No. 21-1342

In the Supreme Court of the United States

JACOBUS PHARMACEUTICAL COMPANY, INC.,
PETITIONER

v.

CATALYST PHARMACEUTICALS, INC., ET AL.

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

BRIEF FOR THE FEDERAL RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

If the Food and Drug Administration approves a new drug application for a drug designated for a "rare disease or condition," 21 U.S.C. 360bb(a)(1), the agency may not approve a subsequent application from a different applicant "for the same drug for the same disease or condition" for a period of seven years, 21 U.S.C. 360cc(a). Agency regulations, promulgated after notice-and-comment rulemaking, provide that the seven-year period of exclusivity applies only with respect to the "use or indication" for which the initial applicant's drug has been approved, and not to any unapproved use or indication. See 21 C.F.R. 316.3(b)(12), 316.31(a)-(b).

The question presented is whether the agency's regulations reflect a permissible interpretation of the statute.

ADDITIONAL RELATED PROCEEDING

Supreme Court of the United States:

Jacobus Pharmaceutical Company, Inc. v. *Catalyst Pharmaceuticals, Inc.*, No. 21A328 (Jan. 18, 2022) (denying stay)

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-27) is reported at 14 F.4th 1299. The order of the district court (Pet. App. 28-51) is not published in the Federal Supplement but is available at 2020 WL 5792595. The report and recommendation of the magistrate judge (Pet. App. 54-78) is not published in the Federal Supplement but is available at 2020 WL 5514187.

JURISDICTION

The judgment of the court of appeals was entered on September 30, 2021. A petition for rehearing was denied on January 7, 2022 (Pet. App. 52-53). The petition for a writ of certiorari was filed on April 7, 2022. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

Respondent Catalyst Pharmaceuticals, Inc. filed suit against the federal respondents in the United States District Court for the Southern District of Florida, challenging the approval by the Food and Drug Administration (FDA) of one of petitioner's drug applications. The district court granted the government's motion for summary judgment and denied Catalyst's motion for summary judgment. Pet. App. 28-51. The court of appeals reversed. *Id.* at 1-27.

1. a. The Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049, provides "financial incentives" for drug manufacturers to develop drugs to treat rare diseases and conditions. § 1(b)(5), 96 Stat. 2049. A rare disease or condition is one that "affects less than 200,000 persons in the United States" or that "affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug." 21 U.S.C. 360bb(a)(2). Because developing drugs to treat such rare diseases and conditions often would produce a return on investment "relatively small * * * in comparison to the cost," Congress sought "to reduce the costs of developing such drugs and to provide financial incentives to develop such drugs." Orphan Drug Act § 1(b)(4)-(5), 96 Stat. 2049.

To receive those incentives, a drug manufacturer or sponsor must first request that FDA "designate" a drug that "is being or will be investigated for" a rare disease or condition. 21 U.S.C. 360bb(a)(1); see *ibid.* (providing that a "request for designation of a drug shall be made before the submission of an application" for FDA approval of the drug). A successful "orphan drug" desig-

nation triggers various financial benefits, including a tax credit for certain clinical testing expenses. See 26 U.S.C. 45C. Designation also helps sponsors to secure grants and contracts to defray the costs of developing orphan drugs. See 21 U.S.C. 360ee. And a sponsor applying for FDA approval of a designated orphan drug may be exempt from the application fee. See 21 U.S.C. 379h(a)(1)(F).

FDA generally must approve a new drug application for an orphan drug before the drug may be introduced into interstate commerce. See 21 U.S.C. 321(p), 331(d), and 355(a). A new drug application must include clinical data demonstrating that the drug is "safe for use" and "effective in use." 21 U.S.C. 355(b)(1)(A)(i). The application must list the drug's "proposed indications for use" and include proposed labeling identifying those indications. 21 C.F.R. 314.50(a)(1); 21 U.S.C. 355(b)(1)(A)(vi). FDA may not approve the application unless the agency determines, among other things, that the applicant has shown that the drug is safe and effective "for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. 355(d). If the applicant demonstrates to FDA's satisfaction that the drug is safe and effective for the proposed uses and indications, and if no other barrier to approval exists, FDA will approve the application. 21 U.S.C. 355(c)(1). Upon approval, the sponsor may market the drug solely for the approved uses or indications. For example, if FDA approves an application for the use of a drug to treat a particular disease only in adults, the applicant may not market the drug for use in children.

