No.

In the Supreme Court of the United States

VANDA PHARMACEUTICALS INC.,

Petitioner,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,
Respondents.

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

PETITION FOR A WRIT OF CERTIORARI

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

Counsel for Petitioner

QUESTION PRESENTED

Congress enacted the Fast Track program to speed the development and approval of certain novel therapies. It required FDA to designate "a new drug" as a "fast track product" if "it is intended * * * for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition." 21 U.S.C. § 356(b)(1).

The questions presented are:

1. Whether FDA has acted contrary to the statutory mandate by substituting an evaluation of the potential of a sponsor's current drug development program for an assessment of "a new drug['s]" own inherent "potential to address unmet medical needs."

2. Whether an approach to statutory interpretation that upholds an agency construction so long as it is "reasonable" and "consistent with" the statute's "goal" (App., *infra*, 17a) unlawfully departs from the Court's instructions in *Loper Bright Enterprises* v. *Raimondo*, 603 U.S. 369, 400-401 (2024).

PARTIES TO THE PROCEEDING

Vanda Pharmaceuticals Inc. is the petitioner before this Court and was the appellant before the court of appeals.

Respondents in this Court, and appellees in the court of appeals, were the United States Food and Drug Administration, the United States Department of Health and Human Services, Martin A. Makary, in his official capacity as Commissioner of Food and Drugs (as substituted pursuant to Fed. R. App. P. 43(c) and S. Ct. R. 35.3), and Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services (as substituted pursuant to Fed. R. App. P. 43(c) and S. Ct. R. 35.3).

CORPORATE DISCLOSURE

Petitioner Vanda Pharmaceuticals Inc. discloses that it has no parent corporation and that BlackRock Fund Advisors owns more than 10% of its stock

RELATED PROCEEDINGS

Vanda Pharms. Inc. v. *Food & Drug Admin.*, No. 23-5200 (D.C. Cir. Dec. 17, 2024)

Vanda Pharms. Inc. v. *Food & Drug Admin.*, No. 22-cv-1432 (D.D.C. Mar. 31, 2023)

Vanda Pharms. Inc. v. *Food & Drug Admin.*, No. 19-cv-301 (D.D.C. Jan. 31, 2020)

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Vanda Pharmaceuticals Inc. respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*., 1a) is reported at 123 F.4th 513. The opinion of the district court (App., *infra*, 23a) is unreported but is available at 2023 WL 6035663.

JURISDICTION

The court of appeals entered judgment on December 17, 2024. On March 12, 2025, the Chief Justice extended the time for filing this petition to May 16, 2025. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

21 U.S.C. § 356(b) provides:

(b) Designation of drug as fast track product

(1) In general

The Secretary shall, at the request of the sponsor of a new drug, facilitate the development and expedite the review of such drug if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition, or if the Secretary designates the drug as a qualified infectious disease product under section 355f(d) of this

title. (In this section, such a drug is referred to as a "fast track product".)

(2) Request for designation

The sponsor of a new drug may request the Secretary to designate the drug as a fast track product. A request for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 355(i) of this title or section 351(a)(3) of the Public Health Service Act.

(3) Designation

Within 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track product and shall take such actions as are appropriate to expedite the development and review of the application for approval of such product.

STATEMENT

Congress enacted the Fast Track program to speed the discovery, development, and approval of novel therapies that address the unmet medical needs of patients suffering from serious diseases. If a drug satisfies two statutory criteria—that (1) it is "for the treatment of a serious or life-threatening disease or condition," and (2) it "demonstrates the potential to address unmet medical needs for such a disease or condition"—the Food & Drug Administration (FDA) is

obligated to grant Fast Track status. 21 U.S.C. § 356(b)(1).

Vanda, a pharmaceutical innovator, is developing a drug called tradipitant. That drug has demonstrated the potential to significantly decrease nausea and vomiting in patients suffering from a disease called gastroparesis. FDA has acknowledged that gastroparesis is a serious condition with an unmet medical need due to the lack of other safe therapies. The sole question presented by Vanda's application for Fast Track, then, was whether tradipitant had demonstrated the requisite "potential" to treat gastroparesis, so as to mandate a grant of Fast Track status.

The evidence of such potential was overwhelming. In evaluating Vanda's clinical studies, FDA itself had informed Vanda that it "s[aw] a potential therapeutic role for tradipitant, particularly for the short-term relief of nausea in gastroparesis patients." C.A. J.A. 565, 657. More, FDA had approved several Expanded Access requests for individual gastroparesis patients to take tradipitant, meaning that FDA necessarily agreed that tradipitant demonstrated "sufficient evidence of * * * effectiveness" to support its use by those patients. 21 U.S.C. § 360bbb(b)(2). All this evidence, Vanda submitted, easily satisfied the statutory criteria inquiring whether the drug "demonstrates the potential to address" an acknowledged "unmet medical need." 21 U.S.C. § 356(b)(1).

But FDA rejected Vanda's Fast Track request, and the court of appeals sustained that rejection, by moving the legal goalposts. Rather than evaluate the question actually posed by the statute—whether tradipitant as a *drug* has the potential to satisfy an unmet medical need—FDA focused instead on

whether Vanda's *development program* was likely to lead to an eventual drug approval by FDA. Because FDA has imposed a partial clinical hold on Vanda's study of tradipitant, based on a scientific disagreement over the necessity of an additional study that would require killing scores of dogs,[1] FDA found that Vanda's drug development program—rather than the characteristics of the "drug" itself—lacked the requisite potential.

This construction defies the clear statutory text, which mandates that FDA consider the "potential" of the "drug," not the broader development program. 21 U.S.C. § 356(b)(1). And it undermines the statute's purpose, as Fast Track is meant for drugs that *need* development assistance to achieve approval, not those already poised for success.

The court of appeals reached the contrary conclusion only by applying a deferential interpretive paradigm that is incompatible with this Court's recent teachings in *Loper Bright*: It affirmed because FDA offered a "reasonable" construction that is "perfectly consistent" with a broad statutory goal. App., *infra*, 17a. The Court should take this opportunity to remediate the D.C. Circuit's erroneous approach to statutory interpretation and, in so doing, address the important underlying legal question of the proper construction of the governing statute.

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[1] Since this litigation began, Congress has weighed in decisively, instructing FDA that it can no longer mandate the thoughtless killing of animals when unnecessary to advance scientific knowledge. See FDA Modernization Act 2.0, Pub. L. No. 117-328, div. FF, tit. III, sub. B, ch. 1, § 3209; page 12, *infra*.

