UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

OUTSOURCING FACILITIES ASSOCIATION, ET AL.,

Plaintiffs,

v. **No. 4:24-cv-0953-P**

UNITED STATES FOOD AND DRUG ADMINISTRATION, ET AL.,

Defendants.

OPINION & ORDER

Before the Court are Plaintiffs Outsourcing Facilities Association's and North American Custom Laboratories LLC Partners' (collectively "Plaintiffs") Motion for Summary Judgment (ECF No. 121); Defendants Dr. Robert M. Califf's and the United States Food and Drug Administration's ("FDA") (collectively, the "Federal Defendants") Motion for Summary Judgment (ECF No. 124); and Intervenor Defendant Eli Lilly and Company's ("Lilly") (collectively with the Federal Defendants, the "FDA Defendants") Motion for Summary Judgment (ECF No. 127). Having considered the briefing, record, applicable legal authorities, and Parties' oral arguments, the Court will **DENY** Plaintiffs' Motion and **GRANT** the FDA Defendants' Motions.

BACKGROUND

The Court's previous order on Plaintiffs' Motion for Preliminary Injunction and Stay thoroughly discusses the statutory and regulatory background, and the Court will not repeat it here. *Outsourcing Facilities Ass'n v. U.S. Food & Drug Admin.*, No. 4:24-CV-0953-P, 2025 WL 746028, at *1–2 (N.D. Tex. Mar. 5, 2025) (Pittman, J.). Thus, the following is a brief recitation of the relevant procedural history of this case.

Plaintiffs filed this case on October 7, 2024, challenging the FDA's removal of Mounjaro® and Zepbound® (collectively the "Lilly Drugs") from the shortage list. Shortly thereafter, on October 11, 2024, the FDA filed an Unopposed Motion to Remand and Stay the Case so the FDA could "reevaluate the decision at issue in this case." The Court granted the motion, and the FDA reconsidered its decision. On December 19, 2024, the FDA issued a "Delisting Action" reaffirming its decision to remove the Lilly Drugs from the shortage list. The Delisting Action was memorialized in two documents. The first, titled the "Decision," presented the evidence considered by the FDA and its reasoning. The second, titled the "Order," summarized the FDA's rationale and provided that the FDA would exercise its enforcement discretion to delay the enforcement of its decision.

Subsequently, on January 1, 2025, Lilly filed its Motion to Intervene, which the Court granted on January 6, 2025. On January 2, 2025, Plaintiffs and the Federal Defendants filed a Joint Motion to Reopen the Case and Enter Scheduling Order. After holding a hearing on January 14, 2025, the Court reopened the case and set a briefing schedule on the Motion for Preliminary Injunction. The Court issued an opinion on March 5, 2025, denying Plaintiffs' Motion for Preliminary Injunction and Stay, which Plaintiffs challenged in an interlocutory appeal. ECF Nos. 100, 103. The Court placed the Parties on a briefing schedule for their respective Motions for Summary Judgment. ECF No. 116. Those Motions have been briefed and are ripe for consideration.

LEGAL STANDARD

In a case challenging an agency action under the Administrative Procedure Act ("APA"), summary judgment "serves as the mechanism for deciding" whether the action "is supported by the administrative record and otherwise consistent with the APA standard of review." *Gadhave v. Thompson*, No. 3:21-cv-2938-D, 2023 WL 6931334, at *1 (N.D. Tex. Oct. 19, 2023) (citation omitted). The agency resolves "factual issues to arrive at a decision supported by the administrative record." *Yogi Metals Grp. Inc. v. Garland*, 567 F. Supp. 3d 793, 797–98 (S.D. Tex. 2021), *aff'd,* 38 F.4th 455 (5th Cir. 2022) (citation omitted). The district court then applies the APA standards of review to determine whether,

as a matter of law, "the evidence in the administrative record permitted the agency to make the decision it did." *MRC Energy Co. v. U.S. Citizenship & Immigr. Servs.*, No. 3:19-cv-2003-K, 2021 WL 1209188, at *3 (N.D. Tex. Mar. 31, 2021) (citation omitted). The entire case is thus a question of law, with the district court sitting as an appellate tribunal. *Id.* at *3.

