No. 24-270

In the Supreme Court of the United States

VANDA PHARMACEUTICALS INC., PETITIONER

v.

CENTERS FOR MEDICARE & MEDICAID SERVICES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether a rule issued by the Centers for Medicare and Medicaid Services defining which drug products qualify as "line extensions" for purposes of the Medicaid Drug Rebate Program was contrary to law or arbitrary and capricious.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-28a) is reported at 98 F.4th 483. The memorandum opinion of the district court (Pet. App. 29a-84a) is available at 2023 WL 2743364.

JURISDICTION

The judgment of the court of appeals was entered on April 10, 2024. On June 11, 2024, the Chief Justice extended the time within which to file a petition for a writ of certiorari to September 6, 2024, and the petition was filed on that date. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Medicaid is a cooperative federal-state program that funds medical care for certain needy people. See Medicaid Act, 42 U.S.C. 1396 *et seq.* Covered forms of

medical care include prescription drugs. See 42 U.S.C. 1396d(a)(12).

In order for a manufacturer's drugs to be eligible for Medicaid coverage, the manufacturer must participate in the Medicaid Drug Rebate Program. See 42 U.S.C. 1396r-8(a)(1). That program requires manufacturers to pay rebates to Medicaid—calculated in accordance with a statutory formula—to offset part of the cost of their drugs. See *ibid.* The formula has two components: the "[b]asic" rebate amount and the "[a]dditional" rebate amount. 42 U.S.C. 1396r-8(c)(1) and (2) (2018 & Supp. IV. 2022).

This case concerns the additional rebate amount, which is designed to ensure that drug manufacturers compensate Medicaid when they increase drug prices more than necessary to account for inflation. See Pet. App. 4a. The additional rebate amount is typically the amount by which the drug's current price exceeds the price of the drug when it was first marketed, adjusted for inflation. See 42 U.S.C. 1396r-8(c)(2) (2018 & Supp. IV 2022). The additional rebate ensures that, "once a drug manufacturer sets an initial price for a drug, Medicaid will not pay more than that price (plus inflation)." Pet. App. 4a.

The rebate formula, as originally enacted, enabled manufacturers to avoid paying the additional rebate in some circumstances. See Pet. App. 4a. The statute requires a distinct rebate calculation for "each dosage form and strength" of a covered drug. 42 U.S.C. 1396r-8(c)(1)(A). Thus, a manufacturer could release a new formulation of a drug at a higher price, yet avoid paying a rebate based on the price increase. See Pet. App. 4a.

Congress addressed that issue in 2010 by enacting a provision known as the "line extension" provision. See

42 U.S.C. 1396r-8(c)(2)(C). "[T]he term 'line extension' means, with respect to a drug, a new formulation of the drug, such as an extended release formulation." *Ibid.* Under the line-extension provision, a manufacturer may set the initial price of a line-extension drug as high as it wishes, but it owes an inflation-based rebate if either the price of the line-extension drug or the price of the original drug rises more than necessary to account for inflation. See *ibid.* In other words, such drugs "are on the hook not only for their own price increases, but also for any price increases to the original drug on which they were based." Pet. App. 4a; see *id.* at 4a-5a (describing the details of the rebate formula).

The line-extension provision applies only to a "drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form." 42 U.S.C. 1396r-8(c)(2)(C)(i); see 42 U.S.C. 1396r-8(k)(7)(A)(ii) and (iv) (Supp. IV 2022) (defining the terms "single source drug" and "innovator multiple source drug"). The line-extension provision also does not apply to "an abuse-deterrent formulation of the drug (as determined by the Secretary [of Health and Human Services])." 42 U.S.C. 1396r-8(c)(2)(C).