A. Legal background

1. Under the Federal Food, Drug, and Cosmetic Act (FDCA), drug manufacturers must generally secure approval from FDA before introducing a new drug into interstate commerce. 21 U.S.C. § 355(a), (d). In order to obtain FDA approval, manufacturers must submit "reports of investigations which have been made to show whether [a] drug is safe for use and whether [the] drug is effective in use" in what is known as a New Drug Application (NDA). *Id.* § 355(b)(1)(A)(i). Manufacturers therefore may use unapproved drugs "to investigate the[ir] safety and effectiveness," notwithstanding the general prohibition on the use of such drugs. *Id.* § 355(i)(1).

The FDCA recognizes two kinds of investigative studies: nonclinical tests, which do not involve humans, and clinical tests, which do. *Id.* § 355(z).

Before clinical testing can begin, the FDCA generally requires nonclinical testing "adequate" to justify the proposed human studies. 21 U.S.C. § 355(i)(1)(A). A manufacturer wishing to run clinical trials for a new drug must therefore file an Investigational New Drug application (IND) with FDA, containing various information about the drug and its properties. 21 U.S.C. § 355(i)(1); 21 C.F.R. §§ 312.20(a), 312.23(a).[2]

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[2] Before or during clinical trials, FDA "may prohibit the sponsor of an investigation" from going forward with a trial by issuing a "clinical hold." 21 U.S.C. § 355(i)(3)(A); 21 C.F.R. § 312.42(a). A clinical hold "will" be lifted by FDA "when the sponsor corrects the deficiency(ies) previously cited or otherwise satisfies the agency that the investigation(s) can proceed." 21 C.F.R. § 312.42(e).

Once an IND is approved, the clinical testing necessary to support an NDA typically takes several years. See Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* (Apr. 2021), perma.cc/B284-YTM2 (*CBO Report*) (finding that "[t]he development process often takes a decade or more" and costs on average $1 to $2 billion).

2. Congress enacted the Food and Drug Administration Modernization Act of 1997 (FDAMA) to accelerate the development and approval of new drugs that might provide much-needed relief to individuals with serious medical conditions. Pub. L. No. 105-115, 11 Stat. 2296. It recognized that "prompt arrival of safe and effective new drugs * * * is critical to the improvement of the public health." 21 U.S.C. § 379g note. The Act thus created several regulatory programs "designed to hasten research of the safety and effectiveness of drugs for terminally or severely ill patients and allow early access where scientifically and medically warranted." *Abigail All. for Better Access to Developmental Drugs* v. *von Eschenbach*, 495 F.3d 695, 699 n.4 (D.C. Cir. 2007).

One of Congress's key creations was the Fast Track program. See 21 U.S.C. § 356(b)(1). The statute provides that the Secretary "shall" provide Fast Track status for a "new drug"—and therefore "facilitate the development and expedite the review" of the drug—if it "is intended * * * for the treatment of a serious or life-threatening disease or condition" and "it demonstrates the potential to address unmet medical needs for such a disease or condition." *Ibid.*

FDA guidance describes an "unmet medical need" as a "condition whose treatment or diagnosis is not addressed adequately by available therapy." FDA,

Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics 4 (May 2014) (*Fast Track Guidance*) (C.A. J.A. 660-699). The guidance further explains that "[t]he type of information needed to demonstrate the potential of a drug to address an unmet medical need will depend on the stage of drug development" at which Fast Track designation is requested. *Id.* at 9. In early stages, "a nonclinical model, a mechanistic rationale, or pharmacologic data" may demonstrate the requisite potential. *Ibid.* Later on, FDA requires that potential be demonstrated by "available clinical data." *Ibid.*

If a new drug meets the Fast Track criteria, the statute mandates that FDA take appropriate actions to facilitate its development and expedite its review. 21 U.S.C. § 356(b)(3). According to its guidance, FDA will, among other things, offer "[f]requent interactions with the review team" and other meetings with FDA to discuss "study design, extent of safety data required to support approval, dose-response concerns [and] the structure and content of an NDA." *Fast Track Guidance*, at 9. FDA may also deem a Fast Track product eligible for priority review "if supported by clinical data at the time" of NDA submission. *Ibid.*

3. In addition to Fast Track, Congress also enacted a mechanism for individual patients to access investigational drugs before the drugs have final approval. FDAMA § 561, 11 Stat. at 2365-2367 (codified at 21 U.S.C. § 360bbb). This "Expanded Access" program allows drug manufacturers to provide a physician with an investigational drug "for the diagnosis, monitoring, or treatment of a serious disease or condition" if, among other things: (1) the physician "determines that the [patient] has no comparable or

satisfactory alternative therapy available" and that the "probable risk" that the drug carries "is not greater than the probable risk from the disease or condition;" and (2) the agency "determines that there is sufficient evidence of safety and effectiveness to support the use of the investigational drug" for that patient. 21 U.S.C. § 360bbb(b).

Finally, in 2012, Congress enacted an additional route to expedited development and review: the "Breakthrough Therapy" designation. See Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144 § 902, 126 Stat. 993, 1086. A Breakthrough Therapy designation will be granted for drugs intended "to treat a serious or life-threatening disease or condition" that have demonstrated "substantial improvement over existing therapies" in "preliminary clinical evidence." 21 U.S.C. § 356(a)(1).

B. Factual and procedural background

Petitioner Vanda Pharmaceuticals Inc. researches, creates, and brings to market innovative drugs, including those that treat rare disorders. This case concerns one of Vanda's drugs in development, tradipitant, which Vanda has studied extensively for use in patients with gastroparesis.

1. Gastroparesis is a rare but debilitating digestive disorder in which patients cannot empty food normally from their stomachs into their small intestines. The result is a constant onslaught of gastrointestinal symptoms, including nausea, vomiting, bloating, and abdominal pain. C.A. J.A. 339. Because the symptoms of gastroparesis overlap with other gastrointestinal conditions and because it is uncommon, it is heavily under-diagnosed. FDA, *Gastroparesis: Clinical*

Evaluation of Drugs for Treatment: Guidance for Industry (Draft) 2 (August 2019), perma.cc/5W97-3X22 (*Gastroparesis Guidance*). Still, it is estimated that around 700,000 American adults suffer from gastroparesis. C.A. J.A. 329.

Gastroparesis symptoms are often so severe that they interfere with patients' employment, social lives, and ability to maintain normal eating patterns. C.A. J.A. 180. The condition tends to be progressive, with symptoms worsening over time as damage to the gastrointestinal system accretes. *Ibid.* Early stages of the disease often involve weight loss, nausea, vomiting, and pain; later stages often require a feeding tube and frequent hospitalization. *Ibid.*

Despite the suffering gastroparesis causes for hundreds of thousands of Americans, treatment options are exceedingly limited. Gastroparesis has different forms—including idiopathic (spontaneously arising) and diabetic—but the underlying symptoms are similar. C.A. J.A. 704. There are currently no FDA-approved treatments for idiopathic gastroparesis. C.A. J.A. 181. FDA approved one drug, Reglan (metoclopramide), to treat diabetic gastroparesis more than 40 years ago, but Reglan is associated with serious adverse reactions preventing long-term use. *Ibid.* FDA thus recommends avoiding treatment with Reglan for longer than 12 weeks, and Reglan's label bears FDA's most serious category of warning, advising patients of the risk of developing tardive dyskinesia, an untreatable and often irreversible movement disorder. *Ibid.*

Because of the paucity of treatment options for gastroparesis patients, FDA has recognized the need for novel therapies. C.A. J.A. 181, 332.

