UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 19-cv-22425-BLOOM/Louis

CATALYST PHARMACEUTICALS, INC.,

Plaintiff,

v.

U.S. FOOD AND DRUG ADMINISTRATION, et al.,

Defendants.
_____/

ORDER

THIS CAUSE is before the Court on Magistrate Judge Lauren F. Louis's Report and Recommendations ("Report"), ECF No. [93], recommending the Court deny Plaintiff Catalyst Pharmaceuticals Inc.'s ("Catalyst") Motion for Summary Judgment, ECF No. [38]; grant Federal Defendants'[1] Cross-Motion for Summary Judgment, ECF No. [47]; grant Intervenor-Defendant Jacobus Pharmaceutical Company, Inc.'s ("Jacobus") Cross-Motion for Summary Judgment, ECF No. [46]; and dismiss the case. Catalyst timely filed Objections to the Report, ECF No. [94]. Federal Defendants and Jacobus thereafter filed Reponses to the Objections, ECF Nos. [98] and [99]. On September 22, 2020, the Court held a hearing on the Objections and had the benefit of the parties' further arguments. The Court has carefully considered the Report, the parties' submissions, the record in the case, the applicable law, and is otherwise duly advised. For the reasons set forth below, the Court agrees with the Report's analysis and conclusions and overrules

[1] The Federal Defendants consist of (1) the United States Department of Health and Human Services; (2) Alex Azar, Secretary of the United States Department of Health and Human Services; (3) the United States Food and Drug Administration ("FDA"); and (4) Norman Sharpless, Acting Commissioner of Food and Drugs.

the Objections.

I. BACKGROUND

The Court assumes the reader's familiarity with the facts underlying this case and set forth in the Report and does not repeat them at length. Catalyst challenges the Federal Drug Administration's ("FDA") approval of Jacobus's drug, Ruzurgi, for orphan drug status due to the FDA's earlier approval for orphan drug exclusivity to Catalyst's drug, Firdapse. Catalyst's legal challenge implicates the proper interpretation of the Orphan Drug Act, Pub. L. 97-414, 96 Stat. 2049 (1983); 21 U.S.C. §§ 360aa–360ee.

A. Orphan Drug Act

Lambert-Eaton Myasthenic Syndrome ("LEMS") is an "orphan disease" — a disease that affects so few people compared to the general population that drug companies do not have the financial incentive to develop drugs to treat it. To remedy this problem, Congress enacted the Orphan Drug Act, Pub. L. 97-414, 96 Stat. 2049 (1983); 21 U.S.C. §§ 360aa–360ee, which "amend[ed] the Federal Food, Drug, and Cosmetic Act to facilitate the development of drugs for rare diseases and conditions, and for other purposes." Pub. L 97–414 (HR 5238), Jan. 4, 1983.

Under the Orphan Drug Act, the term "rare disease or condition" means "any disease or condition which (A) affects less than 200,000 persons in the United States, or (B) 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. If a drug company (or "sponsor") develops a drug to treat a rare disease or condition, it "may request the Secretary to designate" it as such. *Id.* § 360bb(a)(1). If the Secretary finds that [the] drug . . . is being or will be investigated for a rare disease or condition" and "if an application for such drug is approved

under [21 U.S.C. § 355][2] . . . the approval, certification, or license would be for use for such disease or condition," and "the Secretary shall designate the drug as a drug for such disease or condition." 21 U.S.C. § 360bb(a)(1).