2. In 2012, the Centers for Medicare and Medicaid Services (CMS) proposed a notice-and-comment rule defining the statutory term "line extension." See 77 Fed. Reg. 5318, 5338 (Feb. 2, 2012). After reviewing the comments, however, CMS "decided not to finalize the proposed regulatory definition" in the final rule. 81 Fed. Reg. 5170, 5197 (Feb. 1, 2016). The agency stated that it "may consider addressing this [issue] in future rulemaking." *Ibid.* In the meantime, it directed manufacturers "to rely on the statutory definition of line extension" and "to use reasonable assumptions in their

determination of whether their drug qualifies as a line extension drug." *Id.* at 5265.

CMS revisited the issue in 2020. See 85 Fed. Reg. 37,286, 37,294 (June 19, 2020). It explained that, "[a]fter several years of experience with manufacturers self-reporting their line extensions," it had found "inconsistency among manufacturers in their identification of drugs as line extensions." *Ibid.* The agency was also "concerned that manufacturers may have a financial incentive to be underinclusive in their identification of drugs as line extensions because a drug identified as a line extension may be subject to a higher rebate" to be paid to the government. *Ibid.*

CMS accordingly adopted a final rule defining the statutory terms "line extension" and "new formulation." See 85 Fed. Reg. 87,000, 87,101 (Dec. 31, 2020). The rule provides that "*[l]ine extension* means, for a drug, a new formulation of the drug." 42 C.F.R. 447.502. It then provides that "*[n]ew formulation* means, for a drug, a change to the drug, including, but not limited to: an extended release formulation or other change in release mechanism, a change in dosage form, strength, route of administration, or ingredients." *Ibid.* The rule also clarifies that, in order for the line-extension provision to apply, only the original drug needs to be in "oral solid dosage form" (*e.g.*, pill form), and that the line-extension drug may be in a different form (*e.g.*, liquid form). 85 Fed. Reg. at 87,034.

3. Petitioner Vanda Pharmaceuticals Inc., a drug manufacturer that participates in the Medicaid Drug Rebate Program, sued CMS and CMS's Administrator in the U.S. District Court for the District of Maryland. See Pet. App. 29a. Petitioner claimed that the 2020 rule

contravened the Medicaid statute and was arbitrary and capricious. See *id.* at 61a.

The district court granted summary judgment to the government. See Pet. App. 29a-84a. The court rejected petitioner's contention that the rule's definitions of "line extension" and "new formulation" violated the statute. See *id.* at 63a-76a. The court also rejected petitioner's arbitrary-and-capricious claim. See *id.* at 76a-84a.

4. The Fourth Circuit affirmed. See Pet. App. 1a-28a.

The court of appeals resolved petitioners' statutory claim by applying the "traditional tools of statutory interpretation." Pet. App. 11a (citation omitted). The court explained that, because CMS had not relied on *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), the court would not do so either. See Pet. App. 11a. The court stated that it would pay "attention" to CMS's views, *ibid.* (citation omitted), but that it would "adopt those views as [its] own only if they ha[d] the 'power to persuade,'" *id.* at 10a-11a (quoting *Skidmore* v. *Swift & Co.*, 323 U.S. 134, 140 (1944)).

The court of appeals then rejected petitioners' claim that the challenged rule's definitions of "line extension" and "new formulation" violated the Medicaid statute. See Pet. App. 12a-21a. The court observed that CMS's definition of "line extension" "hews quite closely to the statute" and that any differences between the statutory and regulatory language were "patently superficial." *Id.* at 12a. It likewise concluded that the rule's definition of "new formulation" comports with the "plain meaning" and "structure" of the line-extension provision. *Id.* at 16a.

The court of appeals noted, moreover, that the statute defines "line extension" to mean "'a new formulation

of the drug, *such as* an extended release formulation.'" Pet. App. 16a (quoting 42 U.S.C. 1396r-8(c)(2)(C)). The court reasoned that "[t]erms of inclusion like 'such as' are congressional invitations for agencies to apply their expertise to fill out the list with further examples." *Id.* at 16a-17a. It concluded that the additional examples identified in CMS's rule were "reasonable" and "consistent with the statutory framework." *Id.* at 17a (citation omitted).

