IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

CASE NO. 1:19-CV-22425-BLOOM/LOUIS

CATALYST PHARMACEUTICALS, INC.,
Plaintiff,

v.

ALEX AZAR, Secretary of Health and Human Services, *et al.*,

Defendants, *and*

JACOBUS PHARMACEUTICAL COMPANY, INC.,

Intervenor-Defendant.
_____/

REPORT AND RECOMMENDATIONS

THIS CAUSE comes before the Court upon Plaintiff Catalyst Pharmaceuticals, Inc's Motion for Summary Judgment (ECF No. 38);[1] Intervenor-Defendant Jacobus Pharmaceutical Company, Inc's Cross-Motion for Summary Judgment (ECF No. 46).[2] Defendants Alex Azar, Secretary of Health and Human Services, United States Department of Health and Human Services, Norman Sharpless, and United States Food and Drug Administration ("Federal Defendants") cross-moved for Summary Judgment and opposed Plaintiff's Motion for Summary Judgment (ECF No. 47). After briefing was complete, the Parties were permitted to supplement their memoranda following oral argument and the undersigned's order granting Plaintiff's motion to add to the record (ECF Nos. 75, 76). These matters have been referred to the undersigned by the Honorable Beth Bloom, United States District Court Judge (ECF No. 29) for a Report and

[1] Filed under seal without redaction at ECF No. 51.
[2] Intervenor-Defendant Jacobus Motion for Summary Judgment raises the same arguments as are raised in Defendants' Motion for Summary Judgment, as such, I address only Defendant's Motion.

Recommendations. Upon consideration of the Motions, Responses, supplementation, and review of the record as a whole, the undersigned recommends that Plaintiff's Motion be denied, and Defendants' Motion be granted, as explained below.

I. BACKGROUND

This Administrative Procedures Act ("APA") case arises out of Catalyst Pharmaceutical, Inc.'s ("Catalyst") complaint challenging the Federal Drug Administration's ("FDA") approval of Intervenor-Defendant Jacobus Pharmaceutical Company, Inc.'s ("Jacobus") drug, Ruzurgi, despite Catalyst's drug, Firdapse, already receiving approval for seven-year market exclusivity. Plaintiff's claims implicate the FDA's interpretation of the Orphan Drug Act, Pub. L. 97-414, 96 Stat. 2049 (1983); 21 U.S.C. § 360ee(b)(2)(1).

a. Regulatory Framework

The FDA was created in 1938 by Congress through the Federal Food, Drug, and Cosmetic Act ("FDCA"). 21 U.S.C. § 371. Under this Act, the FDA was granted general authority to promulgate regulations for the efficient enforcement of the FDCA. In 1983, Congress passed amendments to the FDCA through the Orphan Drug Act to incentivize the development of "orphan drugs"—those developed to treat rare diseases affecting small numbers of individuals in the United States. Orphan Drug Act, Pub. L. 97-414, 96 Stat. 2049 (1983). The main incentive for development of these drugs under the Orphan Drug Act is a grant of seven-year marketing exclusivity. Pursuant to the Orphan Drug Act, once the FDA approves a drug under the Act the FDA is prohibited from approving the "same drug for the same disease or condition . . . until the expiration of seven years from the date of the approval." 21 U.S.C. § 360cc(a).

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, however, 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, 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).

Many of the provisions of the Orphan Drug Act direct the FDA to promulgate regulations to implement the Act. *See e.g.*, 21 U.S.C. §§ 360aa(b); 360bb(d); 360cc(d). Consistent with that authority, in 1991 the FDA proposed regulations to implement the Orphan Drug Act amendments to the FDCA. *See* 56 Fed. Reg. 3338 (Jan. 29, 1991). The proposed regulations sought to codify the agency's administrative practices and followed a two-day public workshop about how best to implement the new statutory grant from Congress. *Id*. at 3343. Therein, the FDA specifically recognized that "[a]n indication for treatment of a specific disease or condition could involve all patients with that disease or condition or a specified subpopulation of those with the disease or condition." *Id*. The FDA continued "[e]xclusive approval for a disease subset would not bar approval of the same drug for the larger population or other subsets of populations by different sponsors." *Id.* at 3339.

