for the discounts that Agios would owe for covered sales of the existing stock of Tibsovo after the acquisition. *Id.* at 89. Accordingly, Servier's claim fails to satisfy the statutory test.

2.

In response to this reading of the statutory text, Servier raises a host of counterarguments. For the reasons explained below, the Court is unpersuaded that any of these arguments represent the best reading of the statute.

a.

First, and most fundamentally, Servier argues that this reading of the statute embraces a form of "tablet tracing" that is inconsistent with the statutory text. According to Servier, "the statute does not require that Servier created each Tibsovo tablet 'dispensed' to Part D beneficiaries in 2021." Dkt. 15 at 9. "Instead, it simply requires that Servier was a manufacturer of Tibsovo in 2021 and that Part D expenditures for Tibsovo in 2021 account for at least 80% of Part D expenditures for Servier's drugs." *Id.*

Servier begins with its reading of the statutory text and argues that a manufacturer qualifies as a "specified small manufacturer" if (1) it manufactured a Part D drug in 2021, (2) the Part D expenditures for that drug satisfied the 80% threshold, and (3) "the Part D drug was the subject of a Coverage Gap Discount Program agreement in 2021." *Id.* at 10. Servier stresses that the statutory definition "does not include the word 'dispensed,' which [on Servier's telling] Defendants improperly insert in furtherance of their efforts to add a new tablet-tracing requirement." *Id.* (emphasis omitted). But this textual argument relies on a strawman while ignoring key portions of the governing text.

Servier is, of course, correct that the MDP statute does not use the word "dispensed." It does, however, refer to "total expenditures under part D for any one of the specified small manufacturer drugs," 42 U.S.C. § 1395w-114c(g)(4)(C)(ii)(I)(bb), and it defines "total expenditures" to include "total gross covered prescription drug costs," *id.* § 1395w-

114c(g)(4)(D), which, in turn, requires an assessment of "the costs incurred under [each Part D enrollees'] plan . . . including costs directly related to the *dispensing* of covered part D drugs," *id.* § 1395w-115(b)(3) (emphasis added). But more importantly, the absence or presence of the word "dispensed" has no bearing on whether the relevant "expenditures" must be for a drug manufactured by the entity seeking "specified small manufacturer" status. In other words, Servier's contention that the statute fails to include the word "dispensed" is a strawman.

The same is true of Servier's contention that the word "drug" is not narrowly defined to refer to any particular stock of a product, like the supply of Tibsovo that Servier acquired from Agios, but rather refers to a pharmaceutical product more generally, like all Tibsovo. Servier is correct that the statute groups all drugs—regardless of dosage size or method—"approved under a new drug application" as a single "drug" for purposes of the Manufacturer Discount Program, 42 U.S.C. § 1395w-114c(g)(2)(A)(i). An approved New Drug Application does not focus on individual pills or lots of pills or (at least at times) specific dosage forms or strengths. Consistent with this understanding, CMS's Final Guidance advised that:

> In order to determine one drug's share of a manufacturer's Part D total expenditures, which we will use to identify specified small manufacturers, we first note that for drug products, one specified small manufacturer drug will include all dosage forms and strengths of a drug with the same active moiety and the same holder of the New Drug Application.

Dkt. 18-1 at 66. Thus, according to CMS, an applicable "drug" includes all product with (1) the same active moiety and (2) the same holder of the approved New Drug Application. But that broad definition of "drug," once again, says nothing about whether the relevant Part D expenditures attributed to one manufacturer can include expenditures for stock of a drug—no matter how broadly that term is defined—that was produced by a different manufacturer.

In short, neither the fact that the MDP statute does not use the word "dispense" nor the broad definition of "drug" that appears in the statute and in CMS's Final Guidance do anything

to advance Servier's claim. Nor do those arguments help with the more fundamental problem with Servier's overall claim, which is that Servier artificially breaks a single sentence of the statutory text into three discrete and disconnected requirements. On Servier's reading of the statute, the company qualifies as a "specified small manufacturer because [1] it manufactured Tibsovo in 2021, [2] its total Part D expenditures on Tibsovo in 2021 (or after April 1, 2021) exceeded Part D expenditures for all other drugs that Servier manufactured in 2021 (since no Part D expenditures were incurred for any other Servier product in 2021), and [3] Tibsovo "was the subject of a Coverage Gap Discount Program agreement in 2021." Dkt. 15 at 10.