Once a designated orphan drug is approved by FDA, the sponsor may be eligible for a seven-year period of

market exclusivity under the Orphan Drug Act. As relevant here, Congress has directed that if FDA "approves an application * * * for a drug designated under section 360bb of this title for a rare disease or condition," the agency "may not approve another application * * * for the same drug for the same disease or condition for a person who is not the holder of such approved application * * * until the expiration of seven years from the date of the approval of the approved application." 21 U.S.C. 360cc(a). The Act does not define what constitutes "approv[ing] another application * * * for the same disease or condition." *Ibid*; see Pet. App. 5.

In 1992, following notice-and-comment rulemaking, FDA promulgated regulations stating that under the Orphan Drug Act's exclusivity provision, the agency would not approve an orphan-drug application filed by "a subsequent sponsor of the same drug product for the same *indication* for 7 years." 21 C.F.R. 316.3(b)(12) (1993) (emphasis added); see 57 Fed. Reg. 62,076 (Dec. 29, 1992) (final rule); 56 Fed. Reg. 3338 (Jan. 29, 1991) (proposed rule). In 2013, again following notice-and-comment rulemaking, FDA amended the regulations to reiterate that "no approval will be given to a subsequent sponsor of the same drug for the same *use or indication* for 7 years." 21 C.F.R. 316.3(b)(12) (emphasis added); see 21 C.F.R. 316.31(a) ("FDA will not approve another sponsor's marketing application for the same drug for the same use or indication before the expiration of 7 years from the date of such approval."); see also 78 Fed. Reg. 35,117 (June 12, 2013) (final rule); 76 Fed. Reg. 64,868 (Oct. 19, 2011) (proposed rule). The agency explained that "because FDA can only approve a drug for the indications or uses for which there is adequate data" with respect to safety and efficacy "to support ap-

proval," the scope of the seven-year period of market exclusivity "is limited to the indication(s) or use(s) for which the drug is approved for marketing." 78 Fed. Reg. at 35,123.

b. In 1990, petitioner obtained orphan-drug designation for the drug amifampridine to treat Lambert-Eaton Myasthenic Syndrome (LEMS), an autoimmune disorder that affects approximately 950 to 1300 individuals in the United States. Pet. App. 7-8, 58-59. Petitioner did not file an application for FDA approval until August 2017, but physicians have used petitioner's drug to treat LEMS patients "since at least January 1993 under the FDA's 'compassionate use' program." *Id.* at 8. Petitioner's 2017 application was unsuccessful; petitioner re-filed the application in June 2018. *Ibid.* Both applications sought approval for use in adults and children as young as six years of age. *Id.* at 8-9.

Meanwhile, in 2009, Catalyst obtained orphan-drug designation for the same drug, amifampridine, for treatment of LEMS. Pet. App. 7-8. Catalyst filed its first application for FDA approval in December 2015 and a subsequent application in March 2018—three months before petitioner's second application. Unlike petitioner's applications, Catalyst's applications sought approval for treatment of LEMS only in adults. See *id.* at 8-9. In November 2018, FDA approved Catalyst's orphan drug for treatment of LEMS "in adults." *Id.* at 8. FDA also confirmed Catalyst's seven-year period of market exclusivity for amifampridine to treat LEMS in adults. *Ibid.*

FDA then "'administratively divided'" petitioner's then-pending June 2018 application "into two parts: one for the treatment of LEMS in pediatric patients, and the other for the treatment of LEMS in adult patients."

Pet. App. 9; see FDA, *Guidance for Industry: Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees* 2 (Dec. 2004), www.fda.gov/media/72397/download ("The Agency may, for administrative reasons (e.g., review across two divisions or offices), assign separate reference numbers and separately track and take regulatory action on the various parts of what is considered to be one application under the policy described here."). In May 2019, FDA approved petitioner's application for treatment of LEMS "in patients 6 to less than 17 years of age." Pet. App. 9. FDA concluded that the approval "did not violate Catalyst's exclusivity because the approval of [petitioner's drug] for pediatric patients," as distinguished from adult patients, "constituted a different 'indication or use'" of amifampridine under the applicable regulations. *Ibid.*

Catalyst filed suit against FDA and the other federal respondents under the Administrative Procedure Act, 5 U.S.C. 701 *et seq.*, alleging that FDA's approval of petitioner's application was arbitrary and capricious and not in accordance with law. See Compl. ¶¶ 60-89. Petitioner intervened as a defendant. D. Ct. Doc. 43 (Dec. 27, 2019). A magistrate judge recommended that the district court uphold the agency's determination. Pet. App. 54-78.

