No. 24-270

In the Supreme Court of the United States

VANDA PHARMACEUTICALS INC.,

Petitioner,

v.

CENTERS FOR MEDICARE & MEDICAID SERVICES; CHIQUITA BROOKS-LASURE, in her capacity as Administrator of Centers for Medicare & Medicaid Services

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

REPLY BRIEF FOR PETITIONER

PAUL W. HUGHES
Counsel of Record
ANDREW A. LYONS-BERG
ALEX C. BOOTA
CALEB H. YONG
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001
(202) 756-8000
phughes@mwe.com

Counsel for Petitioner

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Cases—continued

Statutes, Rules, and Regulations

Other Authorities

REPLY BRIEF FOR PETITIONER

The Court should grant the petition to address two critically important issues concerning the role of courts under the Administrative Procedure Act (APA).

First, the decision below disregarded a fundamental textual limitation in the governing statute because it deferred to the agency's otherwise "sensible" and "reasonable" interpretation—precisely the approach this Court rejected in *Loper Bright*, only reprised under another name.

Second, the court of appeals held that the agency did not have to consider reliance interests engendered by its previous position simply because the agency announced its position in a non-binding document.

Neither of these holdings can be squared with courts' responsibility under the APA. The Court should take this case to ensure that federal courts continue to fulfil their "solemn duty" to "exercise independent judgment in determining the meaning of statutory provisions" and to "ensure that agencies exercise their discretion consistent with the APA." *Loper Bright Enters.* v. *Raimondo*, 144 S. Ct. 2244, 2257 2262, 2268 (2024).

Tellingly, the government does not deny that these questions are important and frequently recur. Instead, it resists certiorari based on its disagreements with petitioner on the merits. But as we have explained, the decision below is irreconcilable with the analysis required under *Loper Bright* regardless of the merits of the underlying interpretative question. And it is directly contrary to this Court's precedents requiring agencies to consider reasonable reliance interests associated with their prior policies.

Further review is therefore warranted. Alternatively, the Court should grant, vacate, and remand to provide the court of appeals the opportunity to reconsider its statutory interpretation with the benefit of *Loper Bright*.

A. The decision below is inconsistent with *Loper Bright*.

1. As we explained, the court of appeals patches together the same deferential analysis this Court put to rest in *Loper Bright*. Pet. 20-23. Now, a court may no longer "declar[e] a[n] [agency's] reading 'permissible'"; instead, it "must exercise [its] independent judgment" by "deploying its full interpretive toolkit" to determine a statute's "best meaning." *Loper Bright*, 144 S. Ct. at 2271, 2273.

The court of appeals, however, began by concluding that it was "perfectly sensible" for the agency to adopt "a broader definition" of a statutory term than what Congress itself provided. Pet. App. 13a. And after applying interpretive tools to "confirm[] that" the agency's "broad definition" was "appropriate," the court of appeals found the interpretation "reasonable" and "consistent with the statutory framework." *Id.* at 16a-17a. It never "independently interpret[ed] the statute" to find its "best meaning"; the court's reasoning started and ended with the permissibility of the agency's reading. *Loper Bright*, 144 S. Ct. at 2263, 2273.

This deference is incompatible with *Loper Bright*. While courts, in "exercis[ing] [their] independent judgment" to interpret statutes, "may * * * seek aid from the interpretations of those responsible for implementing particular statutes" (*Loper Bright*, 144 S.

Ct. at 2262 (citing *Skidmore* v. *Swift & Co.*, 323 U.S. 134, 140 (1944)), that is not what the court of appeals did below. More than simply "pay 'attention' to CMS's views" (BIO 9 (quoting Pet. App. 11a)), the court of appeals structured its analysis around whether the agency's views were "sensible" (Pet. App. 13a), "permissibl[e]" (*id.* at 14a), "reasonable" (*id.* at 17a), and "consistent with the statutory framework" (*ibid.*). That is *Chevron* reanimated.

Contrary to the government's assertions, these quotations are not "out of context" (BIO 10) simply because some of them describe "additional examples" the agency devised in response to what the court viewed as a "congressional invitation[] for [it] to apply [its] expertise" (*ibid.* (quoting Pet. App. 16a-17a)). For one thing, in addition to the language on which the government focuses, the court *began* its statutory interpretation by observing that the regulation "strikes us as a perfectly sensible way to implement" the statute (Pet. App. 13a); the entirety of its analysis was simply confirmatory of this fundamental conclusion.