2. The drug Vanda is developing to treat gastroparesis, tradipitant, acts by blocking certain receptors, which may increase gastric motility and inhibit signaling of brain regions that trigger nausea and vomiting. C.A. J.A. 182-193.

In 2021, when Vanda submitted its request for Fast Track designation for tradipitant, Vanda had collected substantial evidence resulting from a well-controlled, four-week investigational study. C.A. J.A. 185-199. In the study, participants receiving tradipitant experienced clinically meaningful improvements in nausea and other gastroparesis symptoms compared to subjects receiving a placebo. *Ibid.* The results demonstrated that tradipitant has a statistically significant, positive effect on patients' nausea severity score and their frequency of nausea-free days. *Ibid.*

At the same point, available data uniformly suggested that tradipitant was safe and well-tolerated in human patients. When Vanda requested Fast Track designation, 982 patients had taken tradipitant throughout the various clinical studies and 497 had done so for more than seven weeks. C.A. J.A. 205. The most common side effects, which were observed in less than 10% of the population, were fatigue and sleepiness. C.A. J.A. 206.[3]

In addition to study participants, several patients have taken tradipitant for extended periods of time—some beyond a year—under the Expanded Access program. These patients have not, to date, experienced

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[3] The number of individuals who have taken tradipitant has now surpassed 1,500, without the observation of any specific safety signals.

any significant adverse effects attributable to tradipitant.

All this is to say: No significant safety concerns have been reported by any of the hundreds of human participants in Vanda's trials. Critically, there is no evidence to suggest that tradipitant increases the risk of tardive dyskinesia (the major side effect of Reglan, the only existing approved treatment for gastroparesis). Nor, as FDA itself has acknowledged, is there any theoretical scientific basis to conclude based on tradipitant's mechanism of action that such a risk would exist. C.A. J.A. 335.

3. In 2018, during Vanda's study and development of tradipitant, FDA imposed a partial clinical hold to prevent Vanda from studying the drug in human trials longer than 12 weeks. App., *infra*, at 6a. Vanda had sought to extend its existing four-week clinical trial by 12 months, but FDA insisted that Vanda conduct an additional nine-month non-rodent toxicity study in animals before conducting longer human trials. *Ibid.*

FDA based the clinical hold on regulations allowing that action if an IND "does not contain sufficient information * * * to assess the risks to subjects of the proposed [clinical] studies." 21 C.F.R. § 312.42(b)(1)(iv). The regulations do not specify the non-clinical evidence necessary to justify clinical testing. See 21 C.F.R. § 312.23(a)(8). Rather than base these requirements on federal statute or regulation, FDA guidance instead invokes putative international standards; per FDA, "[s]ix-month rodent and 9-month non-rodent studies" are required to "support dosing for longer than 6 months in clinical trials." FDA, *Guidance for Industry: M3(R2) Nonclinical Safety*

Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals 7 (Jan. 2010), perma.cc/ZN95-WBBJ.

Vanda has declined to conduct the studies FDA has demanded, which Vanda maintains are scientifically inappropriate and will require the needless killing of dozens if not hundreds of animals, typically young beagle dogs. C.A. J.A. 447-449, 481. It sued FDA seeking to vacate the partial clinical hold, but the district court ruled for FDA and Vanda did not appeal. See *Vanda Pharmaceuticals Inc.* v. *FDA*, 436 F. Supp. 3d 256 (D.D.C. 2020).

Notably, since FDA imposed the hold and since the decision in Vanda's earlier suit, Congress has rewritten the legal framework governing animal testing for pharmaceutical drug development. In December 2022, Congress enacted the FDA Modernization Act 2.0 to permit and encourage the use of alternatives to lethal animal testing to satisfy the FDCA's requirements. Pub. L. No. 117-328, div. FF, tit. III, sub. B, ch. 1, § 3209; 21 U.S.C. § 355(i)(1)(A), (z). In so doing, Congress repealed the aspect of the statute relied upon by the district court in 2020. See *Vanda*, 436 F. Supp. 3d at 273 (citing the prior version of Section 355(i)(1)(A), which permitted FDA to require "preclinical tests (including tests on animals)," as evidence that "the legal framework mandates" "conducting animal studies") (quoting 21 U.S.C. § 355(i)(1)(A) (2020)).

4. In March 2019, Vanda submitted a request for Breakthrough Therapy designation for tradipitant. C.A. J.A. 530-564. That program has more stringent requirements than Fast Track. See *supra* page 8. FDA rejected Vanda's request and administrative appeals. In so doing, however, the agency recognized that

gastroparesis is "a serious or life-threatening disease or condition" and stated that it "s[aw] a potential therapeutic role for tradipitant, particularly for the short-term relief of nausea in gastroparesis patients." C.A. J.A. 565, 657.

Given that FDA explicitly acknowledged tradipitant's "potential" to treat the "serious or lift-threatening" condition that is gastroparesis, Vanda submitted its request for Fast Track designation on October 6, 2021. See App., *infra*, 7a. On February 1, 2022—after nearly twice the 60-day window for FDA action allowed by the statute—the agency denied Vanda's request in a short letter. *Ibid.* FDA once again conceded that gastroparesis is a serious condition with an unmet medical need. Yet FDA stated that Vanda's "overall development plan will not currently enable [Vanda] to obtain the data necessary to evaluate the safety and efficacy of [tradipitant]" because of the partial clinical hold. C.A. J.A. 326; App., *infra*, at 7a. Vanda requested clarification as to whether FDA considered an indication for *short-term* nausea relief—for which the agency's own guidance would not require long-term clinical trials—but FDA did not respond.