2. The district court granted summary judgment to the government and petitioner, and denied summary judgment to Catalyst. Pet. App. 28-51. As relevant here, the court rejected Catalyst's argument that approval of petitioner's application for amifampridine to treat LEMS in pediatric patients violated the Orphan Drug Act's exclusivity provision. *Id.* at 39-48. Catalyst had argued that the Act unambiguously requires mar-

ket exclusivity for the orphan drug to apply to all uses or indications within the designated disease or condition, even those uses or indications for which the applicant has not received FDA approval. See *id.* at 39, 45-48. In rejecting that argument, the court emphasized that "the text of section 360cc refers the reader to section 355, which in turn sets forth the requirements to obtain approval for a drug, including evidence that the drug is safe and effective for its intended use." *Id.* at 42. Given that context, the court concluded that the Act was ambiguous on the disputed issue, and that FDA had reasonably interpreted that ambiguity to permit the agency to limit market exclusivity to those uses or indications for which the initial applicant had obtained approval under Section 355. See *id.* at 48.

3. The court of appeals reversed and remanded with instructions to enter summary judgment for Catalyst. Pet. App. 1-27. The court noted the parties' agreement that petitioner's and Catalyst's drugs "are the 'same drug' under the Orphan Drug Act" (namely, amifampridine) and that "LEMS is 'a single disease.'" *Id.* at 10-11. Accordingly, the court characterized the issue in dispute as "the meaning of the word 'same' as used in the phrase 'same disease or condition'" in Section 360cc(a). *Id.* at 15.

Focusing on that language, the court of appeals concluded that the words referred to "the 'rare disease or condition' for which the drug was 'designated under [section] 360bb.'" Pet. App. 16. The court recognized that the designation and approval processes are distinct, see *id.* at 3-4, and that Section 360cc(a) "expressly refers to" the new-drug approval provision (*i.e.*, Section 355) under which drugs can be approved only for uses shown to be "safe and effective," *id.* at 17. The court

nonetheless concluded that the "scope of exclusivity * * * is determined by what has been designated." *Id.* at 16. The court thus deemed it "irrelevant" that Catalyst sought and obtained approval solely for the treatment of LEMS in adults. *Id.* at 24.

The court of appeals also rejected petitioner's and the government's reliance on *Spectrum Pharmaceuticals, Inc.* v. *Burwell*, 824 F.3d 1062 (D.C. Cir. 2016), and *Sigma-Tau Pharmaceuticals, Inc.* v. *Schwetz*, 288 F.3d 141 (4th Cir. 2002), explaining that those decisions addressed the effect of the exclusivity provision on applications for the same drug for different diseases or conditions, not different uses or indications within a single disease or condition. See Pet. App. 21-23.

The court of appeals thus concluded that petitioner's drug could not be approved for the treatment of LEMS in children during the seven-year period following Catalyst's approval because Catalyst holds the exclusive right to market its drug "to treat the rare autoimmune disease, LEMS." Pet. App. 26. After determining that the record did not reflect that any statutory exception to exclusivity applied, the court remanded with instructions for the district court to enter judgment in favor of Catalyst. *Id.* at 26-27.

4. On January 18, 2022, Justice Thomas denied petitioner's application for a stay of the court of appeals' mandate pending the filing and disposition of a petition for a writ of certiorari. See No. 21A328.

ARGUMENT

The court of appeals erred in holding that the text of the Orphan Drug Act's exclusivity provision unambiguously forecloses FDA's longstanding interpretation of that provision, reflected in multiple regulations promulgated through notice-and-comment rulemaking, as au-

thorizing market exclusivity only with respect to uses and indications for which the orphan drug has been approved for marketing. Nevertheless, this Court's review is unwarranted because the decision below, while important, does not conflict with any decision of this Court or another court of appeals. Indeed, the opinion below appears to be the first published appellate decision addressing the question presented, which counsels in favor of further percolation. Moreover, bipartisan legislation currently pending in Congress would, if enacted, codify FDA's longstanding interpretation and thereby resolve any statutory ambiguity. That possibility underscores the prematurity of this Court's review.