But that argument ignores the prepositions that affirmatively link the relevant statutory requirements (and thus prevent the type of disaggregation that Servier proposes), as well as other important statutory clues. The text requires, for example, that the "total expenditures" for 2021 must be "*for*" a "drug that is produced, prepared, propagated, compounded, converted, or processed *by* the manufacturer" "for 2021." 42 U.S.C. §§ 1395w-114c(g)(4)(C)(ii)(I)(bb), 1395w-114c(g)(4)(C)(ii)(II)(aa) (emphasis added). The statute is, concededly, far from a picture of clarity. But this language is best construed to require that the expenditures be *for* the stock of the drug that was produced *by* the manufacturer, rather than also including stock produced by a different manufacturer, so long as the entity seeking to qualify as a "specified small manufacturer" happens to have produced some separate stock of the product that may or may not have resulted in any Part D expenditures. Notably, the entire statutory provision focuses on a single "manufacturer"—"*the* manufacturer is a specified manufacturer;" "applicable drug that is produced . . . by *the* manufacturer;" "drugs of *the* manufacturer;" "the agreement . . . of *such* manufacturer." The statute does not contemplate multiple manufacturers, or as here, a situation where one manufacture produces the stock of the drug that results in the relevant expenditures,

and another manufacturer produces stock that is merely held in reserve in 2021 and not dispensed until 2022.

To the extent that Congress contemplated acquisitions, moreover, it expressly precluded "specified small manufacturer" status from transferring from one manufacturer in 2021 to another after 2021 in the statute. *See* 42 U.S.C. § 1395w-114c(g)(4)(C)(ii)(III). Although that provision does not apply to the present circumstances, it exists within the same statutory scheme and therefore casts some light on the meaning of § 1395w-114c(g)(4)(C)(ii)(I)(bb). Common to both provisions is the concept that *the* manufacturer must itself qualify and that the actions of one manufacturer are not attributable to another. In short, although the rules of grammar do not categorically preclude reading the phrase "expenditures for a drug that is produced by Servier" to mean expenditures for the stock that Agios produced, so long as the drug was one that Servier also produced (but did not sell to consumers) in 2021, that is far from the most natural reading of the statutory text.

Servier's description of how the statute would operate under its view merely reinforces that conclusion. According to Servier, allocation of the relevant Part D expenditures should turn exclusively on who owns the approved NDA for the drug at the time the expenditure occurs. At oral argument, the Court asked how CMS would go about calculating expenditures for the drug following an acquisition under Servier's reading of the statute. Counsel responded as follows:

> [I]n situations like this[,] where there has been a change of control and ownership and you have existing stock sold into the marketplace completely owned by Servier as the economic interest holder and regulatory interest holder and owns and possesses the NDA, there is a disconnect between the labeler code from that inventory stock and who the residual economic interest holder is. In that instance, . . . Servier provided full evidence to CMS demonstrating its interests. It pointed out that it had ownership as of April 1st. It pointed out that it paid the rebates on that product under the existing rebate program over the final nine months of 2021.

. . .

> So, Your Honor, our argument is that . . . in referring to the drugs, all that has to be assigned or determined is who owns the economic interest at the point of time that expenditures occurred, who was the holder of the NDA?

Dkt. 21 at 11-12 (Tr. Oral Arg.); *see also id*. at 14 ("[Y]es, the owner of the NDA at the time . . . the expenditure is recorded in the economic interest holder and is who the expenditure under the program is assigned to."). That is, under Servier's view, so long as the manufacture produced a single pill of the drug at issue in 2021, all expenditures for the drug made in 2021 occurring after the manufacturer acquired the rights to the approved NDA must be attributed to that manufacturer, regardless of who manufactured the product that was actually sold in 2021 and regardless of whether that product was introduced into the supply chain before or after the acquisition. Applying that logic, "Servier estimates that roughly $66 million" of $89 million of the 2021 sales of Tibsovo should be attributed to Servier because the acquisition occurred at the beginning of the second quarter of the year. Dkt. 8-1 at 15 n.7.