In her Report, Judge Louis correctly summarizes the drug designation process, and the ensuing New Drug Application ("NDA") and approval process, as follows:

> During the development stage of a drug, a manufacturer or sponsor may request that the FDA designate its drug as one for use in a rare disease or condition under 21 U.S.C. § 360bb. The designation . . . under 21 U.S.C. § 360bb does not dictate the use or indication for which an orphan drug may ultimately be approved for marketing. The purpose of designation under §360bb is to allow the manufacturer or sponsor to qualify for tax incentives and federal assistance in the form of grants to defray the costs of qualified testing in the process of obtaining marketing approval. Later in development, after testing has occurred, the sponsor proposes a particular use or uses for a drug in its new drug application [("NDA")], which is then reviewed by the FDA to determine whether the application establishes that the drug is safe and effective for the proposed use or uses. *See* 21 U.S.C. § 355(d); 21 C.F.R. § 314.50(a)(1) (requiring a new drug application to include the new drug's proposed indications for use).

Report at 2–3.

To provide a financial incentive to develop orphan drugs, section 360cc of the Orphan Drug Act provides a seven-year Orphan Drug Exclusivity ("ODE") period to the drug sponsor that applies for and obtains approval to market an orphan drug:

> Except as provided in subsection (b), if the Secretary—
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> (1) approves an application filed pursuant to section 355 of this title, or
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> (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. Section 355(c)(2) of this title does not apply to the refusal to approve an application under the preceding sentence.

[2] 21 U.S.C. § 355 is entitled "New drugs" and, as explained in more detail below, sets forth the requirements for filing an application for approval to introduce a new drug into interstate commerce.

21 U.S.C. § 360cc.

Both sections 360bb and 360cc refer to section 355 of the Federal Food, Drug, and Cosmetic Act. Section 355(b) sets forth the requirements for filing an NDA. Section 355(b) requires, among other information, reports or investigations showing "whether or not such drug is safe for use and whether such drug is effective in use" and "specimens of the labeling proposed to be used for such drug." *Id.* § 355(b)(1)(A), (F). Under section 355(c), within 180 days (or as otherwise agreed) from the filing of the application under section 355(b), the Secretary shall approve the application if he finds none of the grounds under section 355(d) apply. Finally, under section 355(d), the Secretary may refuse the application if, among other reasons, "upon the basis of the information submitted to him as part of the application . . . he has insufficient information to determine whether such drug is safe for use under such conditions."

B. FDA Procedural History

Jacobus obtained an orphan drug designation for its amifampridine drug, Ruzurgi, in December 1990. *See* Sealed Joint Appendix, Vol. 1, ECF No. [66-1] at 8. In 2009, the FDA granted Catalyst's amifampridine drug, Firdapse, an orphan drug designation. *See* Sealed Joint Appendix, Vol. 2, ECF No. [66-2] at 247. The parties agree that the two drugs are the same, as Ruzurgi contains the same active moiety to that of the active ingredient in Firdapse.

In 2015, Catalyst submitted an NDA for approval to market Firdapse for the treatment of LEMS in adult patients. ECF No. [66-2] at 249–50. After its initial review, the FDA rejected the NDA. *See id.* at 289–92. In August 2017, Jacobus submitted its NDA for Ruzurgi for the treatment of LEMS in adult and pediatric patients. *See* ECF No. [66-1] at 53–56. As with Catalyst, the FDA reviewed the NDA and initially rejected it. *See id.* at 57–64. In March 2018, Catalyst resubmitted its NDA and, in November 2018, Firdapse was approved for treatment of LEMS in adults. *See*

ECF No. [66-2] at 487. Jacobus resubmitted its NDA in June 2018. *See* ECF No. [66-1] at 70. However, the FDA had already approved Catalyst's NDA for ODE of Firdapse for treatment of LEMS in adults. *See* ECF No. [66-2] at 487. The FDA administratively divided Jacobus's pending NDA into two parts — one for the treatment of adults and one for the treatment of pediatric patients. *See* Report at 5; ECF No. [66-1] at 434. Because Firdapse had already obtained ODE for LEMS in adults, the FDA's Exclusivity Board recommended denying approval of Ruzurgi with respect to the same. *See* ECF No. [66-1] at 424–33. The FDA thereafter approved Ruzurgi with respect to LEMS in pediatric patients, determining Firdapse did not have ODE with respect to that patient group because its NDA was limited to LEMS in adults. *See id.* at 424–43.