1. As petitioner correctly explains (Pet. 20-28), the court of appeals erred in finding FDA's longstanding interpretation to be unambiguously foreclosed by the Orphan Drug Act. The Act's exclusivity provision states that if the agency has approved an application for a designated orphan drug, it "may not approve another application * * * for the same drug for the same disease or condition" for a period of seven years. 21 U.S.C. 360cc(a). All parties agree that petitioner and Catalyst have sought approval for the "same drug," amifampridine. The interpretive dispute concerns "approv[ing] another application * * * for the same disease or condition." The court interpreted that phrase to mean that exclusivity attaches to all uses or indications of the orphan drug for the designated disease or condition, even those uses and indications that FDA has not approved (including, as in this case, uses or indications for which the first applicant never even sought approval). By contrast, the agency has long interpreted the phrase to mean that exclusivity applies only with respect to the uses or indications for which the first application was

approved. See 21 C.F.R. 316.3(b)(12), 316.31(a); see also 21 C.F.R. 316.3(b)(12) (1993).

Although both interpretations are plausible, FDA's makes the most sense in context. The Orphan Drug Act provides an exclusive seven-year window for *marketing* the orphan drug; it even expressly refers to "approv[al] of another application *under section 355* of this title," which describes the marketing-approval process. 21 U.S.C. 360cc(a) (emphasis added); see 21 U.S.C. 355(d). It would be passing strange to interpret the Act as requiring a seven-year exclusive marketing window for a use or indication—in this case for the treatment of LEMS in children—for which the manufacturer or sponsor is *legally prohibited* from marketing the drug. See 21 U.S.C. 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."); 21 U.S.C. 355(b)(1)(A)(i) (requiring an applicant to demonstrate, among other things, that the drug is "safe for use" and "effective in use"); 21 C.F.R. 314.50(a)(1) (requiring applications to list the drug's "proposed indications for use"); see also 21 U.S.C. 355(d). Here, Catalyst has not obtained approval to market amifampridine to treat LEMS in children, and is thus legally prohibited from doing so. Yet under the court of appeals' view, by virtue of obtaining approval to market amifampridine to treat LEMS only in *adults*, Catalyst can preclude all other manufacturers from marketing amifampridine to treat LEMS in *children* too.

That view makes little sense. Congress enacted the Orphan Drug Act to create incentives for the development of orphan drugs in order to benefit patients suf-

fering from rare diseases or conditions. See Orphan Drug Act § 1(b), 96 Stat. 2049. Under the court of appeals' view, however, the approval of an application to market an orphan drug to treat a rare disease or condition in only a subset of patients would prevent any other manufacturer or sponsor from seeking approval to market the drug for treatment of the disease in other patients—potentially meaning that *no one* could market the drug to those patients for up to seven years, thereby potentially impeding their access to that drug during that time. That would run directly counter to and undermine the Act's stated purposes. See *ibid.*

That the Orphan Drug Act's exclusivity provision prohibits the agency only from approving "another" application for the same drug for the same disease or condition lends further support to FDA's interpretation. 21 U.S.C. 360cc(a). In context, the most apt meaning of "another" is "being one more in addition to one or more *of the same kind*." *Merriam-Webster's Collegiate Dictionary* 51 (11th ed. 2014) (emphasis added); see *Webster's New International Dictionary* 110 (2d ed. 1934) ("[b]eing one or more, in addition to a former one or number; a further or remaining (one) of *the same kind or effect*") (emphasis added). The Act's prohibition on approving "another" application for the same drug for the same disease or condition is thus reasonably interpreted as being limited to applications that are "of the same kind" or, if approved, would have the same "effect" as the initial application. An application seeking approval to market the drug for uses or indications for which the earlier applicant never obtained approval—or, as in this case, never even sought approval—ipso facto would not be "of the same kind" or have the same "effect" as the earlier application.