ANALYSIS

Plaintiffs' Amended Complaint raises six claims for why the FDA's Delisting Action should be set aside. *See generally* ECF No. 68. Those claims are: (1) rulemaking without conducting notice and comment; (2) failure to consider the statutory factors; (3) facially contradictory findings that undermine the basis of the agency action; (4) failure to consider countervailing evidence; and (5) failure to publish a rule in the federal registry; and (6) unlawful interpretation of the statute under *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024). *Id.* at 17–24. In their respective Motions, the Parties each contend they are entitled to summary judgment on all of Plaintiffs' claims. ECF Nos. 121, 124, 128. Because claims one and five are both predicated on the premise that the Delisting Action is a rule, the Court considers them together. The Court will then address Plaintiffs' unlawful-interpretation claim. And finally, the Court concludes with Plaintiffs' arbitrary-and-capricious claims.

A. Notice-and-Comment and Failure to Publish Claims

Just as before, the Parties dispute how to classify the FDA's Delisting Action. Plaintiffs assert the Delisting Action is a substantive rule. The FDA Defendants claim the Delisting Action is an informal adjudication. If the Delisting Action is a substantive rule, as Plaintiffs urge, then the FDA was required to comply with the APA's stringent notice-and-comment requirements and that process is reviewed under the arbitrary-and-capricious standard. But if the Delisting Action is an informal adjudication, as the FDA Defendants urge, then the Court simply reviews the decision under the arbitrary-and-capricious standard.

As Plaintiffs state in their Motion, the arguments raised on this issue are the same as the arguments that were presented to the Court in Plaintiffs' Motion for Preliminary Injunction. Thus, the Court has already thoroughly analyzed and decided on these very arguments. *See Outsourcing Facilities Ass'n*, 2025 WL 746028, at *4–8. A decision the United States Court of Appeals for the Fifth Circuit has suggested it agrees with. *See Outsourcing Facilities Ass'n, et al., v. U.S. Food and Drug Admin., et al.*, No. 25-10385 at ECF No. 98-1 ("For substantially the reasons given by the district court in its thorough opinion explaining its denial of a preliminary injunction, we find that Plaintiffs-Appellants have not made their 'clear showing.'"). The Court fully adopts that reasoning and conclusion here and finds that the Delisting Action is not a rule and was thus properly promulgated through adjudication. Therefore, Plaintiffs' Motion is **DENIED,** and the FDA Defendants' Motions are **GRANTED** on these claims.

B. Unlawful Interpretation Claim

Plaintiffs' next claim is based on their assertion that the FDA did not comply with "the best reading of the statute" as required by *Loper Bright*. ECF No. 122 at 15. In support of this assertion, Plaintiffs argue that: (1) a [redacted] analysis conflicts with the statute's "up-to-date" requirement; (2) the FDA erroneously made its decision on a nationwide basis; (3) the FDA erred in determining that some delays in shipping do not evidence a shortage because it is a statutorily enumerated factor that the FDA must consider; and (4) the FDA erred in determining that compounded versions of the Lilly Drugs are not the same as the Lilly Drugs for purposes of past demand. *Id.* at 15–17. For the reasons set out below, the Court will **DENY** Plaintiffs' Motion for Summary Judgment and **GRANT** the FDA Defendants' Motions for Summary Judgment as to this claim.

1. Up-to-date mandate

First, Plaintiffs claim the FDA's decision to base the Delisting Action on a [redacted] time period conflicts with the statute's up-to-date mandate, and unfairly gives [redacted] *Id.* at 15. As a preliminary matter, Plaintiffs' argument is slightly

misleading. Plaintiffs assert that because the FDA looked at a [redacted] time period, the data used in the Delisting Action was "[redacted]" *Id.* However, what Plaintiffs fail to mention in their argument is that [redacted] were projections for *future* months. Thus, what Plaintiffs really are complaining about is that the FDA chose to use the [redacted] rather than only looking at the [redacted] the Delisting Action. Nevertheless, the Court now turns to Plaintiffs' claim that the FDA's choice to use the [redacted] data is inconsistent with Congress's up-to-date mandate.