C. Case Procedural History

On June 12, 2019, Catalyst filed their Complaint against the Federal Defendants alleging the FDA's approval of Ruzurgi was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. Catalyst alleges that the FDA violated the Administrative Procedure Act as follows:

- the labeling that the FDA approved for Ruzurgi "implies and suggests that [Ruzurgi] may be used for adults," and thus encroaches on Catalyst's ODE (Count I);
- the approval of Ruzurgi for any patient population, adults or pediatrics, violated Catalyst's ODE (Count II);
- Jacobus's application for Ruzurgi impermissibly relied upon studies collected and submitted by Catalyst for Firdapse, and (Count III); and
- the FDA treated the NDAs for Firdapse and Ruzurgi differently, in a way that favored Ruzurgi, by (a) allowing Jacobus, but not Catalyst, to submit studies and clinical trials post-approval, and (b) accelerating Jacobus's application (Count VI).

See ECF No. [1].

On December 17, 2019, Jacobus moved to intervene in this action, *see* ECF No. [32], and was added as a Defendant. Catalyst filed a Motion for Summary Judgment, ECF No. [38], setting forth two pared-down arguments: (1) the FDA's approval of Ruzurgi violated Catalyst's ODE; and (2) the FDA violated its own labeling requirements in approving Ruzurgi. On December 20, 2019, the Court referred the matter to the Magistrate Judge Lauren F. Louis for all pre-trial proceedings. *See* ECF No. [41]. On January 17, 2020, Jacobus and the Federal Defendants filed separate Cross-Motions for Summary Judgment, *see* ECF No. [46], and ECF No. [47], respectively.

In her Report, Magistrate Judge Louis recommends that Catalyst's Motion for Summary Judgment be denied; both Jacobus and the Federal Defendants' Motions be granted; and the case be dismissed. The Report relies on *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), which sets forth a two-step process for analyzing Administrative Procedures Act claims, known as the doctrine of "*Chevron* deference." Using the doctrine, described in this Order's "Legal Standards" section, the Report reasons:

1. The language in section 360cc of the Orphan Drug Act, specifically the phrase "disease or condition" is ambiguous under step one of the *Chevron* analysis; and
2. The FDA's interpretation of the statute, i.e. limiting Catalyst's ODE to LEMS in adults only, is reasonable under step two of the *Chevron* analysis.

Judge Louis also found the FDA's approval of Ruzurgi's labeling did not violation the Federal Food, Drug, and Cosmetic Act and the FDA did not inappropriately consider pricing in considering approval of Ruzurgi.

Catalyst filed Objections to the Report, averring it "inappropriately ignore[s] the plain language of the statute and the undisputed fact that LEMS in adults and pediatrics is the same disease[.]" ECF No. [94] at 16. In connection with this Objection, Catalyst argues the Report "misapplie[s]" the *Chevron* deference doctrine." *Id.* at 18. Catalyst further argues that the Report

misconstrues its challenge to the FDA's process of labeling Ruzurgi and that FDA's "reliance solely on adult studies on Jacobus's label falsely and misleadingly suggests the drug can be used *by* adults, in violation of the FDCA and FDA regulations." *Id.* at 25.