At a minimum, FDA's longstanding interpretation, twice promulgated through notice-and-comment rulemaking, reflects a reasonable interpretation of the Orphan Drug Act in light of the statutory context and the statute's express purposes. See *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984) (explaining that "a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency"). The court of appeals' conclusion that the phrase "same disease or condition" unambiguously forecloses FDA's interpretation improperly failed to consider that context and those purposes. Cf. Pet. App. 24-25. Instead, relying on circuit precedent, the court found that because the phrase "same disease or condition," standing alone, was in its view unambiguous, "that is the end of the matter." *Id.* at 25 (citation omitted). But that ignores this Court's admonition that "[t]he meaning—or ambiguity—of certain words or phrases may only become evident when placed in context." *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000). The court of appeals erred in focusing on the phrase "same disease or condition" plucked out of its statutory context—namely, market exclusivity for orphan drugs—and assigning to that phrase a meaning that could potentially create a regime in which no drug manufacturer or sponsor could legally market the orphan drug to a class of patients, thereby undermining the very incentives that the exclusivity regime was designed to provide.

2. Although the court of appeals' decision is both incorrect and important, cf. Pet. 28-31, the government has concluded that this case does not satisfy this Court's traditional criteria for certiorari review. See Sup. Ct.

R. 10. The decision below does not conflict with any decision of this Court or another court of appeals, and this Court's review would be premature, especially given that pending legislation would conclusively resolve the issue.

a. Petitioner contends (Pet. 14-20) that the decision below conflicts with decisions of the D.C. and Fourth Circuits. That contention is incorrect because neither of those decisions involved the question presented here: whether exclusivity applies with respect to uses or indications within a single disease or condition for which the orphan drug has not been approved. Instead, both of those decisions involved orphan drug exclusivity with respect to different diseases or conditions.

In *Spectrum Pharmaceuticals, Inc.* v. *Burwell*, 824 F.3d 1062 (D.C. Cir. 2016), a drug sponsor received orphan-drug exclusivity for a drug to treat liver damage during certain types of chemotherapy. *Id.* at 1064. That sponsor later received another seven-year period of orphan-drug exclusivity for the same drug to treat a different disease or condition: pain in patients with advanced colorectal cancer. *Ibid.* After the first seven-year exclusivity period had expired, FDA approved another sponsor's application to market the same drug for liver damage. *Ibid.* The D.C. Circuit affirmed FDA's approval of that application, notwithstanding the first sponsor's contention that approval would permit physicians to prescribe the competitor's drug "off label" to patients with colorectal cancer, thereby intruding on its market exclusivity. *Id.* at 1066-1069. The court explained that FDA permissibly interpreted the Orphan Drug Act to focus on the diseases or conditions that are "written on the application," not any unstated "off-label uses." *Id.* at 1067. As the district court in this case ob-

served, "*Spectrum* did not consider whether the Orphan Drug Act permits the FDA to limit [exclusivity] to adult or pediatric manifestations of a disease or condition." Pet. App. 43-44.

Similarly, in *Sigma-Tau Pharmaceuticals, Inc.* v. *Schwetz*, 288 F.3d 141 (4th Cir. 2002), a drug manufacturer obtained market approval and exclusivity for a drug to treat carnitine deficiency resulting from "inborn metabolic disorders." *Id.* at 143. After that seven-year period expired, the manufacturer secured another approval for the same drug to treat "a second rare condition—carnitine deficiency in patients with end-stage renal disease." *Ibid.* The Fourth Circuit rejected that manufacturer's bid to prevent FDA from approving other applications for the drug to treat carnitine deficiency resulting from inborn metabolic disorders, notwithstanding the manufacturer's contention that approval would permit physicians to prescribe a competitor's drug off-label for use in end-stage renal disease. *Id.* at 143-145. The court observed that the Orphan Drug Act is "disease-specific, not drug-specific," and explained that approval of the drug for inborn metabolic disorders would be "for a *different disease or condition*, one that was no longer subject to exclusivity." *Id.* at 145 (emphasis added). Like the decision in *Spectrum*, the decision in *Sigma-Tau* had no occasion to address the issue of exclusivity with respect to different uses or indications within a single disease or condition. To be sure, *Sigma-Tau* involved competing applications with respect to carnitine deficiency in two different patient populations, and so at a surface level might be viewed as resembling the situation presented in this case. Cf. 78 Fed. Reg. at 35,124. But the *Sigma-Tau* court itself did not view its decision in that light; instead, it made

clear that it considered the competing applications to be addressing "different disease[s] or condition[s]," not different uses or indications within a single disease or condition. 288 F.3d at 145; see *id.* at 143 (treating carnitine deficiency resulting from end-stage renal disease as "a *second* rare condition") (emphasis added).