The Federal Food, Drug, and Cosmetic Act ("FDCA") requires the FDA to "maintain an up-to-date list of drugs that are determined by the [FDA] to be in shortage in the United States." 21 U.S.C. 356e(a). "[S]hortage" is defined as "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." *Id.* § 356c(h)(2). Plaintiffs insist that allowing the FDA to consider a time period longer than a month or two is inconsistent with the Court's finding that the FDA did not abuse its discretion by proceeding through adjudication rather than notice and comment because the statute requires the list to be "up-to-date." This is not so. The distinction between notice-and-comment rulemaking and adjudication lies in the date of the agency action relative to the age of the data being considered. For example, imagine the FDA posted a proposed rule for notice and comment on December 1, 2023, based on data from June 1, 2023 to November 30, 2023. The FDA then conducted an expeditious notice-and-comment process and issued its final rule on June 1, 2024. The most recent data relied on in issuing that rule would have been seven-months old and, thus, not "up-to-date." In contrast, if the FDA had proceeded through adjudication, the decision could have been issued within days or weeks of receiving the data. Thus, while in both examples the FDA relied upon the same data from the same time period, the agency action was up-to-date in the adjudication example because it included the most recent data available, and it was out-of-date in the notice-and-comment example because the most recent data was months

old. Consequently, despite Plaintiffs' contentions otherwise, the FDA's decision to review [redacted] data, and to project through [redacted] is neither unreasonable nor inconsistent with the FDCA. The statutory scheme provides the FDA with the discretion to determine the relevant time period. As long as that time period includes the latest information available—such as data from November 2024 while making a determination in early December 2024—it is consistent with Congress's mandate.[1]

Plaintiffs' secondary argument on this issue, that the FDA's chosen time period unfairly gives [redacted] also fails. The Court has previously addressed this argument, and thus does so only briefly here. In reviewing its chosen time period, the FDA determined that the total supply outpaced the total demand—a point Plaintiffs seemingly concede here. Plaintiffs, however, argue the FDA should have chosen a different time period because it might have revealed a shortage. But, as discussed above, the FDA had discretion to determine the relevant period of time for its analysis. Plaintiffs' displeasure with the FDA's chosen time period—because it reveals an outcome they do not like—is not grounds for an arbitrary and capricious finding. In fact, reviewing data for more than a month or two ostensibly only provides the FDA with **more** context for the state of supply and demand. Accordingly, the FDA's decision to review [redacted] data, and [redacted], was consistent with the statutes up-to-date mandate.

2. <u>"In" or "Within" the United States</u>

Plaintiffs next argue that FDA erroneously made its decision based on a nationwide basis. ECF No. 122 at 15–16. Specifically, Plaintiffs argue that regions are by definition "in" or "within" the United States and, thus, the FDA erred by failing to consider whether individual

[1]In fact, it makes logical sense to consider more than a month or two of data, as doing so allows for a more holistic view. While Plaintiffs argue here that if the FDA had considered a shorter time period it would have found the shortage persists, it does not stretch the imagination to conceive a circumstance in which a plaintiff would argue that the FDA's choice to consider only the preceding month's data concealed a more pervasive and long-lasting shortage.

regions were in shortage at any given time rather than evaluating the data on a national level. *Id.* Both sides agree "in" and "within" can connotate: (1) something "contained or enclosed by" and "not exhaustive" of a larger space; and (2) something that is exhaustive of the larger space. *See* ECF No. 137 at 29–30; and ECF No. 142 at 13. Both sides similarly argue that since it can mean both exhaustive and non-exhaustive the Court must read it in the manner that favors their side.

Plaintiffs argue that if the Court allows the FDA's reading of "within the United States" to mean that it must evaluate data on a national level then "national companies like Lilly [will] avoid shortages by declining to supply one or a few regions so that supply can exceed demand in many regions and thus avoid FDA's shortage definition." ECF No. 122 at 16. In contrast, the FDA Defendants argue the FDA's reading was appropriate because the FDA is a national agency dealing with nationwide shortages and Plaintiffs' reading has no limiting principle. ECF No. 137 at 29–31. While, as the Parties admit, both versions are plausible interpretations, the Court finds the FDA's reading is the best reading of the statute.