But, as CMS observes, that introduces a number of anomalies into the statutory scheme. Most significantly, Servier could take credit for expenditures incurred under Part D for Tibsovo that was manufactured by Agios and that was introduced into the supply chain before the acquisition occurred—that is, under Servier's reading of the statute, Part D expenditures for Tibsovo that Servier never produced or owned could be attributed to the company. Instead, all that matters on Servier's view is that it owned the approved NDA for Tibsovo at the time the expenditure occurred. But that reading of the statute not only ignores the definition of "specified small manufacturer drug," which applies only to drugs "produced, prepared, propagated, compounded, converted, or processed by the manufacturer," 42 U.S.C. § 1395-114c(g)(4)(C)(ii)(II), but also reads a dispositive NDA-ownership rule into the statute based on

the slimmest of reeds—the use of the proposition "of" preceding a reference to "the manufacturer." Finally, Servier's reading of the statutory text, which defines "specified small *manufacturer*" and uses the word "*manufacturer*" over a dozen times, would leave in place only the most tenuous of connections to the actual manufacturer—it would not matter whether "the manufacturer" produced a single pill that resulted in a Part D expenditure in 2021, so long as it owned the approved NDA and "produced, prepared, propagated, compounded, converted, or processed" at least one pill covered by that NDA.

b.

But even were the Court to accept that peculiar reading of the statute, it would do nothing to address Servier's separate problem: "the specified small manufacturer drugs *of* the manufacturer"—that is, on Servier's view, the drugs for which the manufacturer owns the approved NDA at the time the expenditure occurs—must be "covered by" a CGDP agreement between CMS and "*such* manufacturer." 42 U.S.C. § 1395w-114c(g)(4)(C)(ii)(bb) (emphasis added). Servier concedes, however, that it was never the party to a CGDP agreement covering Tibsovo for 2021; rather, Agios was the party to that agreement, and Servier merely agreed in a separate, private agreement to reimburse Agios for the rebates Agios was required to pay under Agios's CGDP agreement for expenditures incurred after the acquisition.

In attempting to address this deficiency before the agency, Servier acknowledged that "TIBSOVO was technically included on Agios' CGDP agreement throughout 2021, [but] this was only because Servier did not acquire the entire Agios labeler code and a single product cannot be transferred between CGDP agreements." Dkt. 18-1 at 89. Servier contended, however, that Tibsovo's presence on Agios's CGDP agreement could be imputed to Servier because "Servier accepted responsibility for coverage gap discounts for TIBSOVO and fully

reimbursed Agios for such discounts post-acquisition." *Id.* But that argument, which Servier repeats here, merely elides the relevant issue.

To start, it is not a merely administrative quirk that prevented Servier from substituting itself for Agios under the existing CGDP agreement; rather, long before Congress enacted the phase-in rules at issue here, the Medicare Coverage Gap Discount Program required "manufacturers" to enter into CGDP agreements, and, in terms similar to those at issue here, Congress defined "manufacturer" to mean an "entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis." 42 U.S.C. § 1395w-114a(g)(5). The assignment of a labeler code, accordingly, is not a mere administrative proxy but, rather, a means of identifying the "manufacturer," as required by statute.

But, even more importantly, any hurdles that Servier may have faced in entering into a CGDP contract covering sales of Tibsovo for 2021 (which Servier, in any event, did not manufacture) does not eliminate the statutory requirement that the Part D expenditures allocated to a manufacturer for 2021 must be for drugs "covered by" the CGDP agreement of "*such* manufacturer," *id*. § 1395w-114c(g)(4)(C)(ii)(I)(bb) (emphasis added). And, as Servier must concede, it did not satisfy that statutory requirement. The fact that Servier agreed to reimburse Agios for the rebates that Agios owed pursuant to *Agios's* CGDP agreement with CMS, moreover, has no bearing on the proper interpretation or application of the statute. The Tibsovo that resulted in Part D expenditures in 2021 was not covered by a CGDP agreement with Servier, and Servier's private undertaking to reimburse Agios is just that—a private undertaking. It

neither qualifies as a CGDP agreement nor has the effect of substituting Servier for Agios under Agios's agreement. To the contrary, the only reason that a private reimbursement agreement was necessary was that Agios remained responsible for the rebate payments under *its* CGDP agreement with CMS.