Nor should the government's contention that the court's analysis actually "accords with *Loper Bright*" be taken seriously. BIO 10 (quoting the Court's statement that courts still should "identify and respect [congressional] delegations of authority"). The Court in *Loper Bright* observed that "some statutes *expressly* delegate[] to an agency" the power to define statutory terms, and that others similarly contain explicit provisions "empowering an agency * * * to regulate subject to the limits imposed by a term" like "'appropriate' or 'reasonable.'" *Loper Bright*, 144 S. Ct. at 2263 (emphasis added); *see also id.* at 2263 nn.5 & 6 (collecting examples).

The court below, by contrast, was not faced with any express delegation; instead, it did exactly what *Loper Bright* forbids—it "pretend[ed] that *ambiguities* are necessarily delegations." 144 S. Ct. at 2268 (emphasis added); see Pet. App. 16a-17a (basing its analysis on the premise that "[t]erms of inclusion like 'such as' are congressional invitations for agencies to apply their expertise").

Finally, Vanda explained in its petition (at 22-23) that the court of appeals' analysis cannot be recast as an application of *Skidmore*, because the agency's position was neither longstanding nor consistent. The government protests that "*Skidmore* does not limit courts to such interpretations." BIO 9. But the Court's precedents are clear that "[a]n agency interpretation * * * which conflicts with the agency's earlier interpretation is 'entitled to considerably less deference'" under *Skidmore* "than a consistently held agency view." *Good Samaritan Hosp.* v. *Shalala*, 508 U.S. 402, 417 (1993) (quoting *INS* v. *Cardoza-Fonseca*, 480 U.S. 421, 446 n.30 (1987)); see also *Loper Bright*, 144 S. Ct. at 2262 ("[I]nterpretations issued contemporaneously with the statute at issue, and which have remained consistent over time, may be especially useful in determining the statute's meaning."). The government does not respond.

In any event, the government concedes that "the decision below did not rest on *Skidmore*." BIO 10. Instead, it rests on a kind of deference that functionally resurrects *Chevron*, despite the court of appeals' purported disclaimers. The Court should foreclose such an analysis.

2. We also explained that the court of appeals' undue agency deference led it to uphold a regulation

outside the statute's bounds. In particular, the statute specifies that a "drug" is defined by its FDA-approved New Drug Application (42 U.S.C. §§ 1396r-8(k)(7)(A)(ii), (iv)), and a "line extension" must be the same "drug" as the original product from which it is derived (*id.* § 1396r-8(c)(2)(C)). It follows that a product requiring its own New Drug Application cannot be a line extension under the statute because it is a distinct drug. Pet. 23-24.

The lower court's error is directly attributable to its deference to the agency. It acknowledged that "the agency's broad definition of line extension would sweep in drugs for which the FDA requires a new drug application." Pet. App. 19a. But it declined to consider how the statute's "lengthy chain" of textual "cross-reference[s]" limits the definition of "line extension," instead deeming "the agency's broad definition" generally "sensible." Pet. App. 13a, 20a.[1]

This statutory question is properly before this Court, despite the government's protestations. See BIO 11-12. That is, the court of appeals' substantive

---

[1] The government objects that the lower court's explicitly deferential statements came in what it calls "other portions of the opinion" regarding purportedly different "statutory arguments." BIO 11. Not so. The court of appeals first held that the regulations do not "stray outside the general statutory ambit," deferring to the agency as we have described; it then rejected what it characterized as a "specific textual limitation" proposed by Vanda. Pet. App. 12a, 18a. In other words, it deferred in finding the regulation compatible with the statute generally, and then rejected what it treated as a counterargument about a specific statutory incompatibility. In the "holistic endeavor" of statutory interpretation (*Czyzewski* v. *Jevic Holding Corp.*, 580 U.S. 451, 466 (2017)), explicit deference in the first phase of that analysis cannot be separated from the second.

statutory interpretation "is inextricably linked to, and is thus 'fairly included' within," the question whether the court gave too much deference to the agency's interpretation. *City of Sherrill* v. *Oneida Indian Nation of New York*, 544 U.S. 197, 214 (2005); see Stephen M. Shapiro et al., *Supreme Court Practice* 458 (10th ed. 2013) ("Questions not explicitly mentioned but essential to analysis of the decisions below * * * have been treated as subsidiary issues fairly comprised by the question presented."). Plainly, whether the court gave short shrift to the statutory text and whether it unduly deferred to the agency's interpretation are two sides of the same coin.

At the very least, the court of appeals' disregard for important substantive considerations cutting against its statutory interpretation underscores the scope of the deference afforded by that court, as well as the importance of ensuring that such deference does not continue to rise from the ashes of *Chevron*—which is precisely the nature of the first question presented.