5. Vanda thus filed this lawsuit, seeking relief under the Administrative Procedure Act (APA).

The administrative record revealed previously unavailable aspects of FDA's reasoning. App., *infra*, 7a-8a. The agency, for example, treated idiopathic and diabetic gastroparesis identically and declined to consider a short-term treatment indication as part of Vanda's request. *Ibid.* And FDA evaluated Vanda's application using a standardized checklist containing six mandatory prerequisites to granting Fast Track designation. *Id.* at 8a; see C.A. J.A. 330-331. Those

prerequisites considered aspects of a sponsor's "product development plan," including whether the product is on "clinical hold," as *per se* disqualifying a drug from Fast Track status. *Ibid.*

The parties cross-moved for summary judgment, and the district court granted summary judgment to FDA. App., *infra*, at 23a. The court rejected FDA's argument that Vanda lacked standing. *Id.* at 36a. On the merits, the court recognized that Section 356(b) obligates FDA to designate a new drug as a Fast Track product whenever the statute's two criteria are met. *Id.* at 41a. Nonetheless, the court accepted FDA's argument that the statute was compatible with its determination that a partial clinical hold categorically precludes a drug from demonstrating the potential to address an unmet medical need. *Id.* at 42a-44a. The court characterized the statutory interpretation questions at issue as within FDA's "scientific judgment" and afforded it a "high level of deference." *Id.* at 43a.

6. Vanda timely appealed, and a panel of the D.C. Circuit affirmed shortly after this Court issued its opinion in *Loper Bright*. App., *infra*, at 1a.

The court of appeals began by addressing threshold justiciability issues, holding that FDA had waived any non-jurisdictional finality objections and that the dispute was not moot. App., *infra*, 11a-14a.

On the merits of Vanda's claim, the court held that FDA's denial of Vanda's application was not contrary to law. App., *infra*, at 15a. It first observed that the Fast Track provision "leaves it for the FDA to determine whether a drug 'demonstrates the potential to address unmet medical needs.'" *Ibid.* (quoting 21 U.S.C. § 356(b)(1), (b)(3)). It then rejected Vanda's argument that the statute requires an evaluation of the

potential of the *drug*, not of the drug *development program*, as an "untenable distinction." *Ibid.* Because "potential" involves "an inherently prospective analysis," the court stated, "what past and future studies may demonstrate about the potential of the drug, are plainly relevant and permissible considerations." *Id.* at 16a.

In the end, the court held that "[t]he best reading of the statute indicates that, in enacting the fast track, Congress intended to benefit drugs that are not yet fully effective but that can demonstrate their potential effectiveness in addressing an unmet medical need in the future." App., *infra*, 17a. The court reasoned that "[a]ssessing the drug's development plan, including whether future studies may be conducted to demonstrate its potential or cure current data issues, is perfectly consistent with that goal." *Ibid.* It thus concluded that it was "reasonable for the FDA to conclude that Vanda's decision not to conduct additional studies required to lift the partial clinical hold meant that Vanda would not cure those issues and, thus, could not demonstrate tradipitant's potential to address the unmet need that Vanda's application identified." *Ibid.*

REASONS FOR GRANTING THE PETITION

The court of appeals' decision applies an inappropriate method of statutory construction and therefore unsurprisingly reaches the wrong interpretive result. The court upheld the agency's interpretation as merely "reasonable" and "consistent with" the statute's "goal." App., *infra*, 17a. Such analysis is incompatible with federal courts' "responsibility" to "use every tool at their disposal to determine the best reading of the statute," rather than simply "declaring a

particular party's reading 'permissible'" and therefore deferring to it. *Loper Bright Enters.* v. *Raimondo*, 603 U.S. 369, 400 (2024).

Because the decision below threatens to resurrect *Chevron* deference under another name, the Court should grant certiorari to preclude this deviation—and, in so doing, construe a statutory provision that has a critical impact on the speedy availability of life-changing drugs to the American public.

A. The judgment below rests on a misreading of clear statutory text in derogation of *Loper Bright*.

The Fast Track statute requires FDA to provide certain benefits to drug sponsors developing a "drug" that "demonstrates the potential to address unmet medical needs." 21 U.S.C. § 356(b)(1). The plain text of that provision asks whether the *drug* has the potential to help patients in need, not whether the drug is likely to be approved by the FDA under the present development plan. And the statute's unambiguous meaning is reinforced by numerous textual and contextual indicators, each of which points in the same direction: Where the drug product itself meets the statutory criteria, FDA may not deny Fast Track status based on its assessment of the drug development program.

While the D.C. Circuit cited this Court's recent decision in *Loper Bright* (see App., *infra*, 10a), the opinion below is unrecognizable as an attempt to independently determine the "best reading" of the statute, as *Loper Bright* instructs. 603 U.S. at 400. Instead, the court determined that FDA's approach was "reasonable" because the statute "leaves it for FDA to

determine" whether a drug has the potential to address an unmet medical need. App., *infra*, 16a-17a. But that is not statutory interpretation at all; instead, the lower courts' fundamental error was abandoning their obligation to "exercise their independent judgment in deciding whether an agency has acted within its statutory authority." *Loper Bright*, 603 U.S. at 412. That anachronistic approach to statutory construction warrants review.

1. The Fast Track statute requires an assessment of a drug, not a development program.

As in all cases of statutory interpretation, the proper inquiry "begin[s] * * * with the language of the statute." *CSX Transportation, Inc.* v. *Alabama Dep't of Revenue*, 562 U.S. 277, 283 (2011). The Fast Track provision states in relevant part: "The Secretary shall, at the request of the sponsor of a new drug, facilitate the development and expedite the review of such drug if [1] it is intended * * * for the treatment of a serious or life-threatening disease or condition, and [2] it demonstrates the potential to address unmet medical needs for such a disease or condition." 21 U.S.C. § 356(b)(1).

FDA agrees that the first condition is satisfied because gastroparesis is a serious disease or condition. App., *infra*, 7a. It also concedes that gastroparesis has an unmet medical need. *Ibid.* Nonetheless, the D.C. Circuit upheld FDA's decision to evaluate Vanda's Fast Track application based on Vanda's extant drug development program rather than on features of tradipitant itself. That approach is incompatible with the statute.

a. The provision at issue unambiguously focuses on whether the "new drug" (that is, the chemical, molecular entity being studied by a drug sponsor) has the "potential" to address an unmet medical need—irrespective of the drug's development program. Grammatically, the subject that must "demonstrate[] the potential" to address an unmet medical need is "a new drug" for which a sponsor requests Fast Track status. 21 U.S.C. § 356(b)(1). The criteria for Fast Track eligibility are aspects of "such drug." *Ibid.* And it is "the drug" which receives designation "as a fast track product." *Id.* § 356(b)(2); see, *e.g.*, *Nielsen* v. *Preap*, 586 U.S. 392, 408 (2019) ("[T]he rules of grammar govern statutory interpretation unless they contradict legislative intent or purpose.") (quotation marks omitted).

