NO. _____

In the
Supreme Court of the United States

JACOBUS PHARMACEUTICAL COMPANY, INC.,

Applicant,

v.

CATALYST PHARMACEUTICALS, INC.; XAVIER BECERRA, Secretary of Health and Human Services; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; JANET WOODCOCK, Acting Commissioner of Food and Drugs, U.S. FOOD AND DRUG ADMINISTRATION,

Respondents.

On Application to Stay the Mandate of the United States Court of Appeals for the Eleventh Circuit

EMERGENCY APPLICATION FOR A STAY PENDING THE FILING AND DISPOSITION OF A PETITION FOR WRIT OF CERTIORARI

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January 12, 2022

CORPORATE DISCLOSURE STATEMENT

Jacobus Pharmaceutical Company, Inc. certifies that it has no parent company and no publicly traded company owns 10% or more of its shares.

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TO THE HONORABLE CLARENCE THOMAS, ASSOCIATE JUSTICE OF THE SUPREME COURT OF THE UNITED STATES AND CIRCUIT JUSTICE FOR THE ELEVENTH CIRCUIT:

Acting pursuant to Supreme Court Rule 23, Jacobus Pharmaceutical Company, Inc. hereby requests a stay of the Eleventh Circuit's mandate in this case pending the filing and disposition of a petition for a writ of certiorari in this Court. When the Eleventh Circuit issues its mandate reversing the district court's summary judgment order and granting summary judgment to Catalyst Pharmaceuticals, Inc., it will set into motion a chain of events that will leave children (ages six to less than seventeen) suffering from Lambert-Eaton Myasthenic Syndrome (LEMS) without an FDA-approved medicine. On January 10, Jacobus asked the Eleventh Circuit to stay its mandate pending the filing and disposition of a petition for a writ of certiorari in this Court. With the mandate set to issue this Friday, January 14, the Eleventh Circuit has yet to respond to Jacobus's request. This Court should stay the Eleventh Circuit's mandate pending the outcome of Jacobus's petition for a writ of certiorari.

In June 2019, Jacobus's competitor, Catalyst, filed this lawsuit in the U.S. District Court for the Southern District of Florida, attempting to strip Jacobus of the right to market Ruzurgi® for use to treat LEMS in children ages six to less than seventeen years of age. In September 2020, the district court granted summary judgment to Jacobus. *See Catalyst Pharms., Inc. v. FDA*, No. 19-cv-22425-BLOOM/Louis, 2020 WL 5792595 (S.D. Fla. Sept. 29, 2020), App.28–45. On September 30, 2021, the Eleventh Circuit reversed that ruling and ordered the district court to award summary judgment to Catalyst. *See Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), App.1–27. Jacobus then petitioned the

Eleventh Circuit for en banc rehearing, but the court denied that petition on January 7, 2022. *See* Jan. 7, 2022 Order, App.46. The Eleventh Circuit's mandate is thus set to issue on January 14, 2022, Fed. R. App. P. 41(b), beginning a chain of events that will force Ruzurgi® from the marketplace.

This Court should issue a stay to delay that result while Jacobus seeks further review. There is "(1) 'a reasonable probability' that this Court will grant certiorari, (2) 'a fair prospect' that the Court will then reverse the decision below, and (3) 'a likelihood that irreparable harm [will] result from the denial of a stay.'" *Maryland v. King*, 567 U.S. 1301, 1302 (2012) (Roberts, C. J., in chambers) (quoting *Conkright v. Frommert*, 556 U.S. 1401, 1402 (2009) (Ginsburg, J., in chambers). The Eleventh Circuit's decision creates a conflict with decisions in the Fourth and D.C. Circuits on a question of national importance concerning exclusivity rights to market "orphan" drugs. A stay of the mandate is necessary to prevent irreparable harm to children suffering from LEMS. For these reasons, and because the broader equities favor a stay, the Court should grant Jacobus's request.

OPINIONS BELOW

The opinion of the U.S. District Court for the Southern District of Florida was not reported but is available at 2020 WL 5792595 and reproduced at App.28–45. The opinion of the Eleventh Circuit is reported at 14 F.4th 1299 and reproduced at App.1–27. The denial of Jacobus's petition for rehearing en banc is reproduced at App.46.