Finally, Servier points to various exceptions to the CGDP agreement requirement that CMS's Final Guidance recognizes. Dkt. 15 at 19-20; *see also* Dkt. 18-1 at 89 n.11. The Court's task, however, is to construe that statute as Congress wrote it, *see Loper Bright Enters*., 144 S. Ct. at 2261–62 ("reviewing courts [must] exercise independent judgment on questions of law"), and, here, the statutory text is unambiguous: it limits the relevant Part D expenditures to those incurred in 2021 for drugs covered by a CGDP agreement with "such manufacturer"—that is by an agreement with the entity seeking "specified small manufacturer" status. 42 U.S.C. § 1395w-114c(g)(4)(C)(ii)(I)(aa). Because none of the sales at issue were covered by a CGDP agreement with Servier, that ends the matter. But even putting that recent development in administrative law aside, CMS's Final Guidance would carry no weight here. Servier does not contend that it qualifies under any of the exceptions or refinements discussed in the guidance, but only that "the guidance provides for a similar situation." Dkt. 15 at 19. Under certain circumstances, CMS has permitted a manufacturer to participate in a preexisting CGDP agreement by including its own drugs on another manufacturer's CGDP agreement; CMS's Final Guidance treats such manufacturers as if they had a CGDP agreement of their own. *See* Dkt. 18-1 at 29 n.9. But that "similar situation" differs from the present context in a critical respect. There, the manufacturer at issue participated in another manufacturer's CGDP in 2021 using its *own* labeler code. Here, in contrast, the Tibsovo listed on Agios's CGDP agreement bore Agios's labeler code, not Servier's.

c.

Nor is the Court persuaded by Servier's alternative contention that the definition of "manufacturer" is sufficiently capacious to conclude that Servier should be considered a "manufacturer" with respect to the 2021 Part D expenditures for Tibsovo that was produced by Agios (or its contractor) and transferred to Servier in April 2021. Again, Servier presses several arguments in support of its reading of the statute, and, again, each of those arguments fails.

Servier starts by pointing out that "CMS has never defined 'manufacturer' . . . to be the entity that creates a physical drug product." Dkt. 15 at 15. For support, it points to a CMS rule that includes as "manufacturers" companies, like both Agios and Servier, that use "a contract manufacturer to create [their] pill[s]," and also includes as manufacturers companies that repackage or relabel products. *Id.* (citing *Medicare Program; Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Program for Contract Year 2013 and Other Changes*, 77 Fed. Reg. 22072, 22080 (Apr. 12, 2012). But, as CMS explains, it has never posited that the term "manufacturer" is limited to those companies that "physically make" the drug. Dkt. 17 at 14-15. Rather, CMS relies on the statutory definition, which encompasses "any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products." *See* 42 U.S.C. § 1395w-114c(g)(5). The fact that Agios and Servier both engaged a third-party contractor to physically make Tibsovo, under their direction and pursuant to their specifications, is not inconsistent with a finding that both companies were "engaged in the production," "preparation," or "processing" of prescription drugs, and Servier does not argue to the contrary. It is a different matter entirely, however, to find that Servier was engaged in the production, preparation, or processing of stock of Tibsovo that existed at the time of the acquisition and that Servier did not further prepare or process. The

fact that CMS also treats entities that relabel or repackage products as "manufacturers" arguably presents a closer question, but because Servier did not relabel or repackage Agios's stock of Tibsovo, the Court need not address that question.