The FDCA defines "drug" to mean "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." 21 U.S.C. § 321(g)(1). This definition is consistent with dictionaries from the time of the Fast Track provision's adoption, which considered "drugs" in terms of substances and not regulatory programs. See, *e.g.*, Drug, *Black's Law Dictionary* (7th ed. 1999) ("A substance intended for use in the diagnosis, cure, treatment, or prevention of disease."); Drug, *Merriam-Webster's Collegiate Dictionary* (10th ed. 1994) ("a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," or "a substance other than food intended to affect the structure or function of the body").

Next, the term "potential to address unmet medical needs for such a disease or condition" is undefined. 21 U.S.C. § 356(b)(1). Congress thus presumptively intended the words to carry their ordinary meaning.

See, *e.g.*, *Schindler Elevator Corp.* v. *United States ex rel. Kirk*, 563 U.S. 401, 407 (2011). As a noun, "potential" refers to something that can develop or become actual in the future. See Potential, *Webster's Third New International Dictionary* (3d ed. 1993) ("something that exists in a state of potency or possibility for changing or developing into a state of actuality"); Potential, *American Heritage Dictionary* (3d ed. 1992) ("The inherent ability or capacity for growth, development, or coming into being."). And to "address" a condition is to treat, resolve, or ameliorate it. Address, *Webster's Third New International Dictionary* (2002) ("to make straight: set in order; to make right: correct, redress"); Address, *American Heritage Dictionary* (3d ed. 1992) ("to deal with," as an "issue"). The potential to address an unmet medical need for a condition is therefore the future possibility to produce a clinical benefit for patients with that condition.

Taken together, these definitions provide a clear vision of the test Congress sought to establish: FDA "shall" grant Fast Track status for a proposed substance or therapy intended to treat a serious disease, so long as there is evidence that the substance or therapy *may* be effective in treating the unmet medical needs of suffering patients. 21 U.S.C. § 356(b).

While the text is clear enough on its own, Congress's formal findings accompanying the various Fast Track enactments underscore that the legislature's purpose was to promote the development of drug *products* that *might* be able to address unmet medical needs in patients with serious conditions. In 2012, when Congress amended the provision (in ways not material to this dispute), it codified its finding that "patients benefit from expedited access to safe and

effective innovative therapies to treat unmet medical needs for serious or life-threatening diseases." Pub. L. No. 112-144 § 901(a)(1)(D), 126 Stat. 993. Due to path-breaking scientific advances, Congress observed that "[a] new generation of modern, targeted medicines is under development to treat serious and life-threatening diseases." *Id.* § 901(a)(1)(A). As a result, Congress determined that "FDA should be encouraged to implement more broadly effective processes for the expedited develop-ment and review of innovative new medicines intended to address unmet medical needs for serious or life-threatening diseases or conditions." *Id.* § 901(a)(1)(B). Congress thus declared that FDA "should apply the * * * fast track provisions * * * to help expedite the development and availability to patients of treatments for serious or life-threatening diseases or conditions while maintaining safety and effectiveness standards for such treatments." *Id.* § 901(a)(2).

These codified findings make unmistakable Congress's focus on the potential ability of innovative new drug *substances* to help patients in need. And Congress's use of the word "potential" was intentional. The term "potential" rather than some stricter evidentiary standard "suggests that Congress intended to encompass possibilities * * * contingent or remote," not limit benefits to drugs whose therapeutic benefits are "a certainty." *James* v. *United States*, 550 U.S. 192, 207-208 (2007). Congress intended to cast a wide net in identifying drugs that *might* be able to meet the needs of patients, so that the agency can identify them at early stages in the hopes of "facilitat[ing]" their "development." 21 U.S.C. § 356(b)(1). See also page 28, *infra*.

b. With those definitions in hand, there can be no doubt that tradipitant has the potential to address the unmet medical needs of gastroparesis patients. Again, FDA agrees that gastroparesis is a serious condition and that gastroparesis patients have unmet medical needs. App., *infra*, 7a. The only relevant question, then, is whether tradipitant might provide therapeutic benefits for those suffering from gastroparesis. The answer is unequivocally yes.

First, the administrative record is replete with data concerning tradipitant's efficacy. Vanda's application, for example, contained the results of a well-controlled 4-week clinical study (VP-VLY-686-2301) in which tradipitant demonstrated a statistically significant reduction in gastroparesis patients' nausea, measured by either the patients' nausea severity scores or the number of nausea-free days. C.A. J.A. 185-199. When FDA considered this *same data* in the context of Vanda's request for Breakthrough Therapy designation, it concluded that it saw "a *potential* therapeutic role for tradipitant, particularly for the short-term relief of nausea in gastroparesis patients." C.A. J.A. 657 (emphasis added).

Perhaps even more saliently, tradipitant is currently being used to treat nausea by dozens of patients as part of the Expanded Access program. At the time of Vanda's Fast Track request, FDA had already granted approval for eight Expanded Access patients, which means by definition that it had "determine[d] that there is sufficient evidence of safety and effectiveness to support the use of the investigational drug" to treat these patients' medical needs, and that those needs were not adequately addressed by other therapies. 21 U.S.C. § 360bbb(b)(2). Some of those patients

had been taking tradipitant for more than a year. C.A. J.A. 178.

The hard data only confirm what patients themselves have repeatedly reported. In 2024, twenty gastroparesis patients submitted a Citizen Petition urging FDA to approve the tradipitant NDA. *Citizen Petition Requesting FDA Approval of NDA NO. 218489*, Docket No. FDA-2013-S—0610 (Sept. 19, 2024), perma.cc/KDW9-KMBN (*Citizen Petition*). The patients explained that they have all suffered from gastroparesis "for many years" and that the disease "not only causes extreme physical discomfort; it impairs [their] ability to perform daily tasks and maintain a normal quality of life." *Id.* at 2. They had tried "to find relief in various ways, including by taking Reglan (metoclopramide), Zofran, domperidone, Phenergan, gabapentin, and a host of other drugs." *Ibid.* They had also "made extreme modifications" to their diets. *Ibid.* But nothing worked.

Until tradipitant. The patients explained that "[t]aking tradipitant during Vanda's clinical study was life changing." *Citizen Petition*, *supra*, at 2. Each patient noticed "significant improvements" in their condition. "The reduction in nausea and vomiting allowed [them] to eat foods that many of [them] had not been able to eat for years," to "maintain better nutrition," and to enjoy reduced pain and bloating. *Ibid.* Tradipitant allowed these patients "to return to a semblance of normal life, including the ability to go to work, eat out at restaurants, and spend time with family and friends without fear of embarrassing and painful gastrointestinal symptoms." *Ibid.* "None of this was possible before tradipitant." *Ibid.*

The positive experiences of patients in the Expanded Access program—many of which predated Vanda's application and were cited in support of its Fast Track request—demonstrate that tradipitant is currently addressing the unmet needs of at least some gastroparesis patients. It is incoherent to say that a drug that *actually* addresses patients' needs somehow lacks the *potential* to do so. Tradipitant is thus within the heartland of drugs for which Congress designed the Fast Track program.

c. Rather than engage with the overwhelming evidence of tradipitant's potential to help suffering gastroparesis patients, FDA reached its Fast Track rejection by reimaging the legal question posed by the statute.