The court of appeals also rejected petitioner's contention that, if a drug requires a new drug application under the regulatory scheme administered by the Food and Drug Administration (FDA), it is not a line extension under the Medicaid statute. See Pet. App. 19a. The court stated that, "[i]f Congress had meant to limit line extensions" in the manner that petitioner suggests, "it would have done so explicitly within the definition of the term 'line extension.'" *Id.* at 20a. It observed that "[n]o such FDA references are made in the line-extension definition." *Ibid.*

Finally, the court of appeals rejected petitioners' claim that CMS acted arbitrarily by inadequately accounting for manufacturers' reliance on the definition of "line extension" proposed in 2012. See Pet. App. 25a. The court emphasized that CMS "explicitly declined to finalize that proposal and instructed manufacturers instead to 'rely on the statutory definition.'" *Ibid.* (citation omitted). It observed that CMS had no legal obligation "to make allowances for industry players who relied on proposals never implemented." *Ibid.*

ARGUMENT

Petitioner contends (Pet. 20-26) that the court of appeals applied an unduly deferential standard in evaluating the lawfulness of the regulatory definitions of "line

extension" and "new formulation." It also contends (Pet. 26-31) that CMS acted arbitrarily by failing to account for the asserted reliance by manufacturers on the definition of "line extension" that was proposed in 2012 but that was never adopted. Those contentions are incorrect, and the court of appeals' decision does not conflict with any decision of this Court or of any other court of appeals. The petition for a writ of certiorari should be denied.

1. Petitioner errs in contending (Pet. 20-26) that the court of appeals accorded undue deference to CMS's reading of the Medicaid statute, contrary to this Court's decision in *Loper Bright Enterprises* v. *Raimondo*, 144 S. Ct. 2244 (2024).

a. In *Loper Bright*, this Court concluded that the Administrative Procedure Act, 5 U.S.C. 551 *et seq.*, 701 *et seq.*, requires federal courts to exercise "independent judgment in deciding whether an agency has acted within its statutory authority." 144 S. Ct. at 2273. The Court overruled its earlier decision in *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), in which it had held that a court owes deference to an agency's reasonable interpretation of an ambiguous statute that the agency administers. See *Loper Bright*, 144 S. Ct. at 2273.

The *Loper Bright* Court recognized, however, that courts may "seek aid from the interpretations of those responsible for implementing particular statutes." 144 S. Ct. at 2262. The weight owed to an executive agency's reading of a statute depends upon "the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if

lacking power to control." *Id.* at 2259 (quoting *Skidmore* v. *Swift & Co.*, 323 U.S. 134, 140 (1944)).

The *Loper Bright* Court also recognized that, in "a case involving an agency," "the statute's meaning may well be that the agency is authorized to exercise a degree of discretion." 144 S. Ct. at 2263. For example, some statutes "expressly delegate" power to an agency. *Ibid.* (citation omitted). Others empower an agency "to regulate subject to the limits imposed by a term or phrase that 'leaves agencies with flexibility,' such as 'appropriate' or 'reasonable.'" *Ibid.* (citation omitted). When Congress enacts such a statute, "courts must respect the delegation, while ensuring that the agency acts within it." *Id.* at 2273.

b. Although the decision below predates *Loper Bright*, it is fully consistent with the principles set forth there. The court of appeals applied the "'traditional tools of statutory interpretation'" and "independently assess[ed] whether the agency action was unlawful." Pet. App. 10a-11a (citation omitted). Because CMS "did not invoke *Chevron*," the court declined to rely on that decision. *Id.* at 11a. Indeed, petitioner acknowledges (Pet. 20) that the court "expressly disavowed *Chevron* deference."