II. LEGAL STANDARDS

A. District Court Review of a Report and Recommendation

When a magistrate judge's "disposition" has been properly objected to, district courts must review the disposition *de novo*. Fed. R. Civ. P. 72(b)(3). Although Rule 72 is silent on the standard of review, the United States Supreme Court has determined Congress's intent was to require *de novo* review only when objections were properly filed, not when neither party objects. *See Thomas v. Arn*, 474 U.S. 140, 150 (1985) ("It does not appear that Congress intended to require district court review of a magistrate[] [judge]'s factual or legal conclusions, under a *de novo* or any other standard, when neither party objects to those findings." (alterations added)). A proper objection "identifie[s] specific findings set forth in the R & R and articulate[s] a legal ground for objection." *Leatherwood v. Anna's Linens Co.*, 384 F. App'x 853, 857 (11th Cir. 2010) (alterations added; citation omitted). "Frivolous, conclusive, or general objections need not be considered by the district court." *Id.* (quoting *Marsden v. Moore*, 847 F.2d 1536, 1548 (11th Cir. 1988) (internal quotation marks and other citation omitted)); *see also Russell v. United States*, No. 11-20557-Civ, 2012 WL 10026019, at *1 (S.D. Fla. Apr. 17, 2012) (declining to address general or blanket objections not specifically identifying aspects of the magistrate judge's report to which the petitioner objected).

B. The Administrative Procedure Act

To prevail on an Administrative Procedure Act ("APA") claim, a plaintiff must prove an agency's decision was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *see also Salmeron-Salmeron v. Spivey*, 926 F.3d 1283, 1286

(11th Cir. 2019). The Court's "role is to ensure that the agency came to a rational conclusion, not to conduct its own investigation and substitute its own judgment for the administrative agency's decision." *Defs. of Wildlife v. U.S. Dep't of Navy*, 733 F.3d 1106, 1115 (11th Cir. 2013) (internal quotation marks and citation omitted).

When reviewing an agency's interpretation of a statute, the Court is confronted with two questions. *See Chevron*, 467 U.S. at 842. The Court must "first ask whether congressional intent is clear." *Wilderness Watch & Pub. Emps. for Envtl. Responsibility v. Mainella*, 375 F.3d 1085, 1091 (11th Cir. 2004) (citation omitted). If Congress's intent is clear and unambiguous, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* (internal quotation marks omitted; quoting *Chevron*, 467 U.S. at 842–43).

If the statute is silent or ambiguous regarding a specific issue, then the Court must ask "whether the agency's answer is based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843. The agency's construction "governs if it is a reasonable interpretation of the statute — not necessarily the only possible interpretation, nor even the interpretation deemed most reasonable by the courts." *Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208, 218 (2009) (citation and emphasis omitted). At a minimum, the Court gives "an agency interpretation deference under *Skidmore v. Swift & Co.*, [323 U.S. 134 (1944)] corresponding to the 'thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.'" *Martin v. Soc. Sec. Admin., Comm'r*, 903 F.3d 1154, 1159 (11th Cir. 2018) (alteration added; quoting *Skidmore*, 323 U.S. at 140).

III. DISCUSSION

Catalyst sets forth two general Objections. First, Catalyst argues Magistrate Judge Louis

misconstrues the plain language of the Orphan Drug Act, specifically 21 U.S.C. § 360cc. In an expansion of this argument, Catalyst insists there are six specific instances in which Magistrate Judge Louis misapplies *Chevron* deference. Second, Catalyst argues Ruzurgi's FDA-approved label violates 21 U.S.C. section 355(d) and its implementing regulations because the Ruzurgi labeling implies it may be used for adult patients. The Court addresses each argument in turn.

A. Plain Language of 21 U.S.C. § 360cc

The crux of this case is whether the language of section 360cc is ambiguous. If it is, the Court need only determine whether the FDA's interpretation of the statute is reasonable. *See Chevron*, 467 U.S. at 843. A review of the statutory language is necessary. The full text of section 360cc(a) states:

> 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. Section 355(c)(2) of this title does not apply to the refusal to approve an application under the preceding sentence.

(emphasis added).