Instead of evaluating whether the *drug* itself holds the requisite "potential," FDA considered whether Vanda's drug *development program* had such potential. Applying that approach, FDA rested its rejection of Fast Track status on the partial clinical hold, claiming that a drug whose development is subject to a clinical hold necessarily lacks the "potential to address unmet medical needs" (21 U.S.C. § 356(b)(1)), and therefore is categorically ineligible for fast track treatment. Indeed, as noted, FDA reviewers use a rote checklist that requires them to deny fast track status if a clinical hold is present. App., *infra*, 8a; see page 13, *supra*.

The court of appeals seized on this justification to reject the distinction between properties of a drug and aspects of the drug's development program as "untenable." App., *infra*, 15a; see also *id.* at 17a (concluding that "[a]ssessing the drug's development plan, including whether future studies may be conducted to

demonstrate its potential or cure current data issues"—*e.g.*, whether a drug's development is subject to a clinical hold—"is perfectly consistent with [the statute's] goal" of "benefit[ting] drugs that are not yet fully effective but that can demonstrate their potential effectiveness * * * in the future."). But the lower courts' collapsing of the distinction between the potential of the drug itself and current regulatory hurdles to development cannot be squared with the statute's text and structure—and FDA's action is therefore *ultra vires*.

i. Beginning with the text, the Fast Track provision asks FDA to evaluate properties of the *drug*. "Drug" is the subject of the relevant clause, as it is the antecedent of "it." 21 U.S.C. § 356(b)(1). And it is the drug, not the drug's development program, that can potentially "address" a patient's needs. *Ibid.* Congress enacted the program to designate "fast track product[s]," not Fast Track development programs. 21 U.S.C. § 356(b)(1). See also pages 18-20, *supra*.

That the drug's properties are distinct from the drug's development program is especially clear from distinctions Congress drew elsewhere in the statute and related statutory contexts. For one, in the related Breakthrough Therapy context (enacted alongside amendments to the Fast Track program), Congress explicitly distinguished between a drug's clinical capabilities and its development program. *Compare* 21 U.S.C. § 356(a)(1) (providing that a "drug" qualifies for Breakthrough Therapy designation if "preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies") *with id.* § 356(a)(3)(B)(ii) (providing that after Breakthrough Therapy is granted FDA will assist a

sponsor with its "development program"). This distinction reveals plainly that if Congress had wanted to peg Fast Track eligibility to the drug development program rather than the drug, it "knew exactly how to do so." *SAS Inst., Inc.* v. *Iancu*, 584 U.S. 357, 365 (2018).

FDA's basic proposition is that agency-imposed regulatory hurdles nullify a drug's "potential" to treat patients within the meaning of the statute because they limit the chances the drug will be approved. That argument is atextual, for all the reasons we have discussed, but it also fails on its own terms. As noted, there are multiple legal ways for patients to access unapproved therapies for their conditions—including most obviously the Expanded Access program, through which dozens of patients with gastroparesis in fact have had, and continue to have, their "medical needs" "address[ed]" by tradipitant. 21 U.S.C. § 356(b)(1); see pages 21-22, *supra* (describing Expanded Access use of tradipitant); pages 22-23, *supra* (describing citizen petition filed by twenty gastroparesis patients whose symptoms were addressed by tradipitant in clinical trials).[4]

As a result, the fact of the matter is that a drug *can* "address unmet medical needs" (21 U.S.C. § 356(b)(1)) even without FDA approval. Indeed, contemporaneous dictionaries uniformly define the word

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[4] Similarly, doctors are free to prescribe a drug that is approved by FDA for one indication, to treat a patient with a different condition for which the drug is not FDA-approved. See, *e.g.*, *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 350-351 & n.4 (2001) (discussing this "widespread," lawful, and "often * * * essential" practice, known as off-label prescribing) (quotation marks omitted).

"medical" to mean some variation of "relating to the study or practice of medicine"[5]—a strong indication that Congress did *not* intend the inquiry to be concerned with FDA approval, given that FDA is "*prohibit[ed]* * * * from regulating the practice of medicine." *Judge Rotenberg Educ. Ctr.* v. *FDA*, 3 F.4th 390, 394-395 (D.C. Cir. 2021) (emphasis added) (citing 21 U.S.C. § 396 and *Buckman*, 531 U.S. at 349-350); accord, *e.g.*, *Planned Parenthood Cincinnati Region* v. *Taft*, 444 F.3d 502, 505 (6th Cir. 2006) ("FDA regulates the marketing and distribution of drugs in the United States, not the practice of medicine, which is the exclusive realm of individual states.").

The agency's interpretation thus requires courts to read "potential to address" to mean something like "potential to *be approved* and address." But it is black-letter law that the Court will "not narrow a provision's reach by inserting words Congress chose to omit." *Lomax* v. *Ortiz-Marquez*, 590 U.S. 595, 600 (2020); see also, *e.g.*, *Jama* v. *ICE*, 543 U.S. 335, 341 (2005) ("We do not lightly assume that Congress has omitted from its adopted text requirements that it nonetheless intends to apply."); *Romag Fasteners, Inc.* v. *Fossil, Inc.*, 590 U.S. 212, 215 (2020) ("Nor does this Court usually read into statutes words that aren't there.").

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[5] Medical, *American Heritage Dictionary of the English Language* (4th ed. 2000); accord, *e.g.*, Medical, *Merriam-Webster's Collegiate Dictionary* (10th ed. 1994) (same); Medical, *New Oxford American Dictionary* (2001) ("of or relating to the science of medicine, or to the treatment of illness and injuries"). Compare, *e.g.*, Public Health, *American Heritage Dictionary of the English Language* (4th ed. 2000) ("The science and practice of protecting and improving the health of a *community*") (emphasis added).

ii. Confirming what the plain text indicates, FDA's practice of rejecting Fast Track applications due to problems with drug development programs rather than problems with drugs themselves also makes no sense in the context of the statutory scheme.

Regulatory obstacles to approval, like a partial clinical hold, are inherently capable of resolution. Indeed, the regulations explicitly provide as much, setting out standards and procedures for the lifting of a hold. See 21 C.F.R. § 312.42(e). At any moment, Vanda could succeed in convincing FDA that, in this instance, a nine-month lethal dog study is not scientifically necessary to evaluate the safety of tradipitant, particularly in light of the drug's strong human safety record and Congress's new instruction to FDA to consider scientifically viable alternatives to animal testing. See page 12, *supra*.