Plaintiffs' assertion that companies can hide a national shortage by providing product to certain regions and not others, ignores the fact that a nationwide shortage determination looks at nationwide supply and demand. Plaintiffs' scenario would be correct if the FDA made its shortage determination based on whether there are more regions (or states or cities) not in a shortage than there are regions in a shortage. But that is not the case. For example, imagine Lilly chose to supply doses to regions A and B but not C. When making a nationwide shortage determination, the FDA would consider the total supply (region A + region B) and compare it with total demand (region A + region B + region C). Consequently, if Lilly was only supplying regions A and B because it lacked the ability to also supply region C, then that fact would become evident in the FDA's review of the nationwide data. This is consistent with the fact that the FDA is a national agency and must therefore consider drug shortages on a national level. Thus, the Court

finds that the FDA Defendants are entitled to summary judgment on this issue.

3. Shipping delays

Next, Plaintiffs claim the FDA erred in determining that some delays in shipping do not evidence a shortage because it is a statutorily enumerated factor that the FDA must consider. For context, as courts should always do, we begin with the statute. *See, e.g., Shannon v. United States*, 512 U.S. 573, 580 (1994) (Thomas, J.) ("[W]e turn first, as always, to the text[.]"). The FDCA provides that for every drug the FDA adds to its shortage list, the FDA is required to identify "[t]he name of the drug in shortage," "[t]he name of each manufacturer of such drug," "[t]he reason for the shortage" from an enumerated list of seven categories, and "[t]he estimated duration of the shortage as determined by the [FDA]." 21 U.S.C. § 356e(b)(1)–(4). The enumerated categories are: (1) [r]equirements related to complying with good manufacturing practices; (2) [r]egulatory delay; (3) [s]hortage of an active ingredient; (4) [s]hortage of an inactive ingredient component; (5) [d]iscontinuance of the manufacture of the drug; (6) [d]elay in shipping of the drug; and (7) [d]emand increase for the drug. *Id.* Specifically, Plaintiffs assert that 21 U.S.C. § 356e(b) required the FDA to treat some localized shipping delays as dispositive evidence of a shortage. ECF No. 122 at 16.

Plaintiffs' claim fails for three reasons. *First*, the statute does not mandate or even recommend that the FDA must or should consider all of the enumerated categories when making a shortage determination. Rather, it simply mandates that the FDA list one of those seven categories as the reason a drug was placed on the list. *Second*, the Lilly Drugs were placed on the shortage list due to "high demand." *See* ECF No. 126-1 at 4. Thus, even though the FDA considered more than high demand in the Delisting Action, it would not have been unreasonable for the FDA to focus only on whether the reason for the drugs' listing had been overcome—i.e., whether the supply of the Lilly Drugs met or exceeded the "high demand." And *third*, as discussed above, the FDA was required to determine if a nationwide shortage exists. While a pervasive and crippling shipping delay may evidence a nationwide shortage, it was not unreasonable for the FDA to conclude that some

localized shipping delays are not evidence of a nationwide shortage. If Plaintiffs are arguing that some shipping delays necessitate a shortage finding, they are wrong. If Plaintiffs are instead arguing the FDA was required to consider them in its decision, the record is clear that it did. Either way, Plaintiffs have failed to evidence an erroneous application of the statute, and the FDA Defendants are entitled to summary judgment on this issue.

4. Compounding demand

Finally, Plaintiffs assert it was legal error for the FDA to consider compounded volume only as a part of demand for future projections and not past demand because "[t]he statute does not treat a compounded form as 'a different drug' but as functionally the same drug." ECF No. 122 at 17. In support of this argument, Plaintiffs claim the FDA Defendants essentially admit that the compounded versions are the same as the Lilly Drugs by describing them as "knockoffs." *Id.* This argument does not appear to fit within the statutory interpretation and application framework. Instead, it appears to be an argument that the decision was arbitrary because the FDA did not give enough weight to the demand for compounded drugs. Nevertheless, the Court holds that the FDA's choice to determine past demand based on demand for the Lilly Drugs—and not the Lilly Drugs plus compounded versions—was reasonable and consistent with the statutory text.

