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-Defendants.

FEDERAL DEFENDANTS' MOTION TO STRIKE

Federal Defendants, by and through undersigned counsel of record, hereby respectfully request that the Court strike the Declarations of Andrew Prins and David Brennan, which Plaintiff filed in support of its December 18, 2019, Motion for Summary Judgment. *See* Dkt. Nos. 38-1 and 38-2. The proper basis for the Court's review of a challenge pursuant to the Administrative Procedure Act is the administrative record. *See* 5 U.S.C. § 706. Plaintiff has not met its burden to prove that the Brennan or Prins Declarations were considered by the Food and Drug Administration when making the decisions at issue in this case, and therefore should be considered to complete the record. Plaintiff also has not made the required exceptional showing

that the Court should supplement the record by considering the Brennan and Prins Declarations as extra-record materials.

Further, Plaintiff will receive today roughly 1,000 pages of documents from the Food and Drug Administration as a production in a Freedom of Information Act lawsuit filed by Latham & Watkins, LLP. Defendants respectfully request that the Court direct all parties to seek leave of Court to complete or supplement the record with materials not contained in the Revised Administrative Record, prior to filing such materials in support of a dispositive motion.

CERTIFICATION OF GOOD FAITH CONFERENCE

Pursuant to Local Rule 7.1(a)(3)(A), I hereby certify that Counsel for Federal Defendants conferred with Counsel for Catalyst and Counsel for Jacobus by email on January 16 and 17, 2020. Jacobus consents to this motion. Catalyst opposes this motion.

Respectfully submitted,

Dated: January 17, 2020

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MEMORANDUM IN SUPPORT OF MOTION TO STRIKE

INTRODUCTION

Catalyst brought its claims in this matter under the Administrative Procedure Act (APA). The basis for the Court's review of Defendants' decisions is the Revised Administrative Record, an index of which has been filed at Dockets 31 and 44. Courts strongly presume that an agency properly designates the record for review in a challenge under the APA.

On December 18, 2019, Plaintiff Catalyst moved for summary judgment. Along with the motion for summary judgment, Catalyst submitted the Declarations of Daniel Brennan, Dkt. No. 38-1, and Andrew Prins, Dkt. No. 38-2, along with accompanying attachments. In its memorandum in support of its motion for summary judgment, Catalyst also cites to and relies on various "Other Authorities" consisting of news articles related to drug pricing. *See* Catalyst Mem. at v-vi, 7-8, 12-13. As explained below, because the APA confines judicial review to the administrative record that was before the agency at the time of its decision, Defendants respectfully move the Court to strike the declarations and other non-record authorities submitted in support of Plaintiff's motion for summary judgment.

Moreover, Catalyst will receive today roughly 1,000 pages of documents from the Food and Drug Administration (FDA) as a production in a Freedom of Information Act lawsuit filed by Latham & Watkins, LLP. Defendants further request that the Court direct Catalyst not to attach any such additional documents to its response brief, due February 4, 2020, unless it first moves for and receives leave of Court to complete or supplement the record with such materials.

BACKGROUND

On October 8, 2019, FDA filed the administrative record in this case, consisting of documents considered by the agency while reviewing and approving the new drug applications for Catalyst's drug Firdapse and intervenor Jacobus's drug Ruzurgi. The record included, among

other things, summary memoranda from the various FDA components that reviewed and analyzed the data submitted by both companies in support of their new drug applications. *See e.g.* Firdapse Clinical and Statistical Review at FDA A.R. 854-972; Firdapse Summary Memorandum at FDA A.R. 973-1001; Ruzurgi Clinical Review A.R. 313-444; Ruzurgi Summary Review A.R. 445-473.

Over the course of the following month, undersigned counsel and FDA proceeded to negotiate in good faith with Catalyst regarding the terms of a proposed protective order to protect the confidential commercial information of both Catalyst and Jacobus from unnecessary disclosure, and to produce a Revised Administrative Record that contained additional materials considered by FDA that were referenced in the various summary memoranda regarding the approvals of Firdapse and Ruzurgi contained in the October 8, 2019 Administrative Record. *See* Revised Administrative Record Index, Dkt. No. 31; Addendum to Revised Administrative Record Index, Dkt. No. 44.