JURISDICTION

The Eleventh Circuit issued its opinion on September 20, 2021. Jacobus filed a petition for rehearing en banc in the Eleventh Circuit on November 15, 2021. That

petition was denied on January 7, 2022. On January 10, 2022, Jacobus moved for the Eleventh Circuit to stay the issuance of its mandate while Jacobus pursued further appeal in this Court. The Eleventh Circuit has yet to act on Jacobus's motion. Absent a stay by it or this Court, the Eleventh Circuit's mandate will issue on January 14, 2022.

This Court has jurisdiction under 28 U.S.C. § 2101(f) to recall and enter a stay of the Eleventh Circuit's judgment pending review on a writ of certiorari.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

This case principally concerns the meaning of the following provision of the Orphan Drug Act, 21 U.S.C. § 360aa *et seq.*:

> Except as provided in subsection (b), if the Secretary--
>
> (1) approves an application filed pursuant to section 355 of this title, or
>
> (2) issues a license under section 262 of Title 42
>
> for a drug designated under section 360bb of this title for a rare disease or condition, the Secretary may not approve another application under section 355 of this title or issue another license under section 262 of Title 42 for the same drug for the same disease or condition for a person who is not the holder of such approved application or of such license until the expiration of seven years from the date of the approval of the approved application or the issuance of the license.

21 U.S.C. § 360cc(a).

STATEMENT OF THE CASE

1. This case concerns two drugs — Ruzurgi® and Firdapse® — that use the chemical amifampridine to treat a rare and debilitating autoimmune disorder called LEMS. LEMS afflicts the immune systems of those who suffer from it and disrupts their nervous systems' ability to communicate with muscle cells. R.65-1 at 425. That disruption causes muscle weakness and impedes joint function. R.65-1 at 425, 1004. As symptoms worsen, LEMS patients lose the ability to perform basic actions like rising from a chair or lifting their feet to walk. R. 65-1 at 98. Some become bedridden altogether and need a feeding tube or ventilator to survive. *See* R.65-1 at 98. There is no known cure. R.65-1 at 98.

2. Congress has incentivized the development of drugs to treat diseases like LEMS through the terms of the Orphan Drug Act. The ODA was enacted to provide drug manufacturers "with incentives to develop 'orphan' drugs — that is, drugs for the treatment of rare diseases or disorders that affect only small patient populations" by offering, "research assistance, grants, and tax incentives to companies that undertake development of orphan drugs." *Sigma-Tau Pharms., Inc. v. Schwetz*, 288 F.3d 141, 144 (4th Cir. 2002). "In addition, Congress provided for seven years of market exclusivity for approved orphan drugs." *Id.* (relying on 21 U.S.C. § 360cc(a)).

The law works like this. The FDA will "designate" a drug "for" a rare "disease or condition" like LEMS if the drug "is being or will be investigated for [that] rare disease or condition" and if "the approval" of "an application" to market the drug "would be for use for such disease or condition." 21 U.S.C. § 360bb(a). If an application for an orphan-designated drug is subsequently approved "for" its orphan

"disease or condition," the drug may be eligible for a period of orphan drug exclusivity that prevents the FDA from "approv[ing] another application under section 355 ... 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). In other words, the Act helps drug manufacturers recoup their development costs by barring the FDA from approving marketing applications for certain competing drugs for seven years.

3. The FDA designated Jacobus's drug, Ruzurgi®, as an orphan drug "for the treatment of [LEMS]" in 1990. R.65-1 at 8. Ruzurgi's® active ingredient, amifampridine, sets off a series of reactions in the body that aid communication between nerves and muscles, "significant[ly] improv[ing]" the strength of LEMS patients. R. 65-1 at 98; *see also* R.65-1 at 126 (describing the chemical process). This effect lasts "as long as the medication is maintained" and, for obvious reasons, it "improves overall quality of life" for people with LEMS. R.65-1 at 98.

Before Ruzurgi® was approved for marketing, however, the FDA designated a second amifampridine drug, Catalyst's "Firdapse®," as another orphan drug "for the treatment of LEMS." R.65-1 at 787. Although Firdapse® and Ruzurgi® use different chemical forms of amifampridine, *see* R.27-2 at 142, the FDA considers them the "same drug" for purposes of the Act, *see* 21 C.F.R. § 316.3(b)(14). Because both drugs were orphan designated, the FDA's eventual approval of either Firdapse® or Ruzurgi® "for the treatment of LEMS" would have resulted in eligibility for marketing exclusivity that would prevent the approval of the other drug — or any other "same

drug" — "for the treatment of LEMS" for the next seven years. *See* 21 U.S.C. § 360cc(a).