In 2011, the FDA proposed changes to the regulations "to clarify certain regulatory language in the current orphan drug regulations and to propose areas of minor improvement." 76 Fed. Reg. 64868 (Oct. 19, 2011). One of the areas addressed by the FDA was "eligibility for

multiple orphan-drug exclusive approvals when a designated orphan drug is separately approved for use in different subsets of the rare disease or condition." *Id*. at 64869. The FDA explained that when it designates a drug as an orphan drug, it generally does so for use by all persons with the rare disease or condition and expects that a sponsor will seek approval of the drug for all persons with the rare disease or condition. *Id.* at 64870. However, the agency recognized that ultimate approval will only be granted for those for which there is adequate data and information, which may be "limited to subsets of patients with the orphan disease or condition." *Id*. The FDA reiterated that it has interpreted orphan drug exclusivity to be "limited to the approved indication or use, even if the underlying orphan designation is broader." *Id*.

In 2013, the FDA finalized the current scope of orphan-drug exclusivity as follows: "effective on the date of FDA approval as stated in the approval letter of a marketing application for a sponsor of a designated orphan drug, no approval will be given to a subsequent sponsor of the same drug for the same use or indication for 7 years. . . . A designated drug will receive orphan-drug exclusive approval only if the same drug has not already been approved for the same use or indication." 21 C.F.R. § 316.3(b)(12).

b. Factual Background of Plaintiff's Claims

Catalyst is the developer of Firdapse, a medication indicated to treat Lambert-Eaton Myasthenic Syndrome ("LEMS"), a rare autoimmune disease that affects the "neuromuscular junction" where the nerve connects with muscle impeding nerve cells from sending signals to muscle cells (R. 983).[3] There are approximately 950 to 1,300 individuals diagnosed with LEMS in the United States (*id.* at 875).

In 2005, the FDA designated Catalyst's drug Firdapse as an "orphan drug" for the treatment

[3] Citations to the Administrative Record are designated by the letter "R." followed by the page number. The Administrative Record can be found at ECF No. 62-1.

of LEMS (R. 771). In 2015, Catalyst submitted a new drug application for Firdapse (R. 556-95). In that application, Catalyst sought approval to market Firdapse for the treatment of LEMS in adults (*id*.). After an initial review, the FDA determined the application was insufficient to grant approval and refused to file the application in February of 2016 (R. 596-600). Catalyst resubmitted its application in March of 2018 (R. 652-655). In November of 2018, Catalyst received approval to market Firdapse for the treatment of LEMS in adults (R. 2414-16, 1002-08).

Jacobus received "orphan drug" status for its drug, Ruzurgi, in December of 1990 (R.126). Ruzurgi contains the same active moiety, similar to that of the active ingredient, as Catalyst's Firdapse, as such the parties agree that the two drugs are the same.[4] After Jacobus received orphan drug status, Jacobus started supplying its drug, including to pediatric patients, under an Investigational New Drug Application ("IND"). Jacobus submitted its New Drug Application in August of 2017 seeking approval to market Ruzurgi for the treatment of LEMS patients in both pediatric and adult patients (R. 60-63). Upon its initial review, the FDA also found Jacobus' application incomplete and refused to file it in January of 2018 (R. 67-75). Jacobus resubmitted its application in June of 2018, which was accepted for filing in August 2018 (R. 83-86). Again, its application sought approval to market Ruzurgi for the treatment of LEMS in pediatric and adult patients (R. 3668-97).