The Report focuses on the phrase "same disease or condition" and concludes "it is unclear whether that phrase refers to the use for which the drug is approved after it submits its [NDA]"—here, LEMS for adults —"or the disease or condition for which it . . . received orphan [drug] designation" — LEMS for all patients. ECF No. [93] at 10. The statute's silence on this point, the

Report reasons, gives rise to an ambiguity under *Chevron* step one. *See id.*at 9–12.[3]

In its Objections, Catalyst insists the reasoning in the Report contravenes the plain language of section 360cc. *See* ECF No. [94] at 15. Catalyst emphasizes that all parties agree Firdapse and Ruzurgi are the "same drug" and both drugs are intended to treat the "same disease or condition" — LEMS. To elucidate its point, Catalyst points to a "readily diagrammable formula" used in a case it contends is instructive, *Eagle Pharmaceuticals, Inc. v. Azar*: "if x and y, then z." *Id.* at 16 (citing 952 F.3d 323, 328 (D.C. Cir. 2020) (internal quotation marks and citations omitted)).

In *Eagle Pharmaceuticals*, the D.C. Circuit questioned whether the plain language of section 360cc permitted "serial exclusivity," i.e. whether, after the expiration of the seven-year ODE for a certain drug, a *second* drug sponsor could take advantage of the exclusivity provision. *See* 952 F.3d at 328. More specifically, the Court questioned whether the FDA was permitted to require the sponsor of the second drug to demonstrate the drug's clinical superiority after its approval (a "post-approval clinical-superiority requirement") before awarding the sponsor ODE. *See id.* at 329. The Court found the FDA had no such authority, reasoning that by mandating the second drug sponsor demonstrate clinical superiority at the post-approval stage, the FDA created a requirement not intended, or written, by Congress. *See id.* at 331 ("the text leaves no room for the FDA to place additional requirements on a drug that has been designated and approved before granting its manufacturer the right to exclusivity.") Referring to the formula "if x and y, then z," the Court found the corresponding statutory text read, simply, "if designation and approval, then exclusivity." *Id.*

[3] The Report notes that the FDA referred the analysis of Catalyst's ODE to the Exclusivity Board at the FDA's Center for Drug Evaluation and Research. The Exclusivity Board determined LEMS in adults is not the same disease or condition as LEMS in children for the purposes of its exclusivity analysis and recommended Ruzurgi be approved for pediatric patients. The FDA adopted the Exclusivity Board's recommendation. *See* Report at 6; ECF No. [66-1] at 424–33.

Catalyst applies the same formula to this case, contending that the resulting logic is: "if (x) FDA designates *and* (y) approves a drug under the Orphan Drug Act, *then* (z) under the plain language of this provision, the FDA is barred from approving another application for such drug." ECF No. [94] at 16 (alteration adopted, citation, internal quotation marks, and footnote call number omitted).

In this case, the reasoning of *Eagle Pharmaceuticals* is not as easy to import as Catalyst suggests. Catalyst is not wrong to urge the Court to focus on the plain language of the statute, as this is what the Court must do under *Chevron* step one. But Catalyst misses the mark by omitting a portion of section 360cc from its logic, which starts with approval under section 355. Returning to the text, section 360cc states "If the Secretary . . . ***approves an application filed pursuant to section 355*** . . . for a drug designated under section 360bb of this title . . . the Secretary may not approve another application under section 355 of this Title . . . for the same drug for the same disease or condition for a person who is not the holder of such approved application . . . ." On its face, 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. The drug's intended use — which drug companies must describe in the section 355 application — may be for a treatment of all patients with the disease or condition or, as in this case, for the manifestation of the disease in adult patients or pediatric patients only.

Importantly, Catalyst does not dispute its section 355 application was for the treatment of LEMS in adults only, *see* ECF No. [66-2] at 487, nor does Catalyst argue NDA applications do not (or should not have to) distinguish between adult and pediatric patients in the first instance. Thus, 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 section 360bb.