4. This case arose because the FDA never approved an application to market Ruzurgi® or Firdapse® "for the treatment of LEMS" outright. Instead, acting under the specific administrative powers granted to it by Congress, the FDA approved Catalyst's application to market Firdapse® for the specific medical "use" for which the drug had been demonstrated to be safe and effective as reflected on Catalyst's proposed Firdapse® labeling: "[t]reatment of [LEMS] *in adults*." R.65-1 at 879 (emphasis added); *see* 21 U.S.C. § 355(d) ("the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof"). Catalyst itself proposed that more limited "use" after failing to demonstrate Firdapse's® safety and efficacy for the treatment of LEMS in pediatric patients. *See* Jacobus Appellee Br. 15.

Jacobus, by contrast, was able to demonstrate Ruzurgi's® safety and efficacy for both the "treatment of [LEMS] in patients [six] to less than [seventeen]," and the treatment of LEMS in adults. R.65-1 at 434. After approving Catalyst's application to market Firdapse® for the "[t]reatment of [LEMS] in adults," R.65-1 at 879, and recognizing that orphan-drug exclusivity therefore blocked approval of Ruzurgi® for treatment of LEMS in adults, the FDA approved Jacobus's application to market Ruzurgi® only for the "treatment of [LEMS] in patients [six] to less than [seventeen]," R.65-1 at 434.

That action comported with the FDA's duly promulgated Orphan Drug Act regulations, as well as its consistent implementation of that Act for the past four decades. *See* Jacobus Appellee Br. 12–13 (citing 21 C.F.R. § 316.31(b)). For almost 30 years, the FDA has interpreted the scope of orphan-drug exclusivity in a codified rule that was subject to notice and comment. This duly promulgated regulation states that orphan-drug exclusivity protects "only the approved indication or use of a designated drug." 21 C.F.R. § 316.31(b). Thus, the FDA's regulations expressly permit the agency to "approve" a drug "for additional indication(s) or use(s) within the rare disease or condition not protected by the exclusive approval." *Id.* Because Firdapse® is not approved to treat LEMS in a pediatric population, the FDA's regulations expressly permitted the agency to approve Ruzurgi® for a pediatric patient population.

Nevertheless, Catalyst filed this lawsuit against the FDA, challenging that approval decision, in the U.S. District Court for the Southern District of Florida. *See* R.1. Catalyst has not argued that the FDA should have found Firdapse® safe and effective for use to treat LEMS in a pediatric population. *See* Catalyst Appellant Br. 27–46. Nor has Catalyst questioned the FDA's finding that Ruzurgi® is safe and effective for use to treat LEMS in children ages six to less than seventeen years of age. *See id.* Instead, Catalyst has claimed that the Act clearly and unambiguously prohibited the FDA from approving Ruzurgi®. *See* Catalyst Appellant Br. 27–46. The Firdapse® approval for use to treat LEMS in adults, Catalyst argued, triggered orphan-drug exclusivity to treat all patients suffering from LEMS based on

Firdapse's® initial orphan designation: "the treatment of LEMS," even though Firdapse isn't approved for a pediatric population. *See id.* According to Catalyst, the FDA's contrary regulation warrants no deference.

5. Faced with similar circumstances, other federal courts of appeals have already rejected these arguments. Most notably, in *Sigma-Tau Pharmaceuticals, Inc. v. Schwetz*, 288 F.3d 141 (4th Cir. 2002), the Fourth Circuit reached the exact opposite conclusion than did the Eleventh Circuit here. Specifically, the Eleventh Circuit held that the Orphan Drug Act unambiguously *prohibited* the FDA from approving the "same" drug for a different use than the drug currently enjoying marketing exclusivity. *See Catalyst*, 14 F.4th at 1306 (App.13). But the Fourth Circuit held that the Act unambiguously *permitted* the FDA to take that precise action. *See Sigma-Tau*, 288 F.3d at 144–45.