In the course of the meet and confer process over the addition of documents to the Revised Administrative Record, Catalyst requested that FDA supplement the record with a letter from Senator Bernie Sanders to then-FDA Commissioner Gottlieb and with post-approval correspondence between FDA and patients regarding both Firdapse and Ruzurgi. FDA consistently and repeatedly articulated to Catalyst its position that, while FDA responded to these communications, FDA did not consider those communications when approving the new drug applications; therefore, those communications were not properly part of the record. Attached hereto as Exhibit 1 is an email from undersigned counsel to counsel for Catalyst articulating that position.

In his declaration, Mr. Prins also references Catalyst's attempt to obtain certain

documents via two Freedom of Information Act (FOIA) requests to FDA. Prins Declaration at ¶¶ 7-8, Exs. A-B. Latham & Watkins LLP filed a lawsuit under FOIA in the District Court for the District of Columbia on June 25, 2019. *See Latham & Watkins LLP v. U.S. Food and Drug Administration*, No. 1:19-cv-1867 (D.D.C.) (Kelly, J.) (June 25, 2019); Docket attached as Exhibit 2. Based on the status report and scheduling order that were publicly filed in that case, Latham & Watkins should be receiving today a subset of documents they themselves identified as most important to obtain for purposes of briefing in the instant action, consisting of approximately 1,000 documents. *See Latham v. FDA*, Dkt. No. 10, attached here as Exhibit 3; *Latham v. FDA*, Minute Order dated October 21, 2019.

As noted, FDA does not consider its correspondence with Senator Sanders or patients to properly be part of the administrative record because the agency did not consider those documents when approving Firdapse or Ruzurgi. However, undersigned counsel offered in the course of meeting and conferring regarding the schedule in this matter to continue or coordinate the briefing schedule with the production schedule in the FOIA lawsuit, in order to allow Catalyst to move to complete or supplement the record should it choose to do so. *See* Exhibit 1.

ARGUMENT

I. Standard of Review

Section 706 of the APA directs a reviewing court to "review the whole record or those parts of it cited by a party." 5 U.S.C. § 706. The "whole record" under section 706 is the "the full administrative record that was before the [agency decisionmakers] at the time [they] made [their] decision." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971); *Defenders of Wildlife v. U.S. Dept. of Navy*, 733 F.3d 1106, 1120 n. 6 (11th Cir. 2013).

"[T]he general rule, applicable across the board to judicial review of administrative action ... is that the court may not go outside the administrative record." *Najjar v. Ashcroft*, 257

F.3d 1262, 1278 (11th Cir. 2001) (internal quotation marks omitted). Because an agency presumably knows the content of the record the agency considered, an agency's certification of of the administrative record "receives a measure of presumed correction." *Alabama-Tombigbee Rivers Coal. v. Kempthorne*, 477 F.3d 1250, 1262 (11th Cir. 2007) (citing *Citizens to Preserve Overton Park*, 401 U.S. at 420.

Completion of the record entails inclusion of materials "which were actually considered by the agency, yet omitted from the administrative record," while supplementation of the record deals with "materials which were not considered by the agency, but which are necessary for the court to conduct a substantial inquiry." *BBX Capital Corp. v. FDIC*, , 2018 WL 6531601, *1 (S.D. Fla. Aug. 15, 2018). "[A]bsent clear evidence, an agency is entitled to a strong presumption of regularity, that it properly designated the administrative record." *Id.*, *see also Gables by Sea, Inc. v. Lee*, 365 F.Supp. 826, 831 (S.D. Fla. 1973).