In this respect, Jacobus's reliance on *Spectrum Pharmaceuticals, Inc. v. Burwell*, is apt. In *Spectrum*, the D.C. Circuit considered whether the FDA should not have approved the defendant's generic version of the drug, levoleucovorin, used to treat liver damage caused by methotrexate therapy (a type of chemotherapy) and manage pain from colorectal cancer. *See* 824 F.3d 1062, 1064 (D.C. Cir. 2016). The plaintiff, Spectrum Pharmaceuticals — which had obtained ODE for the *colorectal* indication — sued the FDA when it approved the generic drug for *methotrexate* indications. *See id.* Spectrum argued the FDA knew, but ignored, that the generic drug would also be used to treat colorectal pain, thus trenching on Spectrum's ODE. *See id.* at 1065. The court rejected Spectrum's arguments, finding the FDA was permitted to approve the generic drug because the label for the same mentioned only the methotrexate indications and omitted (or "carved-out") the colorectal indication subject to Spectrum's ODE. *See id.* at 1065–67.

The court in *Spectrum* did not consider whether the Orphan Drug Act permits the FDA to limit ODE to adult or pediatric manifestations of a disease or condition. Nevertheless, the court's commentary on the text of the Orphan Drug Act is instructive.

> As the Fourth Circuit reasoned in *Sigma–Tau Pharmaceuticals, Inc. v. Schwetz*, 288 F.3d 141 (4th Cir. 2002), the words "for such disease or condition" suggest Congress intended to make section 360cc "disease specific, not drug-specific," and ***the rest of the statutory language focuses on protecting approved indications***, not intended off-label uses. *See id.* at 145 (reasoning that the statutory language is "directed at FDA approved-use, not generic competitor intended-use***"). The statute creates limits on the approval of an "application," which by implication directs FDA to evaluate what is written on the application***. 21 U.S.C. § 360cc. An application will necessarily include only stated indications, not intended off-label uses. *Id.* § 355(b).

Id. at 1067. (emphasis added). The *Spectrum* court observed, as this Court does here, section 360cc refers to applications, and an application "necessarily includes" the proposed drug's specific use.

See id. Thus, that the FDA interprets section 360cc to refer to the *approved* disease or condition stated in the 355 application by no means contravenes the text of the statute.[4]

In sum, because there is more than one way to reasonably interpret section 360cc, the Court finds the statute is ambiguous under *Chevron* step one. *See* 467 U.S. at 842.

Following this conclusion, the six "fatal flaws" Catalyst identifies may be dealt with in relatively short order:

First, Catalyst argues "the term 'same disease or condition' is simply not ambiguous." ECF No. [94] at 19. For the reasons stated above, there is more than one reasonable interpretation of the words "same disease or condition" given section 360cc's reference to section 355.

Second, Catalyst argues "nothing about the interplay of other Orphan Drug Act provisions can render the straightforward term 'same disease or condition' ambiguous." *Id.* This objection refers only to section 360cc's interplay with section 360bb, glossing over section 355 entirely. In this respect, the Court agrees with the Federal Defendants that the words "same disease or condition" must be considered "in their context and with a view to their place in the overall

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[4] What is more, a case on which Catalyst relies, *Depomed, Inc. v. United States Department of Health & Human Services*, supports the Court's conclusion. In *Depomed*, the court considered whether a pharmaceutical company was entitled to ODE for a drug used to treat post-herpetic neuralgia ("PHN"), where the FDA had already granted marketing approval to a drug called Neurontin. *See* 66 F. Supp. 3d 217, 220 (D.D.C. 2014). The court began its analysis, as this Court does, by looking to the text of section 360cc. After reciting the same, the court noted:

> [T]he plain language of the statute sets forth **two procedural prerequisites for marketing exclusivity**: first, the FDA must have "designated" the drug as an orphan drug, upon request from the drug's sponsor, pursuant to 21 U.S.C. § 360bb and its accompanying regulations; and **second, the FDA must have "approved" the designated orphan drug for marketing to the public pursuant to 21 U.S.C. § 355, which is the section of the FDCA that provides the general procedure for marketing approval of all the pharmaceutical products that the FDA regulates**. **If both conditions are met, then the Act provides that the FDA "may not approve another" such drug for marketing to the public** for "seven years from the date" of the designated drug's approval. 21 U.S.C. § 360cc(a).