Petitioner errs in asserting (Pet. 20) that the court of appeals merely "paid lip service" to the traditional principles of statutory interpretation. The court began with the statutory text, discussing the statutory definition of "line extension," see Pet. App. 12a, and the dictionary definitions of "new" and "formulation," see *id.* at 13a. The court then turned to statutory context, explaining that the exception for abuse-deterrent formulations "confirms that the statutory definition is broader than [petitioner] would have it." *Id.* at 15a. The court

also analyzed "the structure of the statutory line-extension provision" and concluded that it supports "a broad definition of new formulation." *Id.* at 16a. Finally, the court addressed and rejected petitioner's contrary textual arguments. See *id.* at 15a-16a. The court, in short, used "the traditional tools of statutory construction * * * to resolve statutory ambiguities"—just as *Loper Bright* calls for. 144 S. Ct. at 2266.

Petitioner also errs in asserting (Pet. 20) that the court of appeals evaluated CMS's interpretation under an "unduly deferential standard." The court stated that it would pay "attention" to CMS's views, Pet. App. 11a (citation omitted), but that it would "adopt those views as [its] own only if they have the 'power to persuade,'" *id.* at 11a-12a (quoting *Skidmore*, 323 U.S. at 140). That standard is consistent with *Loper Bright*, where this Court explained that "[c]areful attention to the judgment of the Executive Branch may help inform" a court's inquiry and that the weight owed to the Executive Branch's views depends on those views' "'power to persuade.'" 144 S. Ct. at 2267, 2273 (quoting *Skidmore*, 323 U.S. at 140).

Petitioner argues (Pet. 23) that CMS's reading was not entitled to respect under *Skidmore* because it was insufficiently longstanding and consistent. That is incorrect. Although an executive agency's longstanding and consistent interpretation of a statute "may be especially useful," *Skidmore* does not limit courts to such interpretations. *Loper Bright*, 144 S. Ct. at 2262. "[Agency] expertise has always been one of the factors which may give an Executive Branch interpretation particular 'power to persuade.'" *Id.* at 2267 (citation omitted). Consistent with that principle, the court of appeals stated that it would pay "attention to the agency's views

in light of the agency's expertise in the given area." Pet. App. 11a (brackets and citation omitted). In any event, the decision below did not rest on *Skidmore*, which the court cited only once. See *id.* at 12a. The decision instead rested on the court's independent determination that "the agency's rule is in accord with law." *Id.* at 28a.

Petitioner points to the court of appeals' statement that CMS's rule was "reasonable" and "consistent with the statutory framework." Pet. 20 (quoting Pet. App. 17a). But petitioner takes those statements out of context. In the decision below, the court emphasized that Congress defined a line extension as "a new formulation of the drug, *such as* an extended release formulation." Pet. App. 16a (citation omitted). It reasoned that "[t]erms of inclusion like 'such as' are congressional invitations for agencies to apply their expertise to fill out the list with further examples," *id.* at 16a-17a—*i.e.*, examples of what the statute itself includes within the category of new formulations of the drug indicated by Congress's use of the term "such as." The court then stated that "the agency's additional examples here [were] 'reasonable' and 'consistent with the statutory framework.'" *Id.* at 17a (citation omitted). That analysis accords with *Loper Bright*, where this Court explained that courts must "identify and respect [congressional] delegations of authority" to agencies, must "police the outer statutory boundaries of those delegations," and must ensure that "the agency has engaged in 'reasoned decisionmaking' within those boundaries." 144 S. Ct. at 2263, 2268 (citation omitted).

In sum, the court of appeals' opinion, read as a whole, is fully consistent with the principles set forth in *Loper Bright*. In arguing otherwise, petitioner discounts the court's express assurance that it would "adopt [the

agency's] views as [its] own only if they have the 'power to persuade,'" Pet. App. 11a-12a (citation omitted); ignores the court's thorough textual analysis, see *id.* at 12a-18a; and takes statements in the court's opinion out of context, see p. 10, *supra*.

c. Petitioner argues (Pet. 23) that, "[b]ecause the court of appeals gave undue deference to the agency's interpretation, it reached a result that is at odds with the statute." Although petitioner made multiple statutory arguments in the lower courts, it raises (Pet. 24) only one such argument here—namely, that "a product requiring its own standalone New Drug Application * * * by definition *cannot* be a line extension."