Sigma-Tau cannot be reconciled with the Eleventh Circuit's decision in this case. Sigma-Tau developed a drug (Carnitor) to treat a rare condition called carnitine deficiency. *Id.* at 143 n.1. Sigma-Tau originally obtained approval to market Carnitor for people with inborn metabolic disorders suffering from carnitine deficiency. *See id.* at 143. After the seven-year exclusivity period expired, Sigma-Tau sought and obtained approval to treat the same rare condition in people with end-stage renal disease who were undergoing dialysis. *Id.* Sigma-Tau sued the FDA after the agency approved applications for generic drugs to treat the rare condition in people with inborn metabolic disorders. *See id.*

The Fourth Circuit rejected the argument that the FDA's approval of the generic drugs infringed on the seven-year period of orphan exclusivity. It held — in direct conflict with this Court — that "the plain language of the ODA is unambiguous, and that the FDA's approvals of the generics in this case comported with the clear wording of the statute." *Id.* at 144–45. In its view, Congress "made clear its intention" that orphan-drug exclusivity "protects uses, not drugs for any and all uses." *Id.* at 145. So, while the approval of Carnitor for people with end-stage renal disease suffering from carnitine deficiency would block FDA approval of a different manufacturer's "same" drug for that population, that approval did not block the approval of the "same" drug for a different population (people with inborn metabolic diseases suffering from carnitine deficiency).

The D.C. Circuit reached a similar conclusion in *Spectrum Pharmaceuticals, Inc. v. Burwell*, 824 F.3d 1062 (D.C. Cir. 2016). As in *Sigma-Tau*, the FDA defended its regulations and longstanding practice by arguing that the Orphan Drug Act's exclusivity provisions protect "only … the uses included on a drug's [FDA-approved] label[ing]," *id.* at 1067. The D.C. Circuit agreed that "[t]he statute does not unambiguously foreclose [the] FDA's interpretation," which, it concluded, was reasonable. *Id.* The court reasoned that the "FDA's reading of the statute closely hews to the text," because, notwithstanding the Act's general references to "diseases" and "conditions," "[t]he statute creates limits on the approval of an 'application,' which by implication directs [the] FDA to evaluate what is written on the application," and that "will necessarily include only stated indications." *Id.* (citing

Sigma-Tau, 288 F.3d at 145). The *Spectrum* Court added that the FDA's "interpretation" of the law also "conforms to the statutory purposes of the Orphan Drug Act" "by allowing generic producers to enter the market for certain purposes while, at the same time, protecting a company's right to market its pioneer drugs for exclusive uses." *Id.* at 1067–68. Thus, the D.C. Circuit reasoned, it was at least reasonable to read the statute to protect only those uses for which the drug's marketing had been approved. *Id.*

6. The district court in this case applied similar logic. The district court concluded that the Act was ambiguous with respect to how orphan-drug exclusivity works when the FDA approves the same drug but for two independent uses. In the district court's view, "by virtue of section 360cc's reference to Section 355 — which in turn contemplates that drug companies must provide evidence of the effectiveness of their proposed drug for a specific use to obtain marketing approval — it is not clear whether the language 'disease or condition' in section 360cc refers to the approved disease or condition for which the sponsor applies in its NDA, or the disease or condition that was initially designated under 360bb." R.107 at 11–12 (App.38–39). The court therefore deferred to the FDA's interpretation that orphan-drug exclusivity protects "only the approved indication or use of a designated drug." 21 C.F.R. § 316.31(b) (expressly permitting the agency to "approve" a new drug "for additional indications(s) or uses(s) within the rare disease or condition not protected by the exclusive approval"). Because Firdapse® is not approved to treat LEMS in a pediatric

population, the FDA's regulations expressly permitted the agency to approve Ruzurgi® for a pediatric patient population. *Id.*

7. But the Eleventh Circuit held the opposite. *See Catalyst Pharms.*, 14 F.4th at 1302 (App.2). According to the Eleventh Circuit, the FDA's interpretation of the Orphan Drug Act conflicts with the Act's unambiguous terms because those terms pay no regard to the scope of an orphan drug's marketing approval. *Id.* at 1311–12 (App.23–24). In the Eleventh Circuit's view, if the FDA designates a drug "for a rare disease or condition" and then approves the marketing of that drug for use in a limited population, then, for seven years, the FDA cannot approve an application to market a subsequent "same drug" for use for that rare condition in a *different* population. *Id.* at 1308 (App.16) (quotation marks omitted).