Nor is such an outcome at all far-fetched: FDA very recently announced "a groundbreaking step to advance public health by *replacing* animal testing" for certain drugs with "more effective, human-relevant methods." FDA, *FDA Announces Plan to Phase Out Animal Testing Requirement for Monoclonal Antibodies and Other Drugs* (Apr. 10, 2025) (emphasis added); see also FDA, *Roadmap to Reducing Animal Testing in Preclinical Safety Studies* (Apr. 10, 2025). And the sorts of alternative testing FDA intends to implement—"organ-on-a-chip systems, computational modeling, and advanced *in vitro* assays" (*id.* at 1)—are precisely those that Vanda contends supports the safety of tradipitant.

In other words, there is no shortage of possible futures in which the clinical hold is resolved and development goes forward, and nothing about the clinical

hold impacts tradipitant's actual ability to help patients. The hold therefore does not foreclose the "contingent" possibility of therapeutic benefit on which Fast Track status hinges. See *James*, 550 U.S. at 207 (interpreting "potential").

Moreover, assessing Fast Track eligibility based on a drug's current development program is nonsensical in light of the statutory benefits of such status. One of the chief benefits that attends a Fast Track designation is that FDA must "facilitate the development" of the drug. 21 U.S.C. § 356(b)(1). Relying on perceived issues with a sponsor's development plan as precluding the *grant* of these benefits is entirely circular, and undermines or eliminates the benefit.

For example, if a city administered a program to provide computers to bright students from poor backgrounds, it would make no sense to reject a well written application for being handwritten—if the program exists to *provide* computers, an applicant's current lack of one is a logically incoherent reason to deny that benefit. Just so here. Congress intended FDA to work collaboratively with drug sponsors on the development of novel therapies for underserved patients. FDA cannot refuse to do so based only on a prejudgment of the results of that collaboration—particularly since Congress has required only the "potential" for therapeutic benefit.

iii. In its limited attempt to grapple with the text of the statute, the court of appeals fundamentally misunderstood the import of Congress's choice to require evidence of "potential" rather than evidence that can support approval. It explained that "the fast track provision requires the FDA to assess not only whether the drug currently addresses unmet needs, but whether it

has the 'potential' to address them." App., *infra*, 16a. But a drug that *currently* addresses patients' unmet needs necessarily has the potential to do so—irrespective of any barriers FDA itself imposes on the drug's development. "Potential" is a word that Congress used to *decrease* the burden on applicants. *James*, 550 U.S. at 207-208. Just as a litigant who shows that it *is* entitled to relief on the merits has necessarily demonstrated a likelihood of success, an applicant who shows that a drug *does* address patients' needs has shown that it has the potential to do so.[6]

FDA wishes to avoid providing the benefits Congress mandated where it believes they are unlikely to lead to ultimate approval. But that is not the statute that Congress enacted, and "an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate." *Util. Air Reg. Grp.* v. *EPA*, 573 U.S. 302, 328 (2014). Nor may FDA graft its own criteria on top of those selected by Congress. *Fed. Election Comm'n* v. *Ted Cruz for Senate*, 596 U.S. 289,

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[6] Vanda's interpretation is neither "under- [nor] overinclusive." Contra App., *infra*, 16a. Contrary to the court of appeals' understanding, Fast Track designation is *not* available to "an applicant whose drug has yet to show results" (*ibid.*); rather, even an early-stage drug must show potential appropriate to its development stage, including through "a nonclinical model, a mechanistic rationale, or pharmacologic data." *Fast Track Guidance*, at 9. That is evidence about the effects of the drug itself, not its development plan. Nor does Vanda's view require Fast Track status for drugs where "current studies do not show that it is effective and future studies cannot be conducted." App., *infra*, 16a. What FDA cannot do is deny Fast Track to drugs for which "current studies" *do* demonstrate potential effectiveness, just because of a transitory regulatory obstacle to approval that could be lifted at any time.

301 (2022) ("An agency, after all, literally has no power to act * * * unless and until Congress authorizes it to do so by statute."). FDA's insistence that its review of tradipitant's development program can substitute for a review of tradipitant's potential to meet an unmet medical need is thus contrary to the statute.

2. The court of appeals reviewed FDA's interpretation for reasonableness rather than rightness.

Given that every relevant consideration in the statutory analysis points in the same direction, one might reasonably ask how the court of appeals could have come out the other way. The answer is simple: Rather than ascertain the "single, best meaning of the statute" by exhausting the traditional tools of statutory interpretation (*Loper Bright*, 603 U.S. at 400), the court unduly deferred to FDA's approach.

The court of appeals resurrected deference in substance, if not in name. The court observed that, while neighboring provisions are "relatively clear," the Fast Track provision is not. App., *infra*, 15a. It stated that "[t]he best reading of the statute indicates that, in enacting the fast track, Congress intended to benefit drugs that are not yet fully effective but that can demonstrate their potential effectiveness in addressing an unmet medical need in the future." *Id.* at 17a. But rather than actually resolving the question posed as a matter of statutory text, the court held only that FDA's construction was "consistent with that goal." *Ibid.* The court concluded that FDA's interpretation—allowing the agency to base Fast Track determinations on assessments of drug development programs rather than the potential of drugs themselves—was "consistent with the statute's mandate" and

"reasonable." *Ibid.* This was not textual construction, but a gestalt sense that FDA's conclusion accorded with the statutory goals.

The D.C. Circuit's approach breaks from the Court's description of federal courts' role in *Loper Bright*. In the course of overturning *Chevron*, the Court made clear that "statutes, no matter how impenetrable, do—in fact, must—have a single, best meaning." *Loper Bright*, 603 U.S. at 400. Agency cases are no exception: "In an agency case as in any other, * * * even if some judges might (or might not) consider the statute ambiguous, there is a best reading all the same." *Ibid.*

It is the court's job to find that single, best meaning: "[I]nstead of declaring a particular party's reading 'permissible'"—as was sufficient for deference under *Chevron*—courts must "use every tool at their disposal to determine the best reading of the statute and resolve the ambiguity." *Loper Bright*, 603 U.S. at 400; see also, *e.g.*, *id.* at 412 ("[T]he APA[] bars judges from disregarding th[e] responsibility" to "apply their 'judgment' *independent* of the political branches * * * just because an Executive Branch agency views a statute differently.").