On the merits, the government devotes several paragraphs to why it thinks courts should discount Congress's choice to define "line extension" via explicit cross-references to the Food Drug and Cosmetic Act's New Drug Application requirement. 42 U.S.C. § 1396r-8(k)(7)(A)(ii), (iv); Pet. 23-24; see BIO 12-13 (arguing that the phrase "such as an extended-release formulation" and the abuse-deterrent exclusion amendment decouple line extensions from these definitions). But just because an extended-release formulation *can* require a New Drug Application does not mean that it *typically* does. And just because Congress clarified that abuse-deterrent formulations—which

sometimes require a New Drug Application—should *not* be considered line extensions as a general matter does not mean that the statute does not already exclude certain abuse-deterrent formulations from its scope.

In any event, the government cannot be right that courts should disregard "express[] refer[ences] to FDA actions" in the Medicaid statute. BIO 13. Congress "says in a statute what it means and means in a statute what it says there." *Connecticut Nat'l Bank* v. *Germain*, 503 U.S. 249, 253-254 (1992).

3. Finally, the government does not dispute that the question presented is critically important. As we explained (at 31-32), if lower courts recreate a *Chevron*-like deference regime under another name, that result will directly undermine *Loper Bright*. The government does not respond, instead observing that the specific statutory interpretation upheld by the court of appeals conflicts with a district court decision rather than one of another court of appeals. See BIO 13.[2] While that may be true, the underlying statutory question is only an appurtenant issue necessary to resolving the first question presented here. The central question—the manner in and extent to which lower

[2] We of course agree that *Ipsen Biopharmaceuticals* v. *Azar*, 2020 WL 3402344 (D.D.C. June 19, 2020), "did not directly involve the line-extension provisions" (BIO 13)—but "directly" is doing a lot of work in that statement. *Ipsen* interpreted the same Medicaid Act definitional provisions that are incorporated into the line extension provision, and held that "a distinct 'drug' for Medicaid rebate purposes is defined by FDA's approval of a distinct NDA pursuant to [the FDCA]." 2020 WL 3402344, at *10. That holding—in direct conflict with the court of appeals' holding here—is all we take from *Ipsen*, not any "wholesale" incorporation of "distinctions * * * from the FDA context." BIO 13.

courts may defer to agency interpretations post-*Loper Bright*—is one in which virtually every lower court will need clarifying guidance.

4. This Court may alternatively grant, vacate, and remand in light of *Loper Bright*. *Contra* BIO 13-14. *Loper Bright* self-evidently was an "intervening development[]" post-dating the decision below. *Lawrence* v. *Chater*, 516 U.S. 163, 167 (1996) (per curiam). And while the court of appeals purported not to apply *Chevron* deference, there is still a "reasonable probability" (*ibid.*) that it would approach the statutory interpretation question differently with the benefit of *Loper Bright*'s explication of the applicable principles.

That is, with *Loper Bright* in hand, the court of appeals would likely "use every tool at [its] disposal to determine the best reading of the statute" rather than "pretend[ing] that ambiguities are necessarily delegations" and therefore declining to engage deeply with a statute that, while perhaps "impenetrable, do[es]—in fact, must—have a single best meaning." 144 S. Ct. at 2266.

B. The decision below disregards the principle that agencies must consider reasonable reliance interests.

The Court should also grant the petition to clarify that an agency cannot categorically disregard reliance interests engendered by its previous policies simply because the reliance stems from something other than a binding rule.

We explained in the petition (at 26-31) that the decision below contradicts a fundamental principle of administrative law: "When an agency changes course, * * * it must 'be cognizant that longstanding policies

may have engendered serious reliance interests that must be taken into account.'" *DHS* v. *Regents of Univ. of Cal.*, 591 U.S. 1, 30 (2020) (quoting *Encino Motorcars, LLC* v. *Navarro*, 579 U.S. 211, 221-222 (2016)). The court of appeals was "loath to impose [this] obligation" on CMS here because the agency "declined to finalize" a proposed rule that had limited line extensions to oral solid dosage forms. Pet. App. 25a.

1. To be clear, Vanda does not seek an "allowance[]" from the agency for relying on a "proposal[] * * * never implemented." BIO 15 (quoting Pet. App. 25a). Vanda merely seeks to enforce the agency's obligation to *consider* reasonable reliance interests before reversing course. Vanda recognizes that the agency "has considerable flexibility in carrying out its responsibility," but CMS is still "required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." *Regents*, 591 U.S. at 33. It did none of that here.