Upon approval of Catalyst's drug in November of 2018 for the treatment of adult LEMS patients, the FDA administratively divided Jacobus' application into two parts, one for the treatment of LEMS in pediatric patients, and the other for the treatment of LEMS in adults to allow for "independent actions in these populations." (R. 444-73). FDA received and reviewed data submitted by Jacobus in its application which included a clinical trial in adults and dosing and

[4] This is admitted in Federal Defendants' Answer. ECF No. 22 ¶ 6.

safety information for the use of Ruzurgi in pediatric patients. The FDA determined based on that information that the drug was safe and effective for patients as young as six-years old up to seventeen-years old and approved it for being marketed to that subpopulation (R. 428, 444-473).

Prior to approving Jacobus drug, the FDA considered whether Catalyst's exclusivity blocked Jacobus' application and referred the decision to its Center for Drug Evaluation and Research's Exclusivity Board, a group established to provide oversight and recommendations regarding exclusivity determinations. The Exclusivity Board recommended that Jacobus' drug not be approved for treatment of LEMS in adults because of Catalyst's exclusivity but concluded that LEMS in adults is not the same disease or condition as LEMS in children and recommended that Ruzurgi be approved for the treatment of LEMS in pediatric patients (R. 418-27). The recommendations of the board were accepted by the FDA, as reflected in its letter approving Ruzurgi (R. 484-92).

Catalyst then instituted this lawsuit alleging four violations of the Administrative Procedures Act. In Count I, Catalyst avers that the FDA's approval of Jacobus' labeling was arbitrary and capricious because it was false or misleading as it implied and suggested that it was approved for adult populations (ECF No. 1 at ¶¶ 60-67). Counts II-IV allege that the FDA acted in an arbitrary and capricious manner in its approval of Ruzurgi in light of Firdapse's exclusivity (ECF No. 1 ¶¶ 68-89). Count II alleges that the FDA's approval and regulations are inconsistent with the Orphan Drug Act, while Counts III and IV allege that Ruzurgi's approval was arbitrary and capricious. Plaintiff challenges the FDA's conclusion, that LEMS in adults is not the same disease or condition as LEMS in children, as contradicted by the administrative record and accuses the FDA of inventing a new disease in order to defeat its exclusivity. Plaintiff also contends that Defendants caved to external pressure by politicians concerned about the price of its drug.

II. STANDARD OF REVIEW

The Parties have cross-moved for summary judgment in this Administrative Procedures Act Appeal. Summary Judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). Summary judgment is appropriate in cases in which a court is asked to review a decision rendered by a federal administrative agency. *U.S. Steel Corp. v. Astrue*, 495 F.3d 1272, 1279 (11th Cir. 2007).

Even in the context of summary judgment, an agency is entitled to great deference. *Id*. Courts reviewing agency action under the APA apply the "arbitrary and capricious standard," and are required to uphold an agency action unless it is contrary to law, an abuse of discretion or arbitrary and capricious. 5 U.S.C. § 706(2)(A); *Nat'l Parks Conservation Ass'n, Inc. v. U.S. Army Corps of Engineers*, 446 F. Supp. 2d 1322, 1336 (S.D. Fla. 2006). This standard is highly deferential to the agency. *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971).

Agency administrative decisions are entitled to a presumption of validity. *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 743 (1985); *Camp v. Pitts*, 411 U.S. 138, 142 (1973). Courts may not substitute their judgment for that of the agency and can set aside an agency's decision only if the agency relied on improper factors, failed to consider important relevant factors, or committed a clear error of judgment that lacks a rational connection between the facts found and the choice made. *Arango v. United States Dep't of Treasury*, 115 F.3d 922, 928 (11th Cir. 1997).

It is also important that a reviewing court only review information that was before the agency at the time of its decision in assessing whether the decision was permissible. *United States v. Guthrie*, 50 F.3d 936, 944 (11th Cir. 1995) ("a court does not consider any evidence that was

not in the record before the agency at the time that it made the decision or promulgated the regulation.").