The statute requires the FDA to consider whether "demand or projected demand for the drug . . . exceeds the supply of the drug." 21 U.S.C. 356c(h)(2). "[T]he drug" the FDA must base its shortage determination on is "the drug" listed on the shortage list. At all points the statute requires the FDA to consider supply and demand for the "the drug" on the list. Thus, to consider a particular drug's eligibility for the shortage list, the FDA must look to the supply of, and demand for, the drug itself. But, as here, if the manufacturer again becomes able to meet the demand for its drug, then it is appropriate to consider how many patients will transition to the manufacturer's drug when analyzing the *future* demand. This is appropriate because once a drug leaves the shortage list, the compounded forms will no longer be available, and some patients will transition to the manufacturer's drug. Here, the FDA

accounted for those patients who would transition to the Lilly Drugs in crafting its projected demand. Therefore, the Court holds that the FDA correctly applied the statute when determining the demand for the Lilly Drugs, and the FDA Defendants are entitled to summary judgment on this claim.

C. Arbitrary and Capricious Claims

The Court now turns to Plaintiffs' claims that the Delisting Action was arbitrary and capricious. Agency decisions are "presumptively valid; the [plaintiff] bears the burden of showing otherwise." *Barr v. SEC*, 114 F.4th 441, 447 (5th Cir. 2024); *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, 120 F.4th 494, 504 (5th Cir. 2024) (internal quotation and citation omitted). "If the agency articulates a rational relationship between the facts found and the choice made it does not act arbitrarily or capriciously." *Joseph v. Dir. of Tex. Serv. Ctr., U.S. Citizenship & Immigr. Servs.*, No. 24-40249, 2025 WL 458001, at *3 (5th Cir. Feb. 11, 2025) (quoting *Louisiana ex rel. Guste v. Verity*, 853 F.2d 322, 327 (5th Cir. 1988)). The "focal point" of that review "should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973). And "[j]udicial review under that standard is deferential, a[s] a court may not substitute its own policy judgment for that of the agency." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). While courts "may not supply a reasoned basis for the agency's action that the agency itself has not given," courts are to "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Tex. Med. Ass'n,* 120 F.4th at 504 (citing *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983)).

Here, Plaintiffs assert that the Delisting Action is arbitrary and capricious because: (1) the FDA failed to sufficiently explain the grounds of its decision; (2) it is facially illogical and inconsistent; and (3) the FDA improperly ignored countervailing evidence. *See* ECF No. 122 at 8–15, 17–27. For the reasons set out below, the Court will **DENY** Plaintiffs' Motion for Summary Judgment and **GRANT** the FDA Defendants' Motions for Summary Judgment as to these claims.

1. Claim two: sufficient explanation of the grounds for the decision

Plaintiffs first argue that the Delisting Action is arbitrary and capricious because the FDA: (1) outsourced its decision-making responsibility to Lilly; (2) did not explain its choice of time period and why it did not choose an alternative; and (3) did not explain any findings of supply or demand. ECF No. 122 at 8–15. The Court addresses each.

Plaintiffs first claim the FDA impermissibly delegated its authority to Lilly by allowing Lilly to "decide[] what evidence to present and on what time frames." ECF No. 122 at 9. This assertion is contradicted by the record evidence. In fact, the record shows that the data provided by Lilly and relied upon by the FDA in the Delisting Action was produced by Lilly only in response to requests for data made by the FDA. *See, e.g.*, ECF No. 126-1 at 45 (Lilly providing data requested by the FDA), 50 (same), 51 (same), 53 (same), 67–68 (same), 156–201 (same). While it is clear the FDA worked closely with Lilly in making its decision, such coordination was evidently necessary as the FDA decision involved Lilly's product, for which only Lilly had the relevant data. Therefore, the Court concludes that the FDA did not arbitrarily delegate its decision-making authority to Lilly.