With regard to any request for the Court to consider material that was not considered by the reviewing agency, "[t]he reviewing court is generally not empowered to conduct a *de novo* inquiry into the matter being reviewed and to reach its own conclusions based on such an inquiry ... [The court is] to decide, on the basis of the record the agency provides, whether the action passes muster under the appropriate APA standard of review." *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 744, 105 S.Ct. 1598, 84 L.Ed.2d 643 (1985). The Eleventh Circuit has made clear that, "while certain circumstances may justify going beyond the administrative record, a court conducting a judicial review is not 'generally empowered to do so.'" *Preserve Endangered Areas of Cobb's History, Inc. v. United States Army Corps of Engineers*, 87 F.3d 1242, 1246 n. 1 (11th Cir.1996) (noting but not considering circumstances in which the Ninth Circuit has specified that a court may go beyond the administrative record) *citing Animal*

Defense Council v. Hodel, 840 F.2d 1432, 1436–37 (9th Cir.1988). When determining whether to consider extra-record material, the Eleventh Circuit has "focused pointedly on whether the petitioners have made 'a strong showing of bad faith or improper behavior by the agency.'" *Nat'l Mining Ass'n*, 812 F.3d at 875 (*citing Alabama-Tombigbee Rivers Coalition*, 447 F.3d at 1262. A party "seeking to supplement the administrative record must meet a heavy burden to show that supplementation is necessary." *SOSS2, Inc. v. United States Army Corps of Engineers*, 403 F. Supp. 3d 1233, 1239 (M.D. Fla. 2019) *citing Altamaha Riverkeeper, Inc. v. U.S. Army Corps of Eng'rs*, 2007 WL 1830864, at *4 (S.D. Ga. June 21, 2007) (Bowen, J.).

II. Catalyst Cannot Meet its Burden to Show the Record is Incomplete.

As Catalyst did not file a motion to complete or supplement the record, it also did not set out a clear argument as to why the materials contained in and attached to the Brennan and Prins Declarations should be included in the Administrative Record. To the extent Catalyst has articulated an argument that Exhibit B to the Brennan Declaration, the letter from Senator Sanders to FDA, and Exhibit C to the Brennan Declaration, a response letter from FDA to a LEMS patient, should properly be included in the administrative record, its argument appears to be: (1) those documents were in the possession of FDA, and (2) Catalyst referenced those documents in its Complaint. *See* Catalyst Mem. at 2; Prins Declaration at ¶¶ 2-3; Brennan Declaration at ¶¶ 10-11. However, this argument misunderstands the standard for the proper scope of the administrative record, which turns on the question of whether the agency *considered* a document when making its decision, not merely whether that document was in the possession of the agency (or was referenced in a complaint challenging agency action).

To overcome the strong presumption that FDA properly designated the record, Catalyst bears the burden of establishing that FDA "directly or indirectly considered in its decision-

making process" the "omitted" materials. *Gupta v. U.S. Atty. Gen.*, No. 6:13-cv-1027-ORL, 2015 WL 5687829 (M.D. Fla. Sept. 25, 2015), *citing Cobb's History*, 87 F.3d at 1242, 1246 n. 2. Catalyst has not pointed to any evidence or made a colorable argument that FDA actually considered any of the material contained in or attached to the Brennan or Prins Declarations when deciding to approve Firdapse and Ruzurgi. Further, as noted in Defendants' summary judgment briefing, FDA has specifically and repeatedly taken the position that it could not consider cost in making decisions regarding drug approval or exclusivity under the Orphan Drug Act. Def. Mem. at 9, 11, 16. As the materials included in and appended to the Brennan and Prins Declarations were not considered by the FDA decisionmakers, they were properly excluded from the administrative record in this matter.

III. Catalyst Cannot Establish that the Record Must be Supplemented.

Catalyst's attempt to supplement the administrative record is also unavailing, as Catalyst fails to make the requisite "strong showing of bad faith or improper behavior by the agency" to justify consideration of the extra-record materials. *Nat'l Mining Ass'n*, 812 F.3d at 875 (internal cite omitted).