Servier also cites to guidance issued by CMS pursuant to another program, CMS's Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027, at 187 (Oct. 2, 2024) ("Negotiation Program Guidance"), to support its contention that, in similar circumstances, CMS has "interpreted the statutory phase 'the manufacturer' of a selected drug to refer to 'the entity that owns the NDA(s) . . . for the selected drug.'" Dkt. 15 at 16–17 (quoting Negotiation Program Guidance). That guidance, however, dealt with a very different question; it considered how to choose between multiple entities that meet the statutory definition of manufacturer. *See* Negotiation Program Guidance at 35, 187. Here, in contrast, Servier did not meet the statutory definition of manufacturer at the time the relevant stock of Tibsovo was produced, and, applying the statutory definition, the relevant Part D expenditures were not "for" any quantity of Tibsovo "produced, prepared, propagated, compounded, converted, or processed by" Servier. *See* 42 U.S.C. §§ 1393w-114c(g)(4)(C)(ii)(I)(bb), 1393w-114c(g)(4)(C)(ii)(II)(aa).

Finally, invoking the dictionary, Servier argues that it "was a 'manufacturer' of the Tibsovo stock existing at the time of the 2021 acquisition because" it "produced" or "propagated" that stock. Dkt. 15 at 18. In particular, Servier argues, "the common meaning of 'produce' includes 'to make available for public . . . dissemination,' and 'propagate' includes 'to cause to spread out and affect a greater number or greater area.'" *Id.* (quoting *Merriam Webster Online Dictionary*, Produce & Propagate (2024)). Under the *noscitur a sociis canon*, however, courts must ascribe terms in a series meaning based on the company that they keep. *See Yates v.*

United States, 574 U.S. 528, 543 (2015). Doing so "avoid[s] ascribing to one word a meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth to the Acts of Congress." *Gustafson v. Alloyd Co*., 513 U.S. 561, 575 (1995) (quoting *Jarecki v. G.D. Searle & Co.*, 367 U.S. 303, 307 (1961)). Here, the statutory definition of "specified small manufacturer drugs" includes words that focus on the creation or making of a product, 42 U.S.C. § 1395w-114c(g)(4)(C)(II)(aa), as does the statutory definition of "manufacturer," *id.* § 1395w-114c(g)(5). Understood in this light, the word "produce" is better understood to mean "to cause to have existence" or "to compose" or "create," while the term "propagate" is better understood to mean "to cause to continue or increase by sexual or asexual reproduction." *Merriam Webster Online Dictionary*, Produce & Propagate (2024). Servier did not "cause" the Tibsovo dispensed under Part D in 2021 to come into existence, nor did it "increase" the stock of Tibsovo dispensed under Part D in 2021. Under a common-sense reading of the statutory text, none of the stock of Tibsovo dispensed under Part D in 2021 was "produced, prepared, propagated, compounded, converted, or processed by" Servier, and it would strain the text to read verbs like produce and propagate to include acts of dissemination, which are more closely associated with wholesalers and pharmacies than with manufacturers.

* * *

For all of these reasons, the Court concludes that the best reading of the statutory definition of "specified small manufacturer" requires that the Part D 2021 expenditures for any one applicable drug produced, prepared, propagated, compounded, converted, or processed by that manufacturer amount to at least 80% of the total Part D 2021 expenditures for all applicable drugs produced, prepared, compounded, converted, or processed by that manufacturer, and that the drug was covered by a CGDP agreement "of such manufacturer" that was in place for 2021.

Although portions of Servier's argument make *plausible* sense of at least portions of the statutory text, the Court's task is to discern the *best* reading of the statutory text as a whole, even in the face of some ambiguity. *See Loper Bright Enters*., 144 S. Ct. 2244. Considered in that light, the Court is persuaded that CMS offers the better reading of the statute—the reading that makes better sense of the statutory text as a whole, that gives each clause and preposition meaning, and that gives the words that Congress employed their most natural and common-sense interpretation.

The Court, accordingly, concludes that CMS's determination that Servier fails to qualify as a "specified small manufacturer" is not contrary to law.

B. Arbitrary and Capricious

Servier also contends that CMS's determination that Servier did not qualify as a "specified small manufacturer" was arbitrary and capricious for two reasons. First, Servier maintains that CMS erred when it continued to rely on labeler codes to attribute drug expenditures to manufacturers, even after Servier provided evidence that those labeler codes were (according to Servier) "flawed" or "incomplete." Second, Servier argues that CMS failed adequately to explain its decision when it denied Servier's recalculation request. The Court will consider these arguments in turn.