The Eleventh Circuit opinion conflicts with *Sigma-Tau* and *Spectrum*, which both reached the sound conclusion that the scope of an orphan drug's marketing approval *does* impact the scope of its marketing exclusivity under the Orphan Drug Act. More importantly, the Eleventh Circuit's decision will strip Jacobus of the right to market the only drug deemed safe and effective for use to treat LEMS in children ages six to less than seventeen. Because Jacobus intends to seek *certiorari* of the Eleventh Circuit's decision, this Court should stay the Eleventh Circuit's mandate until that petition is resolved.

REASONS FOR GRANTING THE STAY

This Court should stay the Eleventh Circuit's mandate pending resolution of Jacobus's forthcoming *certiorari* petition. To obtain a stay pending the filing and disposition of a petition for a writ of certiorari, an applicant must show "(1) a

reasonable probability that four Justices will consider the issue sufficiently meritorious to grant certiorari; (2) a fair prospect that a majority of the Court will vote to reverse the judgment below; and (3) a likelihood that irreparable harm will result from the denial of a stay." *Maryland*, 567 U.S. at 1302 (quotation marks omitted). Jacobus has satisfied that standard.

I. The petition will present a substantial question regarding the scope of "orphan drug" exclusivity, on which the circuit authorities do not agree, and which the Eleventh Circuit wrongly decided.

Jacobus's petition for *certiorari* will present a substantial question worthy of Supreme Court resolution: which federal appellate court — the Eleventh Circuit or the D.C. Circuit and Fourth Circuit — has correctly interpreted the Orphan Drug Act. This Court often takes cases in which "a United States court of appeals has entered a decision in conflict with the decision of another United States court of appeals on the same important matter." Sup. Ct. R. 10(a). The Eleventh Circuit has done so here and, in so doing, erred.

The Circuit split is ripe. The question presented is simple: Does the Orphan Drug Act unambiguously tie marketing exclusivity to the scope of a drug's initial designation alone? The Eleventh Circuit has held that it does, reasoning that the statutory terms governing marketing approval are not "relevant" to the Orphan Drug Act, *Catalyst*, 14 F.4th at 1309 (App.18), and that the FDA can and should "grant[] … exclusivity," *id.* at 1304 (App.8), based solely on an orphan drug's designation, regardless of the use for which the drug's marketing has been approved, *id.* at 1308 (App.21). The Fourth Circuit in *Sigma-Tau* held just the opposite — that the Act unambiguously permitted the FDA to approve the application of a generic where

orphan drug exclusivity for the specific approved use had run, even though orphan drug exclusivity continued to block approvals of that drug with respect to another specific approved use. *See* 288 F.3d at 144–45 ("[T]he plain language of the ODA is unambiguous" in favor of the FDA.). The D.C. Circuit in *Spectrum* reached yet another conclusion that conflicts with the Eleventh Circuit's decision when it held that the Orphan Drug Act was ambiguous, but the FDA's interpretation was a reasonable one. *See* 824 F.3d at 1067 ("The statute does not unambiguously foreclose FDA's interpretation.").

These different takes on the Orphan Drug Act will sow confusion unless and until this Court intervenes. "[F]ederal law … is supposed to be unitary." *Menowitz v. Brown*, 991 F.2d 36, 40 (2d Cir. 1993) (per curiam). And the need for uniformity is especially strong in this area, because "developing new drugs is a risky … endeavor" with many twists and turns. *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1300 (11th Cir. 2012), *rev'd and remanded on other grounds sub nom. FTC v. Actavis, Inc.*, 570 U.S. 136 (2013). Drug manufacturers need to know the benefits that they may reap if they invest in drug research and development, especially for drugs indicated to treat rare diseases, which will be in "comparatively small demand." *Eagle Pharms., Inc. v. Azar*, 952 F.3d 323, 325 (D.C. Cir. 2020) (quoting *Spectrum*, 824 F.3d at 1064).