Next, Plaintiffs assert the Delisting Action does not explicitly state what time period the FDA evaluated, why the FDA chose that time period, and why it was better than the alternatives. ECF No. 122 at 10–13. As Plaintiffs acknowledge in their Motion, courts will "uphold a decision of less than ideal clarity if the agency's path may be reasonably discerned." *BNSF Ry. Co. v. Fed. R.R. Admin.*, 62 F.4th 905, 911 (5th Cir. 2023) (internal citation omitted). The Court previously found that the FDA sufficiently identified that it was considering actual [redacted] data [redacted] and projected data [redacted] Plaintiffs fault the FDA for considering data based on different time periods. But it is not unreasonable for the FDA to request and consider data from different time periods in order to get a holistic

picture. It is certainly more reasonable than only considering mass data from an extended period or a screenshot from one particular point in time. Thus, the Court finds the time period considered by the FDA is reasonably discernible and reasonable.

Furthermore, Plaintiffs impermissibly attempt to place an additional burden on the FDA that is not required by the APA when the FDA proceeds through an adjudication. Specifically, Plaintiffs claim that the FDA was required to explain why it chose the time period it did and why it did not choose an alternative. In support of this assertion, Plaintiffs cite to a series of cases. *See* ECF No. 122 at 8, 11–13 (citing *DHS v. Regents of the Univ. of Cal.*, 591 U.S. 1, 27–30 (2020); *State Farm*, 463 U.S. at 48; *Clarke v. CFTC*, 74 F.4th 627, 641 (5th Cir. 2023); *10 Ring Precision, Inc. v. Jones*, 722 F.3d 711, 724 (5th Cir. 2013); *Off. of Commc'n of United Church of Christ v. F.C.C.*, 707 F.2d 1413, 1424 (D.C. Cir. 1983)). All of these cases stand for the proposition that when an agency acts through notice-and-comment rulemaking it "must consider and explain its rejection of 'reasonably obvious alternative[s],' [but] it need not consider every alternative ***proposed nor respond to every comment made***. Rather, an agency must consider only 'significant and viable' and 'obvious' alternatives." *See 10 Ring Precision*, 722 F.3d at 724 (emphasis added). As explained above, the FDA properly proceeded through adjudication. Therefore, the general proposition that agencies are required to explain their rejection of reasonable alternatives that were proposed during the comment period, is inapplicable here. Consequently, the Court holds that the Delisting Action was not arbitrary and capricious because it failed to explain why the FDA chose the time period used over reasonable alternatives.

Lastly, Plaintiffs argue the Delisting Action is arbitrary and capricious because the FDA failed to "explain basic supply and demand choices." ECF No. 122 at 13. Specifically, Plaintiffs fault the FDA for considering different data (inventory and cumulative charts), different periods of time, and Lilly's statement that they could supply [redacted]. *Id.* at 13–14. Additionally, Plaintiffs claim the "FDA failed to consider obvious questions about product storage, loss, and longevity." *Id.* at 14–15. The Court addresses each.

Plaintiffs correctly point out that the FDA considered different types of data from different points in time. While Plaintiffs criticize the FDA for doing so, as discussed above, the record shows the FDA was requesting said data in an attempt to get a holistic view. Plaintiffs, however, insist that some of the data is irreconcilable. For example, Plaintiffs contend that the FDA must have been confused because Table 1 (showing available inventory of [redacted]) and Table 4 (showing cumulative supply [redacted]) are seemingly in contradiction. ECF No. 122 at 13–14. But the record demonstrates that the FDA noticed this potential discrepancy, asked Lilly about it, and was satisfied that there was good reason for the seeming discrepancy. *See* ECF No. 126-1 at 185–86. Specifically, as Lilly responded to the FDA's questions, the Tables show different data points because, [redacted] *Id.* Consequently, the Court finds that it was not unreasonable for the FDA to consider different data points in making its shortage determination, and that the record does not support Plaintiffs' assertion that the FDA was confused by the data.