1. *Whether CMS relied on incomplete or flawed information*

The APA requires that an agency "examine the *relevant* data" before making a determination. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (emphasis added). The "relevant data" must be reliable, and it must offer an accurate measure of what is at issue. An agency action is arbitrary and capricious if the agency "use[s] data ill-suited to the task," *Am. Public Gas Ass'n v. U.S. Dep't of Energy*, 22 F.4th 1018, 1029

(D.C. Cir. 2022), or "brushe[s] aside critical facts," *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 932 (D.C. Cir. 2017).

Here, CMS relied on Prescription Drug Event data when attributing drug expenditures to manufacturers. As explained above, a Prescription Drug Event record is created each time a drug is dispensed to a Part D beneficiary. That record includes, among other things, the date that the drug was dispensed, the price paid, and the drug's National Drug Code. The National Drug Code, in turn, begins with a "labeler code," which is a five- or six-digit number that identifies the entity that "manufactur[ed], repack[ed], [or] relabel[ed]" the drug. 21 C.F.R. § 207.33(c)(1). To determine a manufacturer's 2021 expenditures under Part D, CMS looked to all of the Prescription Drug Event records from 2021 and attributed each sale to the manufacturer identified by the labeler code portion of the recorded National Drug Code.

All Prescription Drug Event records for Tibsovo dispensed in 2021 (exclusively) bear National Drug Codes with Agios's labeler code and covered under Agios's CGDP agreement. CMS thus attributed all 2021 Tibsovo expenditures to Agios. According to Servier, those Prescription Drug Event records were "incomplete" because they did "not accurately reflect Part D sales in the event of a change in ownership." Dkt. 8-1 at 20. According to Servier, "CMS [was] well aware" that Prescription Drug Event data "does not reflect which manufacturer owned" the approved NDA at the time the Part D expenditure occurred, and thus, on Servier's telling, CMS acted arbitrarily when it relied on that data even "when presented with more accurate and reliable data of Servier's 2021 Part D sales"—namely, information about Servier's ownership of Tibsovo. *Id.*

The parties do not dispute that Prescription Drug Event data accurately reflects the manufacturer of the drug—that is, the company that produced the relevant product. As CMS

observes, Servier does not contend that "Tibsovo dispensed to Part D beneficiaries in 2021 was mislabeled with the wrong labeler code;" rather, Servier "admits that Agios manufactured all Tibsovo dispensed to Part D beneficiaries in 2021." Dkt. 13-1 at 25. According to CMS, moreover, the manufacturer is all that matters for relevant purposes; it is of no moment that the labeler code does not provide any information about who owns the approved NDA after an acquisition. "The fact that the labeler information is less-well-suited to determine what happened to that drug product once it left Agios's possession," moreover, "is irrelevant for purposes of the statute." *Id.*

In short, the parties' dispute does not turn on the facts but, rather, on the law. If Servier is correct, and the definition of "specified small manufacturer" turns, at least at times, on whom owns the approved NDA, then it would also be correct that CMS needed to consider Servier's supplemental information. But if CMS is correct and the relevant question is whether the company at issue actually manufactured the product that resulted in the Part D expenditures, then the agency would not need any information apart from the Prescription Drug Event data to render its decision.

As a result, the question of statutory interpretation considered above answers Servier's arbitrary and capricious challenge as well. The Court has already concluded that the definition of "specified small manufacturer" turns, in part, on whether 2021 Part D expenditures on an applicable drug produced by that manufacturer, and covered by a CGDP agreement "of such manufacturer" in 2021, equaled or exceeded 80% of total Part D expenditures on applicable drugs produced by that manufacturer in 2021. Under that reading of the statute, Servier does not qualify as a "specified small manufacturer" because it did not produce any Tibsovo in 2021 that resulted in any 2021 Part D expenditures. That ends the matter, and the fact that Servier

acquired the approved NDA in April 2021, acquired Agios's existing stock of Tibsovo, and agreed to reimburse Agios's for the rebates that Agios's was required to pay under its CGDP agreement for Tibsovo sales after April 1, 2021 is irrelevant.

The Court, accordingly, concludes that CMS's reliance on the manufacturer drug codes included in Prescription Drug Event data, and failure to rely on the supplemental information that Servier provided regarding its acquisition, was neither arbitrary nor capricious.