b. This Court's review of the question presented in this case also would be premature. As noted, the decision below appears to be the first published appellate decision addressing FDA's longstanding interpretation of orphan-drug exclusivity with respect to different uses or indications within a single disease or condition. That counsels in favor of further percolation in the courts of appeals. That it has taken nearly 40 years since Congress enacted the Orphan Drug Act, and almost 30 years since FDA first promulgated the relevant regulations, for this issue to arise in a published appellate decision further suggests that addressing the issue does not warrant use of this Court's limited resources. Indeed, while FDA previously has approved orphan drugs targeted at different subpopulations, "this was likely the first time it ever 'approved an application for a drug with an indication to treat pediatric patients for a certain disease while another sponsor has obtained orphan drug exclusivity for a drug application for the same drug with only an indication to treat adult patients for that disease.'" Pet. App. 9.

Further underscoring the prematurity of this Court's review is Congress's consideration of bipartisan legislation to codify FDA's longstanding interpretation of the Orphan Drug Act's exclusivity provisions in the statute itself. See H.R. 7667, 117th Cong., 2d Sess. § 812(a)(1) (as passed by the House on June 8, 2022) (proposing to amend 21 U.S.C. 360cc(a) by "striking

'same disease or condition' and inserting 'same approved indication or use within such rare disease or condition'"); S. 4185, 117th Cong., 2d Sess. § 2(a)(1) (as introduced in the Senate on May 11, 2022) (same); see also Baldwin Amendment No. 1 to S. 4348, 117th Cong., 2d Sess. 1 (as agreed to by the Senate Committee on Health, Education, Labor & Pensions on June 14, 2022) (same). Provisions in each of those bills, proposed in direct response to the court of appeals' decision in this case, would codify FDA's longstanding interpretation of the Act "to ensure that the scope of the orphan drug exclusivity is clarified to apply only to the same approved use or indication within such rare disease or condition." Press Release, Office of Senator Tammy Baldwin, *Senators Baldwin and Cassidy Introduce Bipartisan Legislation to Preserve Access to Treatments for Rare Disease Patients* (May 11, 2022), go.usa.gov/xJ9Tb; see H.R. Rep. No. 348, 117th Cong., 2d Sess. 59 (2022) (criticizing the court of appeals' opinion in this case and explaining that the House bill would "clearly provide that orphan exclusivity applies only to the specific indication or use approved by FDA"). The House of Representatives passed its proposed bill by a vote of 392-28. See 168 Cong. Rec. H5402-H5403 (daily ed. June 8, 2022).

If Congress were to adopt and the President sign legislation similar to that currently under consideration, it would obviate the need for this Court's review. As noted, the House already has passed such a bill by an overwhelming majority. Nor would it be the first time that Congress has amended the Orphan Drug Act in response to a judicial interpretation of the Act. In 2017, after at least one district court had concluded, contrary to FDA's interpretation, that the Act permitted manufacturers to obtain successive periods of exclu-

sivity for the same drug for the same use or indication, Congress amended the Act's exclusivity provisions to restore FDA's position that serial exclusivity is prohibited absent a showing that the later-in-time drug is clinically superior. See FDA Reauthorization Act of 2017, Pub. L. No. 115-52, Tit. VI, § 607(a), 131 Stat. 1049 (amending 21 U.S.C. 360cc); *Eagle Pharmaceuticals, Inc.* v. *Azar*, 952 F.3d 323, 329 & n.9 (D.C. Cir. 2020) (recounting the statutory history). Congress also has enacted other legislation to clarify provisions of the Orphan Drug Act. See Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, Div. BB, Tit. III, Subtit. C, § 323, 134 Stat. 2933. That Congress now appears poised to amend the Orphan Drug Act in response to the court of appeals' decision in this case counsels against this Court's review at this time.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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