Further, Plaintiffs argue the FDA materially and inappropriately relied on Lilly's assertion that it could supply [redacted]. However, Plaintiffs have failed to demonstrate how the FDA's acknowledgment of Lilly's assertion is material to the Delisting Action. *First*, there is no evidence to show that the FDA's reliance on the statement was unreasonable. In fact, the record shows Lilly's past projections were not only [redacted] ECF No. 122-1 at 30–31. *Second*, Plaintiffs' assertion that reliance on such number is unsupported by the previous supply numbers ignores the fact that those numbers did not include or account for the [redacted]. And *third*, the projected supply numbers demonstrate

that the FDA did not simply rely on Lilly's assertion and place a [redacted] into the chart. *See id.* at 31. Even with the [redacted] actually considered by the FDA, the total supply for the relevant period still outpaced the total demand. Thus, the Court finds that Plaintiffs are not entitled to summary judgment on this issue.

Finally, Plaintiffs claim the FDA failed to consider product storage, loss, and longevity. ECF No. 122 at 14–15. In essence, Plaintiffs assert it was unreasonable for the FDA to rely on cumulative numbers if there was no evidence in the record that a dose from [redacted]. This argument fails for the reasons pointed out by the FDA Defendants in their briefs and at the hearing. Specifically, the FDA understood that it is a general business practice across all industries for companies to ship out its older product first when filling orders to minimize wasted product. Further, in providing inventory numbers to the FDA, Lilly was representing that the number provided reflected the number of doses which it had on hand that were available to fill orders. Notably, Plaintiffs do not accuse Lilly of improperly inflating its inventory numbers with expired or unusable doses. Thus, it was not unreasonable for the FDA to conclude that the inventory numbers provided by Lilly represented viable and usable doses. Accordingly, the FDA Defendants are entitled to summary judgment on claim two.

2. Claim three: facially illogical and inconsistent

Plaintiffs raise three grounds for why the Delisting Action is facially illogical and inconsistent. ECF No. 122 at 17–23. *First*, Plaintiffs claim the Delisting Action is arbitrary because it considers cumulative data from [redacted]. *Id.* at 19–20. *Second*, Plaintiffs assert the FDA erroneously relied on Lilly's assertion that it can supply [redacted].[2] *Id.* at 20–21. And *third*, Plaintiffs argue the cumulative data hides contradictions that are fatal to the Delisting Action's reasoning. *Id.* at 21–23. For the reasons set out below, the Court

[2]The Court fully addressed this issue in the preceding section and declines to do so again here.

will **DENY** Plaintiffs' Motion for Summary Judgment and **GRANT** the FDA Defendants' Motions for Summary Judgment as to this claim.

The crux of Plaintiffs first argument on this issue is that if the FDA had chosen to look at a different time period it may have reached a different conclusion. Here, Plaintiffs fault the FDA for its chosen time period and argue that the chosen time period hides a shortage and is inconsistent with the up-to-date mandate. It is not in dispute that the FDA has discretion to choose the relevant time period. As discussed above, as long as the FDA's chosen time period contains the most recent data, as it does here, the FDCA grants the FDA broad discretion to choose the time frame for its analysis. Whether a different time period may have been "better" is not for the Court to say. *See Prometheus Radio Project*, 592 U.S. at 423 ("a court may not substitute its own policy judgment for that of the agency"). In making its shortage determination, the FDA chose a time period and considered the relevant data from that time period.[3]

Next, Plaintiffs claim that because the FDA relied on data showing different metrics, the FDA was confused and missed that the data actually reveals a shortage. ECF No. 122 at 21–23. Plaintiffs specifically point to data from Tables 4 and 5 and argue that it shows a [redacted] *Id.* at 22. Plaintiffs insist this fact demonstrates the unreliable nature of the data because if [redacted] *Id.*

Plaintiffs' argument fails for two reasons. *First*, Table 5 represents the number of doses shipped to wholesalers while Table 4 reflects [redacted]. *Compare* ECF No. 126-1 at 206–09 ([redacted]

[3]"The statute does not require more of the FDA and neither does this Court." *Outsourcing Facilities Ass'n*, 2025 WL 746028, at *11 n.11.