2. *Whether CMS adequately explained its decision*

The APA also requires that an agency "articulate a satisfactory explanation for its action including a rational connection between the facts found and the choices made." *Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 56–57 (D.C. Cir. 2015) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)) (emphasis omitted). According to Servier, CMS failed to satisfy this requirement because it did not adequately explain in its letter denying Servier's recalculation request "why it found that Servier's sales of Tibsovo in 2021 using the legacy Agios labeler code were 'not relevant to [the] eligibility determination' under the statute." Dkt. 8-1 at 23 (quoting Dkt. 18-1 at 94).

In that letter, CMS explained that expenditures on applicable drugs dispensed in 2021, "[a]s stated in the Methodology [Memorandum]," "are attributable to each manufacturer, as determined by the labeler code extracted from the [National Drug Code]." Dkt. 18-1 at 94. It noted that Tibsovo's labeler code "remained under [Agios]'s Coverage Gap Discount Program agreement in 2021" and that, "[w]hile there may have been Part D expenditures in 2021 for [Tibsovo], . . . that is not relevant to Servier's eligibility determination because, in 2021, [Tibsovo] was not attributable to Servier, as determined by the labeler code." *Id.* And, finally, it explained that because none of the 2021 Tibsovo Part D expenditures were attributable to

Servier, "Servier had no ($0.00) Part D expenditures in 2021 for applicable drugs under its labeler code, 72694," and therefore "no applicable drug had 2021 Part D expenditures totaling 80 percent or more of the total 2021 Part D expenditures." *Id.* For these reasons, CMS reaffirmed its conclusion that "Servier Pharmaceuticals does not meet the specified small manufacturer criteria." *Id.*

That explanation is sufficient to satisfy the agency's obligation to articulate a satisfactory explanation for its action. CMS's guidance made clear that Part D expenditures would be allocated to manufacturers using the labeler code from Prescription Drug Event Data. Moreover, although neither the Final Guidance nor the Methodology Memorandum explain why CMS was focused on the identity of the manufacturer, that premise is sufficiently obvious that it required no explanation: it requires little sleuthing to discern that CMS was focused on the identity of the manufacturer because it read the statute, as this Court does, to define "specified small manufacturer" to turn, in part, on the percentage of total 2021 Part D expenditures for applicable drugs produced by that "manufacturer" that were attributable to a single drug produced by that "manufacturer." A "reviewing court must 'uphold' even 'a decision of less than ideal clarity if the agency's path may be reasonably discerned.'" *Garland v. Ming Dai*, 593 U.S. 357, 369 (2021) (quoting *Bowman Transp., Inc. v. Ark.-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974)); *see also Casino Airlines, Inc. v. Nat'l Transp. Safety Bd.*, 439 F.3d 715, 717 (D.C. Cir. 2006). Here, that path is readily discernable.

In any event, no purpose would be served by a remand because the agency correctly interpreted the statute and correctly determined that Servier did not qualify as a "specified small manufacturer." "When an agency raises a purely legal argument for the first time in litigation, a court may consider that argument if it is both clearly correct and would render remand pointless

under the harmless error standard." *Oglala Sioux Tribe v. U.S. Nuclear Regulatory Comm.*, 45 F.4th 291, 304 (D.C. Cir. 2022) (citing 5 U.S.C. § 706). Here, the agency's more fully developed arguments are both purely legal and, as the Court has concluded, correct. As a result, a remand would be pointless. The Court has determined that Servier does not qualify as a "specified small manufacturer" under the plain language of statute, and on remand the agency would have no choice but to deny Servier's request anew. "To remand would be an idle and useless formality," and *Chenery* "does not require that [courts] convert judicial review of agency action into a ping-pong game." *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 766 n.6 (1969) (plurality).

CONCLUSION

For the foregoing reasons, Servier's motion for summary judgment, Dkt. 8, is hereby **DENIED**, and CMS's cross-motion for summary judgment, Dkt. 13, is hereby **GRANTED**.

A separate order will issue.

/s/ Randolph D. Moss
RANDOLPH D. MOSS
United States District Judge

Date: January 3, 2025