Petitioner fails to connect its statutory argument with its claim that the court of appeals accorded undue deference to CMS's views. Petitioner identifies no way in which the court deferred to the agency in the course of rejecting petitioner's contention that the definition of line extension depends on whether a drug requires its own new drug application. The language petitioner cites—for example, the statement that CMS's reading was "reasonable" and "consistent with the statutory framework," Pet. App. 17a (citation omitted)—instead comes from other portions of the opinion that rejected statutory arguments that petitioner does not renew in this Court.

The statutory argument that petitioner does raise also is not properly before this Court. The petition for a writ of certiorari presents (at i) only the question whether the court of appeals' decision "comport[s] with *Loper Bright*," not the question whether the court correctly interpreted the statute—or, more precisely, not whether the court of appeals correctly rejected petitioner's contention that a drug requiring its own new

drug application cannot be a line extension. "Only the questions set out in the petition, or fairly included therein, will be considered by the Court." Sup. Ct. R. 14.1(a); see, *e.g.*, *Yee* v. *City of Escondido*, 503 U.S. 519, 535-538 (1992).

Petitioner's statutory argument, in any event, fails on its own terms. The Medicaid statute defines the term "line extension," and that definition says nothing about whether the drug requires a new drug application under FDA's regulations. See 42 U.S.C. 1396r-8(c)(2)(C). This Court "ordinarily resist[s] reading words or elements into a statute that do not appear on its face." *Bates* v. *United States*, 522 U.S. 23, 29 (1997).

The text that the statute does use defines a line extension as "a new formulation of the drug, *such as an extended release formulation*." 42 U.S.C. 1396r-8(c)(2)(C) (emphasis added). Extended-release formulations often require new drug applications. See Pet. App. 19a. Petitioner's own product, for example, is an extended-release formulation that required a new drug application. See *id.* at 70a. "That alone shows that a new drug application is not the silver bullet [petitioner] imagines." *Id.* at 19a.

The statute, moreover, excludes "abuse-deterrent formulation[s]" from the definition of "line extension." 42 U.S.C. 1396r-8(c)(2)(C). Such formulations, too, "require new innovations" and thus may require new drug applications. Pet. App. 15a. The "fact that they had to be carved out" confirms that Congress did not limit the statutory definition as petitioner suggests. *Ibid.*; see *Brown* v. *Maryland*, 12 Wheat. 419, 438 (1827) (Marshall, C.J.) ("[T]he exception of a particular thing from general words, proves that, in the opinion of the lawgiver,

the thing excepted would be within the general clause had the exception not been made.").

Petitioner also errs in relying (Pet. 25) on the Medicaid statute's "cross-references" to the regulatory scheme administered by FDA. It is true that some of the statute's provisions expressly refer to FDA actions. See Pet. App. 20a. But "[n]o such FDA references are made in the line-extension definition at issue here." *Ibid.*

d. Petitioner does not argue that the decision below conflicts with the decision of any other court of appeals. Petitioner instead asserts (Pet. 24-25) a conflict with a district-court decision, *Ipsen Biopharmaceuticals, Inc.* v. *Azar*, No. 16-cv-2372, 2020 WL 3402344 (D.D.C. June 19, 2020). But the *Ipsen* court did not adopt petitioner's interpretation; to the contrary, the case did not directly involve the line-extension provision, and the court in any event *rejected* the contention that the Medicaid statute incorporated wholesale distinctions drawn from the FDA context. See *id.* at *10-*11. Regardless, this Court ordinarily grants certiorari to resolve conflicts among the courts of appeals—not to resolve a purported conflict with the decision of a district court. See Sup. Ct. R. 10(a).