Id. at 221 (emphasis added; footnote call number omitted). Thus, in the *Depomed* court's view, section 360cc makes clear that ODE is tied to application approval under section 355.

statutory scheme." ECF No. [99] at 12 (citing *King v. Burwell*, 576 U.S. 473, 486 (2015) (other citations omitted)). Because section 360cc's interplay with section 355 is central to the Court's finding, Catalyst's argument is misplaced.

Third, Catalyst argues "although the R&R infers that the term 'same disease or condition' in 360cc(a) must be tied to the scope of Catalyst's approval in this case, no text in the provision supports this, either directly or indirectly." ECF No. [94] at 20. Not so. Section 360cc refers directly to section 355, and section 355 concerns NDAs, which may be limited in scope.

Fourth, Catalyst argues "although Congress used the terms 'indication' or 'uses' elsewhere in the FDCA to draw distinctions between specific approved uses of a drug, Congress chose not to use those terms in the ODE provision." ECF No. [94] at 21. Although this is true, Congress also specifically referred to section 355 in section 3600cc. Congress could have, but did not, omit reference to section 355, or make clear that the term "same disease or condition" refers only to the disease or condition *as designated* in section 360bb. For example, Congress could have written: "if the Secretary approves an application for a drug designated under section 360bb of this title for a rare disease or condition, the Secretary may not approve another application for another drug with the same designation." Congress did not do so, and the Court cannot simply ignore its reference to section 355.

Fifth, Catalyst argues "other provisions of the Orphan Drug Act show that Congress explicitly did not intend for a 'disease or condition' to be sliced and diced by FDA according to 'subpopulations or 'subgroups.'" ECF No. [94] at 21. This argument does not hold up against the language of section 355, which requires a drug company to substantiate the effectiveness of its drug for a particular *use*. *See* 21 U.S.C. § 355(b). Catalyst points to section 360ee(b)(1)(C)(ii), which encourages research to "understand the full spectrum of the disease manifestations, including . . . identifying and defining distinct subpopulations affected by ***a*** rare disease or

condition.'" Yet this section of the statute does not explain away section 360cc's reference to section 355. Certainly, it does not give rise to the conclusion that the FDA's interpretation of section 360cc contravenes the plain meaning of the statute.

Finally, Catalyst argues "the Orphan Drug Act explicitly provides three specific circumstances where FDA may actually approve a second 'same drug' for the 'same disease or condition' notwithstanding ODE[.]" ECF No. [94] at 22. Catalyst points to three exceptions enumerated in 21 U.S.C. section 360cc(b), including (1) if the company with ODE "cannot ensure the availability of sufficient quantities" of its drug," *id.* section 360cc(b)(1); (2) the entity with ODE consents "in writing," *id.* section 360cc(b)(2); or (3) a subsequent drug company can demonstrate its drug "clinically superior" to the drug with ODE, *id.* section 360cc(c). The Court agrees with the Federal Defendants that each of these exceptions pertains to whether a "sponsor's orphan drug exclusivity may be 'broken' by a second applicant, none of which apply here." ECF No. [99] at 14. As explained above, Catalyst only sought and obtained approval under section 355 with respect to the treatment of LEMS in adults, *not* LEMS for all patients. Had another sponsor arrived with a competing drug for LEMS in *adults*, the Court might scrutinize the foregoing exceptions. It need not do so here.

The Court emphasizes that Catalyst's view of section 360cc is not necessarily *wrong*, but it is not the only reasonable way to interpret the plain language of the statute. As noted, an agency's construction of a statute "governs if it is a reasonable interpretation . . . not necessarily the only possible interpretation, nor even the interpretation deemed most reasonable by the courts." *Entergy Corp*, 556 U.S. at 218 (citation and emphasis omitted).