III. DISCUSSION

a. Orphan Drug Act Claim

Plaintiff avers that the FDA violated the clear terms of the Orphan Drug Act by approving Ruzurgi because the statutory text is plain and unambiguous and prohibits the FDA from approving a second, same drug for the same disease or condition. Plaintiff cites to the statutory language in 21 U.S.C. § 360cc(a) which states that once the FDA approves a drug under the Act the FDA is prohibited from approving the "same drug for the same disease or condition . . . until the expiration of seven years from the date of the approval." 21 U.S.C. § 360cc(a). Plaintiff avers that this statutory language sets out a clear and unambiguous "if-then" test: if the FDA approves a drug that has been designated for a rare disease or condition, then it may not approve another application for the same drug for the same disease or condition for seven years (ECF No. 40 at 14).

Defendants urge the Court to defer to its interpretation of the FDCA pursuant to *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Under *Chevron*, a court reviewing an agency's interpretation first considers "whether Congress has directly spoken to the precise question at issue." *Id.* at 842. If the statute is "silent or ambiguous with respect to the specific issue," the Court proceeds to the second step of Chevron, where the "question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843. The court need not find that the agency construction was the only one it permissibly could have adopted; so long as the agency's reading was permissible, it must be sustained. *Id.* at 843-44, n.11. The Supreme Court has "long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer." *United*

States v. Mead Corp., 533 U.S. 218, 227-28 (2001) (quoting *Chevron*, 467 U.S. at 844). An agency reading of an ambiguous rule that reflects its "fair and considered judgment" is entitled to deference. *Auer v. Robbins*, 519 U.S. 452, 462 (1997).

i. "Disease and Condition"

The first question before the Court is whether Congress directly addressed the precise question at issue. If the intent of Congress is clear, that is the end of the matter for the court. *Chevron*, 467 U.S. at 842. If, however, the Court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, but rather examines whether the agency's answer is based on a permissible construction of the statute. *Id*. at 843.

In *Chevron*, the Supreme Court explained that Congress' "intent to delegate" rulemaking authority to the agency is manifest when the statute leaves the agency room "to fill any gap left, implicitly or explicitly, by Congress." 476 U.S. at 843. Other courts have further clarified that "Congress leaves gaps in [a] program, either explicitly by authorizing the agency to adopt implementing regulations, or implicitly by enacting an ambiguously worded provision that the agency must interpret[.]" *Nat'l Fuel Gas Supply Corp. v. FERC*, 811 F.2d 1563, 1569 (D.C. Cir. 1987). Accordingly, in order to proceed to *Chevron* step two, an agency must affirmatively identify either an explicit or implicit gap in the statutory scheme that is indicative of congressional intent to provide that agency with the power to interpret the statute.

The Orphan Drug Act has two relevant components: once a drug obtains exclusivity, the FDA may not for seven years approve the "same drug" for the "same disease or condition." The first component here is easily satisfied as there is no dispute as to Firdapse and Ruzurgi being the "same drug." It is the second component at issue and under review: whether LEMS in adults and

pediatric patients constitutes the same "disease or condition."

Defendants aver that the phrase "same disease or condition" leaves such a gap in the statutory scheme because it is unclear whether that phrase refers to the use for which a drug is approved after it submits its new drug application, including subpopulations and subgroups, or the disease or condition for which it has received orphan designation, which occurs much earlier in the process before it has undergone qualified testing. Defendants state that the temporal structure of the statute reinforces this gap because the FDA may designate a drug as an orphan drug under § 360bb early in the development of the drug before data is generated to support the uses of the drug that will ultimately be proposed in the new drug application.