Moreover, the Eleventh Circuit was wrong. The Orphan Drug Act does not unambiguously tie exclusivity to a drug's orphan designation alone. Instead, its exclusivity "protects uses, not drugs for any and all uses." *Sigma-Tau*, 288 F.3d at 145. Indeed, "[t]he statute creates limits on the approval of an 'application,' which by

implication directs [the] FDA to evaluate what is written on the application." *Spectrum*, 824 F.3d at 1067. That "will necessarily include only stated indications." *Id.*

Moreover, if future judicial decisions follow the Eleventh Circuit's opinion to its logical conclusions, the consequences will be dire. *Cf. Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982) (noting the importance of avoiding statutory interpretations that "produce absurd results'). Tying exclusivity to orphan designations alone, without regard to the scope of each drug's marketing approval, will entice drug developers to seek broad designations and narrower marketing rights as a quick and easy way to corner the market for treating a rare "disease or condition." These dire practical consequences, and the questionable and conflicting interpretive choices underlying them, make this case a prime candidate for Supreme Court review and reversal.

II. A stay would prevent the Eleventh Circuit's mandate from harming children afflicted by LEMS, and the broader equities favor a stay.

This Court should also issue a stay because "irreparable harm will [otherwise] result." *Ind. State Police Pension Tr. v. Chrysler LLC*, 556 U.S. 960, 960 (2009) (per curiam) (quoting *Conkright v. Frommert*, 556 U.S. 1401, 1402 (2009) (Ginsburg, J., in chambers)).

In this case, the Eleventh Circuit's mandate will irreparably harm children currently using Ruzurgi® to treat their LEMS symptoms. Those symptoms are completely debilitating, amounting to paralysis in some cases. *See supra* at 4. And because Catalyst has not shown Firdapse® to be safe and effective for treating

pediatric patients, Ruzurgi's® removal from the marketplace will leave those patients with no FDA-approved drug treatment.

To recognize the harm that will flow from this result, the Court need look no further than the testimonial of Lori Dunham, filed in the district court. *See* R.78; *see also* Dunham Declaration, App.47–49 (attached as an exhibit to Jacobus's stay motion in the Eleventh Circuit to attest to the veracity of R.78). Lori's daughter, G.D., started experiencing LEMS symptoms two years ago at the age of fourteen. *See* R.78 at 1. As her symptoms progressed over just a few months, G.D. "went from playing sports to needing assistance to move around the house." *Id.* She eventually "could not get out of bed without assistance, gagged when she ate, slurred her words, and had to use a walker." *Id.* Then G.D. started taking Ruzurgi®, and it "g[ave]" G.D. "her life back." *Id.* "[H]er slurred speech and gagging reflex corrected itself. She visibly gets stronger the moment she takes her medicine, which she [does] three times a day." *Id.* If Ruzurgi® leaves the marketplace — even for a short time — it will impede G.D.'s ability to manage her LEMS symptoms and rob her of the basic independence she now enjoys.

Irreparable harms will also befall Jacobus. The company expended considerable time and effort on its application to market Ruzurgi® for the treatment of LEMS patients, including children like G.D. If Ruzurgi® is forced off the market prematurely, Jacobus will have no way of recouping its lost revenue. *Cf. Philip Morris USA Inc. v. Scott*, 561 U.S. 1301, 1304 (2010) (granting stay; reasoning in tha part that "[i]f expenditures cannot be recouped, the resulting loss may be

irreparable."). Jacobus should not be forced to forgo its hard-earned marketing rights while it pursues a vindication of those rights before the Supreme Court.

The broader equities also favor a stay. "[I]n a close case it may be appropriate to balance the equities" of a stay by "explor[ing] the relative harms to [the parties], as well as the interests of the public at large." *Conkright*, 556 U.S. at 1402 (quoting *Rostker v. Goldberg*, 448 U.S. 1306, 1308 (1980) (Brennan, J., in chambers)). In this case, the Eleventh Circuit's mandate will strip Jacobus of any right to market Ruzurgi® at all for the next several years. But Jacobus's loss will not be Catalyst's gain: the FDA has not deemed Firdapse® safe and effective for treating LEMS in children. This means that Catalyst cannot market its drug to a pediatric population in Jacobus's stead. As for the public, its interests clearly favor the legal marketing of Ruzurgi® to treat children with LEMS alongside the legal marketing of Firdapse® to treat adults with LEMS. The equities are not close. They favor maintaining the status quo.

CONCLUSION

There is a reasonable probability that this Court will grant certiorari review and reverse the Eleventh Circuit's decision. Because irreparable harm will likely result in the interim, and because the broader equities favor a stay, this Court should stay the Eleventh Circuit's mandate.

Respectfully submitted,

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January 12, 2022