[redacted]."[4]); *with* ECF No. 122-1 at 28 ("Lilly Reported Volume of [the Lilly Drugs] Pre-Filled Pens Shipped to Wholesalers . . .). Thus, it is hardly surprising that a [redacted]. And *second*, because Plaintiffs draw this data from a short time period—evidencing the non-arbitrary nature of the FDA's decision to review cumulative data for more than a month or two—the charts fail to account for orders that may have been placed at the end of one month but filled in the next. For example, wholesalers could have placed various orders on [redacted], that were fulfilled by Lilly shipping doses on [redacted]. The orders would appear in the [redacted] numbers for demand, but the prompt shipment would not be included in the [redacted] "shipped" number. Therefore, the Court finds Plaintiffs failed to show that the Delisting Action was arbitrarily illogical or inconsistent. Accordingly, the FDA Defendants are entitled to summary judgment on claim three.

3. Claim three: countervailing evidence

Finally, Plaintiffs assert that the Delisting Action "arbitrarily waved away all evidence of shortage." ECF No. 122 at 23–27. Specifically, Plaintiffs claim the FDA reviewed all of the evidence provided by them, and others, with "hyper-skepticism."[5] *Id.* at 23. Plaintiffs, and others, provided four categories of evidence to the FDA: (1) screenshots of pharmacy wholesalers' websites; (2) patient reports; (3) news reports; and (4) compounding numbers. *Id.* at 23–27. Plaintiffs re-urge the arguments they raised on this issue in their Motion for Preliminary Injunction and argue that the FDA arbitrarily failed to adequately consider this evidence in its shortage determination. *Id.* Thus, the Court

[4] [redacted] ECF No. 126-1 at 146–47.

[5]As a preliminary matter, the Court notes that the FDA also scrutinized and rejected some of Lilly's evidence based on the same standards it applied to the countervailing evidence. *See, e.g.*, ECF No. 122-1 at 29 n.44., 29–30 n.53. If nothing else, this shows the FDA did not blindly rely on Lilly's assertions and evidence.

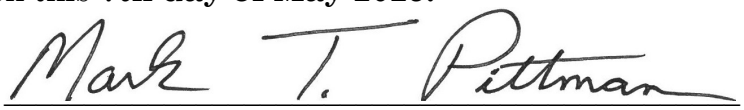
has already thoroughly analyzed and ultimately rejected these very arguments in this case. *See Outsourcing Facilities Ass'n,* 2025 WL 746028, at *12–14. The Court's prior determination has only been bolstered by a review of the full administrative record. At the hearing, Plaintiffs' counsel specifically identified the following pages from their appendix as their best evidence on this issue: "680, 667, 669, 679, 682, and 714." ECF No. 148 at 25–26. But Plaintiffs' "best evidence" seemingly cuts directly against their position. *See* ECF No. 122-9 at 680 (showing all doses in stock); 667 (same); 669 (same); 679 (same); 682 (same); 714 (same); *see also* 683–94 (same). Accordingly, the Court fully adopts its prior reasoning and conclusion here. Therefore, the Court finds that the FDA's choice to "give more weight to specific, reliable, comprehensive, and current information from Lilly" was not unreasonable in light of the evidence before it. *Outsourcing Facilities Ass'n*, 2025 WL 746028, at *13. Consequently, the FDA Defendants are entitled to summary judgment on claim four.

CONCLUSION

For the reasons set out above, Plaintiffs' Motion for Summary Judgment is **DENIED,** and the FDA Defendants' Motions for Summary Judgment are **GRANTED.**

Given the agreed confidentiality agreement that was entered into by the Parties, and enforced by the Court, the undersigned finds it appropriate to file this unredacted opinion under seal. Shortly after the opinion is filed, the Parties will be provided, via email, an unsigned PDF version of the order. It is **ORDERED** that, **on or before 4:00 p.m., May 13, 2025**, the Parties shall submit, via response to the email, an agreed upon version of the order containing any appropriate redactions. After receiving and reviewing the Parties' version, the Court will issue the redacted order.

SO ORDERED on this **7th day of May 2025.**



Mark T. Pittman
UNITED STATES DISTRICT JUDGE