During the development stage, a drug manufacturer or sponsor may request that FDA designate its drug as one for use in a rare disease or condition. 21 U.S.C. § 360bb. A drug so designated is considered an "orphan drug" and is eligible for tax incentives and federal assistance in the form of grants and contracts to defray expenses of "qualified testing." 26 U.S.C. § 45C; 21 U.S.C. § 360ee. "Qualified testing" includes studies and other analyses conducted to assist in the understanding of the "natural history of a rare disease or condition and in the development of a therapy, including studies and analyses to . . . 'understand the full spectrum of the disease manifestations, including describing genotypic and phenotypic variability and identifying and defining distinct subpopulations affected by a rare disease or condition.'" 21 U.S.C. § 360ee(b)(1)(C)(ii). Thus, if the statute is read to be based on approval of the disease or condition on which the orphan drug designation is based, it would be for the entire disease, exclusive of subgroups and subpopulations because such subgroups have yet to be identified. However, if the statute is read to be based on the approval for marketing, which comes much later in the development process, it could be for only a subpopulation or subgroup because these have now

been identified and established by the FDA. As such, the statute as written is silent as to what the same "disease or condition" actually means: that disease or condition which the drug received orphan drug designation, or that disease or condition for which it was ultimately approved for marketing.

Plaintiff cites to *Eagle Pharm., Inc. v. Azar*, CV 16-790 (TJK), 2018 WL 3838265 (D.D.C. June 8, 2018), *aff'd*, 952 F.3d 323 (D.C. Cir. 2020), for the proposition that the statutory text of § 360cc is clear. There, the court addressed whether the text prohibited serial exclusivity, that is whether the FDA could grant successive approvals of orphan-drug exclusivity for the "same drug" to treat the same disease after the first orphan drug's exclusivity period had expired. *Id*. at 2. In that case, the FDA refused to grant a second drug manufacturer orphan-drug exclusivity after a previous manufacturer's grant had expired because it determined the second drug was not "clinically superior." *Id*. at *6. The court there found that because the text did not contain a provision relating to clinical superiority, the FDA was not free to invent one. *Id*. While the court did find the statute was unambiguous in this context, it noted that the statute does not explain when two "drugs" are the same or different, even though that distinction controls the scope of the statute's exclusivity provision. *Id*. at *2. As such, the court did not make a blanket rule, as Plaintiff avers, that the statute is unambiguous; rather in the specific facts applicable in that case, the court found the plain reading of the statute relating to serial exclusivity was unambiguous. Additionally, here, the statute does not explain when two "diseases or conditions" are the same or different.

Additionally, Plaintiff cites to *Depomed, Inc. v. United States Dep't of Health & Human Servs.*, 66 F. Supp. 3d 217, 231 (D.D.C. 2014) for the same proposition, that is that the statute is clear and unambiguous and leaves no room for the FDA to impose additional limitations on exclusivity. This case too is distinguishable. There, the court addressed whether the FDA could

refuse to grant exclusivity to a drug when another drug with the same active ingredient, whose manufacturers had not sought orphan drug designation, was already on the market for that disease. The court found that because the FDA had designated plaintiff's drug for the rare disease or condition and granted it marketing approval, it was entitled to exclusivity, regardless of the fact that there were other drugs being marketed for the same disease or condition because those drugs had not been designated orphan drugs. It concluded that the FDA could not require a showing of clinical superiority to grant such exclusivity. Here, however, the FDA is not imposing an additional condition, that is it is not requiring Catalyst or Jacobus to demonstrate anything additional, rather it is interpreting the permissible scope of exclusivity afforded under the statute. The Court notes that in both *Eagle Pharm.* and *Depomed*, both cases resulted in the court requiring the FDA to grant exclusivity to the drug in question and neither dealt with whether one drug's exclusivity could prohibit the granting of another's exclusivity.

Because the statute is silent and does not provide whether the same "disease or condition" refers to that disease or condition for which the drug was designated as an orphan drug or the disease or condition for which it ultimately received marketing approval, I find that Congress has not "directly spoken to the precise question at issue," and therefore proceed to step two. *Chevron*, 467 U.S. at 842-43.

ii. The FDA's Interpretation is Reasonable

In the absence of clear intent in the statutory language, the Court must determine whether the FDA's interpretation is "a permissible construction" of the Orphan Drug Act. *See Chevron*, 467 U.S. at 843. As the Supreme Court has noted, the reasonableness standard is a generous one, requiring deference "even if the agency's reading differs from what the court believes is the best statutory interpretation." *Nat'l Cable & Telecomm. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967,

980 (2005).