Though the court of appeals acknowledged *Loper Bright* (App., *infra*, 10a), the standard it actually applied is functionally indistinguishable from the very analysis the Court put to rest in that decision. The panel upheld an agency interpretation because it was "reasonable" and "consistent with" the statute's "goals" (App., *infra*, 17a)—in other words, simply because it was permissible. But that is *Chevron* restored. See, *e.g.*, *Cuozzo Speed Techs.* v. *Commerce for Intell. Prop.*, 579 U.S. 261, 276-277 (2016) (Under

Chevron, "where a statute leaves a gap or is ambiguous, we typically interpret it as granting the agency leeway to enact rules that are reasonable in light of the text, nature, and purpose of the statute.") (quotation marks and brackets omitted). After *Loper Bright*, that is not the law: "In the business of statutory interpretation, if it is not the best, it is not permissible." 603 U.S. at 400.

Thus, rather than undertake the hard work of grappling with the statute, the court of appeals here upheld FDA's interpretation because it was, in the court's view, a sensible way to implement the statutory scheme. Because such analysis revives exactly the kind of deference that *Loper Bright* rejected in favor of "independent legal judgment" (603 U.S. at 401), the Court should grant certiorari.

B. This case presents a rare and compelling vehicle to prevent the serious harms caused by FDA's erroneous interpretation.

This case presents a rare vehicle for the Court to address a legal issue of critical importance both to drug manufacturers and to countless patients, and which is certain to recur.

1. The Court's decision in *Loper Bright* marked a sea change in its administrative law jurisprudence, discarding four decades of deference to agencies under *Chevron* in favor of a renewed focus on the "independent legal judgment" the Framers expected of the federal courts. 603 U.S. at 401. Unsurprisingly, many jurists supported the *Chevron* regime as both legally correct and a normatively desirable method of "allocating responsibility for statutory construction

between courts and agencies." *Id.* at 448 (Kagan, J., dissenting).

Given this long history of deference, it is understandable that even a lower court attempting in good faith to apply this Court's directions could slip back into a deferential posture, even without applying *Chevron* by name. But of course, if the lower courts effectively recreate *Chevron* deference by upholding "reasonable" and "consistent" agency interpretations of "[un]clear" statutes (App., *infra*, 15a), *Loper Bright*'s express overruling of *Chevron* would be rendered a nullity. It is therefore critical that the Court intervene to reaffirm that courts may not uphold agency interpretations without "us[ing] every tool at their disposal to determine the best reading of the statute" and ultimately "apply[ing] their judgment *independent* of the political branches." *Loper Bright*, 603 U.S. at 400, 412.

2. On the merits, the question presented is of exceptional importance to pharmaceutical innovators and patients alike. Drug sponsors like Vanda invest tens if not hundreds of millions of dollars into developing novel therapies for treatment of diseases with unmet medical needs. See *CBO Report*, *supra* (average cost of clinical trials alone required for approval "was about $375 million"). For innovation to be financially viable, drug manufacturers must be able to recoup the required large upfront investments in research and development by earning sufficient revenues from drug sales. Their window to do so coincides with their limited period of exclusivity for their new drugs, which begins to elapse before they even submit their NDAs and ticks away while they await FDA's review. While manufacturers pay millions of dollars

to FDA for each application, FDA is still nowhere near hitting its statutory 180-day deadline for NDA reviews. See *FDA Drug Review Timeline Transparency; Statement of Policy* 86 Fed. Reg., 4,083, 4,083 (Jan. 15, 2021).

Fast Track's benefits, which enable sponsors to sidestep regulatory delays and capitalize on their limited exclusivity period, are therefore immensely valuable to drug sponsors. This value is evident from FDA's "priority review" program, in which sponsors of certain types of drugs are eligible to receive a "priority review voucher" that can be redeemed with the submission of a future drug application to guarantee that FDA will act on that application within six months. See 21 U.S.C. § 360ff. These vouchers are transferrable, and a recent GAO report reviewed prior sales of priority review vouchers and determined that the sale value ranged from $67.5 to $350 million. See Gov't Accountability Office, *Drug Development: FDA's Priority Review Voucher Programs* (Jan. 2020), perma.cc/69AZ-WN46.

In other words, prompt FDA review is a key incentive for innovators to discover and develop treatments for diseases with unmet medical needs. That is precisely why Congress created the Fast Track program—to speed the discovery and approval of new drugs patients desperately need.

Tradipitant is a prime example of this phenomenon. Many patients whose lives are dominated by their acute gastroparesis symptoms have testified that tradipitant has given them new hope. See *supra* pages 22-23. FDA itself has recognized the drug's potential to help these patients in at least two other regulatory contexts. *Supra* pages 21-22. But when Vanda

sought Fast Track status, FDA dodged a true evaluation of Vanda's application by fixating on one alleged issue with Vanda's drug development program. FDA's restrictive approach, through which the agency has arrogated to itself the power to augment the statutory criteria for eligibility, will leave a graveyard of unapproved therapies that could benefit these patients. Such an outcome is intolerable both as inconsistent with Congress's design and as a policy that fails countless Americans who are left to suffer untreated.

3. This case presents an appropriate and vanishingly rare opportunity for the Court to remedy the FDA's erroneous approach to the Fast Track program. The court of appeals correctly held that this case is not moot, and there are no other jurisdictional or procedural defects to impede this Court's review. App., *infra*, 10a-14a; see page 14, *supra*. And the question presented was squarely addressed by both courts below, as it is the heart of Vanda's legal challenge.

Moreover, absent certiorari now, this issue will likely escape this Court's review. To be sure, Fast Track designations—and FDA's denial of them—frequently recur. FDA has received 3,704 Fast Track designation requests for drugs since 1998. FDA, *CDER Fast Track Designation Requests Received*, (Jan. 13, 2025), perma.cc/K2D5-673P. It has denied 1,042 of those—more than 25%. *Ibid.* Yet out of more than 1,000 denials, Vanda was the first company that dared challenge FDA in court.

That should be no surprise: It is widely recognized that FDA's unlawful behavior is almost never challenged by the regulated industry because the cost of doing so is simply too high. As one former agency official explained, "[a] company with (say) thirty

approved drugs at the FDA could not afford to get 'crosswise' with the agency. Industry therefore does what the agency says." Nicholas R. Parillo, *Federal Agency Guidance and the Power to Bind: An Empirical Study of Agencies and Industries*, 36 Yale J. on Reg. 165, 199 (2019). That is, FDA's unlawful "'arm-twisting' succeeds, and evades judicial or other scrutiny, in part because companies in pervasively regulated industries believe that they cannot afford to resist agency demands." Lars Noah, *Governance by the Backdoor: Administrative Law(lessness?) at the FDA*, 93 Neb. L. Rev. 89, 123 (2013). As the general counsel of one large pharmaceutical company has described, "if the FDA says 'jump,' you ask, 'how high.'" Parillo, *supra*, at 186.

If the Court does not take this opportunity to remediate FDA's egregious departure from Congress's scheme, it may not get another chance.

CONCLUSION

The Court should grant the petition.

Respectfully submitted.

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

Counsel for Petitioner