Petitioner argues (Pet. 26), in the alternative, that this Court should grant the petition for a writ of certiorari, vacate the court of appeals' judgment, and remand the case (GVR) in light of *Loper Bright*. In general, however, a GVR order is "potentially appropriate" only if "intervening developments * * * reveal a reasonable probability that the decision below rests upon a premise that the lower court would reject if given the opportunity for further consideration." *Lawrence* v. *Chater*, 516 U.S. 163, 167 (1996) (per curiam). This case does not satisfy that standard. Neither the agency nor the

court of appeals relied on *Chevron*, the overruling of which was the subject addressed in *Loper Bright*. And as discussed above, the court of appeals' decision fully comports with the principles set forth in *Loper Bright*. In these circumstances, "this Court has no appropriate legal basis to vacate the [court of appeals'] judgment." *Grzegorczyk* v. *United States*, 142 S. Ct. 2580, 2580 (2022) (statement of Kavanaugh, J., respecting the denial of certiorari).

2. Petitioner also argues (Pet. 26-31) that, when CMS issued the challenged rule in 2020, it did not properly account for reliance on the definition of "line extension" set forth in the proposed rule that it had issued in 2012. That contention does not warrant further review.

In 2012, CMS proposed a rule under which the line-extension provision would apply only if both the original drug and the line-extension drug came in pill form. See 77 Fed. Reg. at 5338. But CMS ultimately "decided not to finalize" that definition in the final rule it issued in 2016. 81 Fed. Reg. at 5197. CMS stated that it "may consider addressing this [issue] in future rulemaking" and that, in the meantime, manufacturers should "rely on the statutory definition." *Id.* at 5197, 5265. In 2020, CMS issued a final rule stating that only the original drug, not the line-extension drug, must be in pill form in order for the line-extension provision to apply. See 85 Fed. Reg. at 87,034. CMS acknowledged that its final rule differed from its 2012 proposal, but it explained the rationale for the change. See *id.* at 87,036.

Petitioner argues (Pet. 27) that the definition set forth in CMS's 2012 proposal "led to reasonable reliance throughout the industry." But "a proposed rule is just a proposal." *In re Murray Energy Corp.*, 788 F.3d 330,

334 (D.C. Cir. 2015) (Kavanaugh, J.). Indeed, the "notice-and-comment procedure is designed so that an agency can float a potential rule to the public without committing itself to enacting the proposed rule's content." Pet. App. 25a. Requiring an agency to make "allowances for industry players who relied on proposals [that were] never implemented" would "dissuade agencies from making exploratory proposals in the first place." *Ibid.* Petitioner cites no case in which this Court or any court of appeals required an agency to make such allowances. See *ibid.*

Contrary to petitioner's suggestion (Pet. 29), the decision below does not conflict with this Court's decisions in *Encino Motorcars, LLC* v. *Navarro*, 579 U.S. 211 (2016), and *DHS* v. *Regents of University of California*, 591 U.S. 1 (2020). In *Encino Motorcars*, this Court held that the Department of Labor acted arbitrarily by issuing a final rule that, with "barely any explanation," departed from a proposal to codify an agency policy on which industry actors had relied "since 1978." 579 U.S. at 222. Before the proposed rulemaking, the agency's policy had been reflected in sub-regulatory agency documents. See *id.* at 217. It was the decades-old agency policy—not the unadopted proposal—that engendered serious reliance interests that the agency was required to consider. See *id.* at 222-223. In this case, by contrast, CMS never adopted, in sub-regulatory documents or otherwise, the definition of "line extension" proposed in 2012. The proposal was just that—a proposal.

In *Regents*, this Court held that the Department of Homeland Security had acted arbitrarily by rescinding the Deferred Action for Childhood Arrivals (DACA) program without first considering the potential reliance interests of DACA beneficiaries. See 591 U.S. at 9. But

Regents involved reliance on a program that the agency had adopted and implemented—not reliance on a never-adopted proposal.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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