First, FDA's reading of the statute fits closely with the statute's text. *See Abbott Labs. v. Young*, 920 F.2d 984, 988 (D.C. Cir. 1990) (recognizing that the reasonableness of an agency's interpretation turns in part on the "construction's 'fit' with the statutory language"). As the Fourth Circuit reasoned in *Sigma-Tau Pharmaceuticals, Inc. v. Schwetz*, 288 F.3d 141, 145 (4th Cir. 2002), "the statute as written protects uses, not drugs for any and all uses. Congress could have written § 360cc(a) more broadly by prescribing that the FDA 'may not approve another application . . . for such drug,' but it chose not to draft the statute in that way." The statute creates limits on the approval of an "application,' which by implication directs the FDA to evaluate what is written on the application. An application will necessarily include only stated indications, thus the FDA's interpretation comes close to the statutes text.

Second, FDA's interpretation conforms to the statutory purposes of the Orphan Drug Act. *See Abbott Labs.*, 920 F.2d at 988 (recognizing that an interpretation's "conformity to statutory purposes" affects its reasonableness). Plaintiff does not assert any reason why the FDA's interpretation would be antithetical to the goals of the Orphan Drug Act. Instead, it focuses on what it claims are impermissible considerations the FDA relied on in making its decision, which will be discussed below. However, the FDA's interpretation does conform to the statutory purposes of the Orphan Drug Act. As stated above, the point of the Orphan Drug Act is to expand drug access to individuals with rare diseases. Under the FDA's interpretation, manufacturers are rewarded for developing drugs for individuals who do not have access to such medications.

The FDA's interpretation recognizes the need to encourage sponsors to continue to develop a drug for subpopulations or indications within a rare disease or condition. *See Spectrum Pharm., Inc. v. Burwell*, 824 F.3d 1062, 1067-68 (D.C. Cir. 2016) (finding the FDA's interpretation of the

Orphan Drug Act reasonable when it "accommodate[d] both interests 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."). As the Supreme Court said in *Chevron*, an agency's "reasonable accommodation of conflicting policies that were committed to the agency's care by the statute" should control unless Congress would not have approved of its choice. 467 U.S. 845. As such, the Court finds that the FDA's interpretation is reasonable and aligns with the purpose of the Orphan Drug Act.

b. Other Attacks on Approval

Catalyst also raises two other attacks on the FDA's approval of Ruzurgi. First, it avers that the FDA's approval of Ruzurgi violates the FDCA's labeling requirements. Second it avers in its supplement (ECF No. 75), that the FDA's approval should be remanded because the FDA improperly relied on materials on which it was not permitted to rely, specifically pricing.

i. The FDA's Approval of Ruzurgi's Labeling Does Not Violate FDCA

Catalyst avers that the FDA's approval of Ruzurgi should be reversed and remanded because it claims Ruzurgi's approved labeling is false and misleading. Ruzurgi's approved labeling reads: "**INDICATIONS AND USAGE** RUZURGI is indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 to less than 17 years of age." (R. 494).

Defendants challenge Plaintiff's standing to challenge the FDA's approval under the FDCA for allegedly violating its own regulations because there is no private right of action to enforce the FDCA. *See* 21 U.S.C. §337(a) ("[A]ll such proceedings for enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."). Instead, FDA's regulations require the agency to exercise its judgment and expertise in reviewing proposed labeling against the statutory and regulatory labeling standards. *See* 21 C.F.R. § 201.57.

Nonetheless, Plaintiff avers that because Jacobus only conducted clinical trials in adults, approval for pediatric use without studies in children violates FDA's regulation which provides that it is false or misleading for labeling to discuss a "clinical study" in a manner that "impl[ies] or suggest[s] indications or uses" that are not approved. 21 C.F.R. §§ 201.57(c)(2)(iv) and 15(i). Defendants however aver that it was within its Congressionally-delegated expertise to approve the labeling.