B. Catalyst's Challenge to Ruzurgi's Label

Catalyst next argues Ruzurgi's label is "false or misleading," in violation of 21 U.S.C. section 355(a), because it implies or suggests Ruzurgi may be used for adults even though it has

only been approved for pediatric patients. *See* ECF No. [94] at 24. The label for Ruzurgi states "Use of RUZURGI in patients 6 to less than 17 years of age is supported by evidence from adequate and well-controlled studies of RUZURGI in adults with LEMS." ECF No. [66-1] at 448. According to Catalyst, the "specific reliance solely on adult studies on Jacobus's label falsely and misleadingly suggests the drug can be used *by* adults, in violation of the FDCA and FDA regulations." ECF No. [94] at 25.

Catalyst points to (1) 21 U.S.C. section 355(d), providing the Secretary may refuse an NDA if he finds the labeling for the same is "false or misleading;" (2) 21 C.F.R. section 201.57(c)(2)(iv), providing "indications . . . must be supported by substantial evidence of effectiveness based on adequate and well-controlled studies as defined in [section] 314.126(b) of this chapter; " and (3) 21 C.F.R section 201.57(c)(15)(i), providing "any clinical study that is discussed in prescription drug labeling that relates to an indication for or use of the drug must be adequate and well-controlled as described in [section] 314.126(b) of this chapter and must not imply or suggest indications or uses or dosing regimens not stated in the 'Indications and Usage' or 'Dosage and Administration' section."

"As with all agency rules . . . regulations implementing [a statute] are accorded *Chevron* deference." *See Falken v. Glynn Cty., Georgia*, 197 F.3d 1341, 1346 (11th Cir. 1999); *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 359 (1989) (noting an agency's interpretation of its own regulation is controlling if it is not "plainly erroneous or inconsistent with the regulation." (citation omitted)). Save for a general citation to the premise set forth in *Simmons v. Block*, 782 F.2d 1545, 1550 (11th Cir. 1986) (noting "the failure of an agency to comply with its own regulations" is unlawful under the APA), Catalyst fails to present any case law in support of its position. Certainly, it presents no authority that would call into question the FDA's interpretation of its regulation under *Chevron's* highly deferential standard.

With this standard in mind, the Court declines Catalyst's invitation to substitute its interpretation of "misleading" for the FDA's interpretation. The Court notes Ruzurgi's label does not affirmatively represent the drug is approved for adult patients, but merely discloses pediatric approval was based on adult studies. Moreover, as noted by Jacobus, *see* ECF No. [98] at 24, this disclosure is required under 21 C.F.R. section 201.57(c)(15): "[t]his section must discuss those clinical studies that facilitate an understanding of how to use the drug safely and effectively."

The Court agrees with Judge Louis that the record reflects the FDA "reviewed the label for Ruzurgi after the application had been split for pediatric patients and adults and concluded that it was not misleading for pediatric patients." ECF No. [93] at 16.

IV. CONCLUSION

For the foregoing reasons, it is

ORDERED AND ADJUDGED that:

1. Magistrate Judge Louis's Report and Recommendations, **ECF No. [93]**, is **ADOPTED;**
2. Plaintiff Catalyst Pharmaceuticals Inc.'s Objections, **ECF No. [94]**, are **OVERRULED;**.
3. Plaintiff Catalyst Pharmaceuticals Inc.'s Motion for Summary Judgment, **ECF Nos. [38], [40]**, is **DENIED;**
4. Federal Defendants' Cross-Motion for Summary Judgment, **ECF No. [47]**, is **GRANTED;**
5. Intervenor-Defendant Jacobus Pharmaceutical Company, Inc.'s Cross-Motion for Summary Judgment, **ECF No. [46]**, is **GRANTED**; and
6. The Case is **DISMISSED**. The Clerk of Court shall **ADMINISTRATIVELY CLOSE** the case.

DONE AND ORDERED in Chambers at Miami, Florida, on September 29, 2020.

BETH BLOOM
UNITED STATES DISTRICT JUDGE

Copies to:
Counsel of Record