The government is wrong to suggest that it matters whether an agency's interpretation can be traced back to a proposed rule. It quotes from *In re Murray Energy Corp.*, 788 F.3d 330, 334 (D.C. Cir. 2015), that "a proposed rule is just a proposal" (BIO 14), but that statement simply explained that "proposed agency rules" are not "final" agency actions subject to judicial review. *Ibid.* The case had nothing to do with reliance interests.

CMS's interpretation, moreover, *was* "implemented" for nearly a decade as manufacturers "self-report[ed] their line extensions" consistent with the agency's stated interpretation. BIO 4 (quoting 85 Fed. Reg. 37,286, 37,294 (June 19, 2020)). Drugmakers'

reliance on the agency's prior interpretation was entirely foreseeable under these circumstances: the agency (1) announced its interpretation, which it deemed "consistent with" the statute, in a 2012 notice of proposed rulemaking (77 Fed. Reg. 5,318, 5,338 (Feb. 2, 2012)); (2) decided not to finalize the rulemaking in 2016, but gave no indication that its position on this interpretive question had substantively changed (81 Fed. Reg. 5,170, 5,197 (Feb. 1, 2016)); and (3) instructed drugmakers to "rely on the statutory definition of line extension" (*id.* at 5,265)—which it had just interpreted to be "consistent with" Vanda's preferred reading (77 Fed. Reg. at 5,338)—as they reported their line extensions each quarter. CMS's interpretation was thus worlds away from a "float[ed]" or "exploratory proposal[]." Pet App. 25a.

2. The decision below therefore conflicts with this Court's precedents, the government's contrary assertions notwithstanding. See BIO 15. The Court has held that an agency must consider reliance on its previous position stated in a non-binding agency "memorandum" (*Regents*) and a "notice of proposed rulemaking" (*Encino Motorcars*). This situation is no different—and the court of appeals failed to even cite either case.

Encino Motorcars is not distinguishable, as the government argues, just because the "prior policy" (579 U.S. at 222) in that case "had been reflected in sub-regulatory agency documents" (BIO 15), whereas the prior policy here "was just * * * a proposal" (*ibid.*). Whatever "sub-regulatory agency documents" are, they are not final rules; the agency expressed the "prior policy" in *Encino Motorcars* in an "opinion letter," a "Field Operations Handbook," and ultimately—

like here—a "notice of proposed rulemaking" that the agency did "not proceed[] with." 579 U.S. at 217-218. Even though these documents were non-binding, the Court held that the agency had to account for "the serious reliance interests at stake" when it changed its position in a final rule. *Id.* at 224.

Nor does it matter that *Regents* "involved reliance on a program that the agency had adopted and implemented" rather than "a never-adopted proposal." BIO 16. The Court did not identify that fact as relevant in *Regents*, and to the extent it is, it goes to "the strength of any reliance interests," not whether they must be considered at all. *Regents*, 591 U.S. at 31. And again, CMS's prior interpretation *was* "implemented" and "adopted" (BIO 16) for nearly a decade as manufacturers self-reported their line extensions consistent with the agency's stated interpretation.

3. The government does not dispute that this question has significant national importance and is likely to recur. In just the few years since *Regents*, lower courts have repeatedly grappled with this precise issue. See, e.g., *Navient Sols., LLC* v. *Dep't of Educ.*, 646 F. Supp. 3d 705, 721-722 (E.D. Va. 2022) (agency violated the APA by failing to account for reliance on agency's Dear Colleague Letters); *MediNatura, Inc.* v. *FDA*, 496 F. Supp. 3d 416, 455-456 (D.D.C. 2020), *aff'd* 998 F.3d 931 (D.C. Cir. 2021) (guidance document's "lack of binding effect" did not absolve agency of its obligation to consider reliance interests).

As we explained (at 32-33), in an era where the regulatory state subjects citizens to constant whiplash in policy positions, it is all the more important to enforce the APA's guardrails with vigor. If allowed to

stand, the decision below would seriously undermine the Court's repeated warning to agencies that they must at least consider reasonable reliance interests when reversing course on a policy. See *Regents*, 591 U.S. at 30-33; *Encino Motorcars*, 579 U.S. at 221-222; *F.C.C.* v. *Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). Certiorari is warranted.

CONCLUSION

The Court should grant the petition. Alternatively, it should grant, vacate, and remand in light of *Loper Bright*.

Respectfully submitted.

PAUL W. HUGHES
Counsel of Record
ANDREW A. LYONS-BERG
ALEX C. BOOTA
CALEB H. YONG
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001
(202) 756-8000
phughes@mwe.com

Counsel for Petitioner