Where an agency is operating within its area of Congressionally-delegated expertise, review by a court under the APA is under the "deferential 'arbitrary and capricious' standard." *See Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2569 (2019). A court's scope of review under this standard is narrow, and the court's job is only to determine whether the agency examined the relevant data and articulated a satisfactory explanation for its decision. *Id*. The court must not substitute its judgment for that of the agency's but instead must confine itself to ensuring that the agency remained "within the bounds of reasoned decisionmaking." *Id*.

The administrative record reflects that the FDA, including multiple groups and divisions within it, carefully reviewed several versions of Ruzurgi's proposed labeling for several different reasons as part of its consideration of Jacobus' application. For instance, the record shows that the Division of Medication Error and Prevention and Analysis reviewed the carton label and determined it was acceptable from a medication error perspective (R. 694-95). Additionally, the record reflects that Sharon W. Williams, MSN, BSN, RN, a senior patient labeling reviewer in the Division of Medical Policy Programs reviewed the labeling including the Medication Guide and Instructions for use and determined that it was acceptable (R. 700-01). Furthermore, the record reflects that the Office of Prescription Drug Promotion within the FDA reviewed the label for Ruzrugi after the application had been split for pediatric patients and adults and concluded that it

was not misleading for pediatric patients. (R. 715-16). The record shows that the FDA applied its judgment and expertise to the data in the new drug application and made determinations about what to include and what to exclude. Several different departments and divisions of the FDA reviewed, commented on, and ultimately contributed to the approval of the approved Ruzurgi drug label. The parties do not dispute that it is within the FDA's statutory powers to approve labeling for pharmaceuticals in the United States. The FDA has advanced sufficient evidence to demonstrate that it adequately considered and articulated a sufficient rationale for approving Ruzurgi's labeling. As such, deference is required to the agency's interpretation and implementation of the statute.

ii. The FDA Did Not Inappropriately Consider Drug Pricing

Plaintiff last avers that the Defendants' decision should be reversed and remanded or vacated because the FDA inappropriately considered a prohibited factor in its approval of Ruzurgi: the cost of the drug. A procedural aside is necessary to frame this issue. During the course of this litigation, Catalyst discovered documents that were not part of the administrative record pursuant to a separate Freedom of Information Act lawsuit. Plaintiff moved to expand and complete the record to include these documents. The undersigned granted the motion, in part, and found that the FDA had considered some of the documents (and Defendants agreed as to other documents at issue that they should be part of the record). The Court ultimately allowed three sets of documents to be added to the administrative record: first, emails and a background memorandum relating to the FDA's Center for Drug Evaluation and Research's Exclusivity Board's meeting at which the Board considered whether Catalyst's orphan drug exclusivity blocked approval of Jacobus' drug; second, an email chain relating to the scheduling of that meeting; and third, a letter to the FDA from Senator Bernard Sanders.

While the Court agreed that the FDA had considered the documents at issue, the Order granting Plaintiff's Motion observed that this alone would not suffice to evidence that the agency relied upon the contents of the documents: "While the standard of review in deciding whether the agency's actions were arbitrary and capricious turns on whether the documents were *relied* on, for purposes of completing the record, the agency must include all documents it *considered* . . ." *See* ECF No. 74 at 9 (quoting *Georgia Dep't of Ed. v. United States Dep't of Ed.*, 883 F.3d 1311, 1314 (11th Cir. 2014). Indeed, Plaintiff had advanced additional documents to be supplemented to the record because, Plaintiff averred, those documents were indicative of improper behavior by the agency. The undersigned rejected Plaintiff's argument, noting that "Plaintiff's contention that the records, taken as a whole, demonstrate improper agency action falls below the threshold necessary for supplementation[.]" (ECF No. 74 at 11).