Catalyst argues that the letter from Senator Sanders and the letter from FDA to a LEMS patient "are relevant to whether FDA was influenced by an improper motive (pricing) that 'Congress has not intended [the agency] to consider.'" Catalyst Mem. at 2, *citing Sierra Club v. Zinke*, 2018 WL 3126401, at *4 (N.D. Cal. June 26, 2018) and *Nat'l Mining Ass'n v. U.S. Dep't of Labor*, 812 F.3d 843, 875 (11th Cir. 2016). However, the Eleventh Cirucit has articulated a high bar for consideration of extra-record materials in APA cases, stating that "in determining the propriety of reviewing extra-record material…we generally have focused pointedly on whether the petitioners have made 'a strong showing of bad faith or improper behavior by the

agency.'" *Nat'l Mining Ass'n*, 812 F.3d at 875 (*citing Alabama-Tombigbee Rivers Coalition v. Kempthorne*, 447 F.3d 1250, 1262 (11th Cir. 2007)).

Here, Catalyst offers only the conclusory assumption that because FDA received a letter from Senator Sanders complaining about high drug prices, including the price of Firdapse, and FDA later approved Ruzurgi for treatment of LEMS in pediatric patients, FDA must have approved Ruzurgi in order to undercut Catalyst's high price for Firdapse. *See* Catalyst Mem. at 2-3. Catalyst provides *no evidence* that FDA improperly considered drug pricing when making its decisions related to the approval of Ruzurgi, beyond the existence of the Sanders letter itself. Catalyst thus falls well short of the "strong showing of bad faith or improper behavior by the agency" required by the Eleventh Circuit before reviewing Courts may consider extra-record evidence.[1] *Id.*

Catalyst also attempts to supplement the record with a letter, written by an employee of the Division of Drug Information, Office of Communications, within the Center for Drug Evaluation and Research (CDER) at FDA. Brennan Decl. Exhibit C. The Division of Drug Information is not the division within CDER that has responsibility for approving new drug applications. Rather, the Division of Drug Information is "CDER's focal point for public inquiries and serves to promote timely, accurate, and useful information about human drug products…." *See* CDER Division of Drug Information on FDA website, available at

[1] Catalyst also cites various internet sources regarding bills Senator Sanders introduced to address high drug prices and Senator Sanders's "role in a public dialogue complaining about Catalysts's pricing." *See* Catalyst Mem. at 8. While these extra-record materials show that Senator Sanders was concerned about Catalyst's pricing, they provide no evidence that FDA considered Catalyst's pricing when it made the decision to approve Ruzurgi.

https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-division-drug-information.

The letter at issue responds to a letter FDA received from an individual suffering from LEMS who apparently expressed some sort of "concerns" about treatment options. FDA provides accurate, publicly available information in response, and ends with the boilerplate disclaimer, "Please talk with your doctor about the right treatment option for you." *Id.* Catalyst's characterization of this letter as FDA "advis[ing] at least one…adult LEMS patient[] that they could ask their doctors to prescribe Jacobus's drug 'off label,'" is frankly disingenuous. This letter provides no evidence that FDA "was influenced by an improper motive" when approving Ruzurgi, and Catalyst has established no valid ground for including it in the administrative record.

Notwithstanding Catalyst's unfounded suspicion that FDA was motivated by improper drug pricing considerations in its approval of Ruzurgi, the more mundane truth, as reflected in the record of this case, is that FDA based its decision on an interpretation of the text of the Orphan Drug Act that differs from Catalyst's preferred interpretation of that statute. Catalyst has offered no evidence of "bad faith or improper motive" on the part of FDA and cannot make the required exceptional showing to either supplement or complete the administrative record with any of the material included in or appended to the Brennan and Prins Declarations.

CONCLUSION

For the foregoing reasons, this Court should strike the Brennan and Prins Declarations as containing material that is not part of the administrative record in this case. Further, pursuant to the scheduling order in the FOIA lawsuit Plaintiff's counsel filed in District Court for the District of Columbia, Catalyst will be receiving a production of documents today. Given that it failed to

move to complete or supplement the record prior to filing extra-record materials in support of its Motion for Summary Judgment, Catalyst may contemplate filing additional extra-record documents in support of its Responses to Federal Defendants' and Intervenor Defendant's Motions for Summary Judgment. Federal Defendants respectfully move the Court to direct all parties to seek leave of Court to complete or supplement the record with materials not contained in the Revised Administrative Record, prior to filing such motions in support of a dispositive motion.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the CM/ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

Dated: January 17, 2020

/s/ Ann F. Entwistle
Ann F. Entwistle