Plaintiff's supplemental briefing (ECF No. 75) continues to advance the argument that the FDA *considered* the documents, however, this alone is insufficient to evidence that the agency relied on the contents in considering an impermissible factor. Review of the record as a whole, including those documents that have been added, fails to reveal that the FDA relied on relative cost of the drugs in reaching its exclusivity determination. Rather, and despite outside sources' observations about the cost of Firdapse, the record demonstrates that the agency recognized that it did not have authority to take price into consideration. The examples on which Plaintiff rests its argument fails to show that the reference to cost indicates reliance by the agency on cost in reaching its determination, as follows.

The first set of documents is an email chain that contains a background memorandum relating to FDA's Center for Drug Evaluation and Research's Exclusivity Board's upcoming meeting at which the Board was set to discuss Catalyst's orphan drug exclusivity and its impact

on approval of Ruzurgi. The background memorandum includes an "Additional Background" section that notes the public controversy regarding the high price of drugs. In this pre-meeting document, the limited mention of cost in a section titled "Additional Background," does not support the inference that it was a direct consideration of the Board.

The second document is a letter from Senator Bernard Sanders to Defendant Azar and Scott Gottlieb, Commissioner of the FDA, in which Senator urges the FDA to announce that it would not enforce action against manufacturers who were previously providing LEMS medication in favor of Catalyst's exclusivity approval of Firdapse. The record reflects that members of the FDA were aware of this letter, as well as other published articles reporting on the high cost of Firdpase. While the undersigned recognized that these documents "might have influenced the agency's decision," and thus were necessary to include in the record, there is no evidence that the concerns raised outside of the FDA regarding Firdapse's cost did in fact influence the agency's decision. *See Amfac Resorts, L.L.C. v. United States Dep't of the Interior*, 143 F. Supp. 2d 7, 12 (D.D.C. 2001).

The third set of documents is an email chain which relates to the scheduling of the Exclusivity Board meeting. Therein, one of the emails notes that Catalyst's drug, Firdapse, is the subject of Congressional interest and states "our exclusivity discussions, while technical and legalistic as they always are, will by necessity have to occur against this backdrop."[5] Again, while the emails were added because they evidenced discourse by the decisionmakers on the issue, no evidence has been adduced to demonstrate reliance on the cost of the drug in reaching the agency's decision.

While the FDA may have been aware of the public and private interests involved in its

[5] FDACDER000485, found at ECF No. 70-2 at 7.

approval of Ruzurgi, Plaintiff has failed to adduce evidence to show that the FDA relied on improper factors in rendering its decision.

IV. CONCLUSION

For the foregoing reasons, I respectfully recommend:

1. Plaintiff Catalyst Pharmaceuticals, Inc's Motion for Summary Judgment (ECF No. 38) be DENIED;
2. Intervenor-Defendant Jacobus Pharmaceutical Company, Inc's Cross-Motion for Summary Judgment (ECF No. 46) is GRANTED;
3. and Federal Defendants Alex Azar, Secretary of Health and Human Services, et al.'s Cross-Motion for Summary Judgment and Opposition to Plaintiff's Motion for Summary Judgment (ECF No. 47) be GRANTED and the case dismissed.

Pursuant to Local Magistrate Rule 4(b), the Parties have fourteen (14) days from the date of this Report and Recommendation to serve and file written objections, if any, with the Honorable Beth Bloom, United States District Judge. Failure to timely file objections shall bar the Parties from de novo determination by the District Judge of any factual or legal issue covered in the Report and shall bar the parties from challenging on appeal the District Judge's Order based on any unobjected-to factual or legal conclusions included in the Report. See 28 U.S.C. § 636(b)(1); 11th Cir. Rule 3-1; Patton v. Rowell, 2017 WL 443634 (11th Cir. Feb. 2, 2017); Cooley v. Commissioner of Social Security, 2016 WL 7321208 (11th Cir. Dec. 16, 2016).

RESPECTFULLY SUBMITTED in Chambers this 30th day of July, 2020.

LAUREN LOUIS
UNITED STATES MAGISTRATE JUDGE