IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division

OUTSOURCING FACILITIES ASSOCIATION, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	Civil Action No. 4:24-cv-00953-P

Plaintiffs' Reply in Support of a
Preliminary Injunction and Stay Pending Review

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Introduction

The Administrative Record confirms that FDA initially declared the tirzepatide shortage resolved in October knowing nothing about the supply or demand for branded tirzepatide products, let alone compounded products. [redacted] FDA did not bother to ask the most basic questions about the materials until *after* this action was filed and this Court remanded to the agency. *See* FDA415. FDA's second attempt in the Delisting Action is equally reckless and arbitrary. FDA apparently missed (and still does not acknowledge) that [redacted] Even as the agency insists it understood [redacted] FDA's evident confusion only underscores its error in departing from the straight course that it initially set out for itself: determining whether the shortage is over because supply exceeds demand over a "set period of time." Decision 3. Unless and until FDA can reasonably answer that question, it has no basis to put patients at risk by depriving them of access to compounded drugs. The agency's failure to safeguard patient access according to Congress's design requires the Court's intervention.

I. Plaintiffs Are Substantially Likely To Succeed on the Merits

A. FDA Unlawfully Promulgated the Delisting Action

No party disputes that the Delisting Action qualifies as a substantive rule, which would ordinarily be subject to the APA's rulemaking procedures. Instead, FDA insists that it could proceed through adjudication rather than rulemaking. But FDA did not conduct an adjudication and could not have consistent with the statute.

1. FDA argues (at 19) that an agency can end-run the APA's rulemaking requirements by conducting an "adjudication" involving no parties to declare generally applicable substantive law. But "[t]he existence of a dispute concerning particular individuals is a distinguishing characteristic of adjudication." *McDonald v. Watt*, 653 F.2d 1035, 1042 (5th Cir. 1981); *see also BNSF Ry. Co. v. Fed. R.R. Admin.*, 105 F.4th 691, 701 (5th Cir. 2024) (similar). FDA and Lilly do not dispute that there were no parties to this "adjudication," *see* Mot.9, and that the Delisting Action applies "not to any individual parties" but an entire industry, *Safari Club Int'l v. Zinke*, 878 F.3d 316, 333 (D.C. Cir. 2017). There was no adjudication.

Unable to find any case approving this kind of non-adjudicatory adjudication, FDA quotes loosely worded *dicta* discussing two cases involving bog-standard adjudications of party petitions seeking relief that, collaterally and through *res judicata*, also affected other parties. *City of Arlington, Tex. v. FCC*, 668 F.3d 229, 243 (5th Cir. 2012) (discussing *Qwest Services Corp. v. FCC*, 509 F.3d 531 (D.C. Cir. 2007), and *Chisholm v. FCC*, 538 F.2d 349 (D.C. Cir. 1976)). The same case recognized that adjudication involves an agency's determination of "rights…of parties properly before it" and cannot be "divorced from any specific application of the statute." *Id*. at 242–43. Here, by contrast, FDA had no parties before it and made a decision intended "for prospective application only, rather than in adjudicating a particular set of disputed facts." *United States v. Florida East Coast Ry. Co*., 410 U.S. 224, 246 (1973). If that qualifies as adjudication, then the APA's rulemaking procedures are entirely optional.

2. FDA has no direct answer to the point that statutes requiring agencies to make listings that trigger generally applicable legal consequences necessarily entail rulemaking. *See* Mot.8. The reason is that listing actions—whether for endangered species, tax-abusive transactions, CERCLA sites, or drugs in shortage—that create prospective obligations without respect to specific party are rules. FDA cannot distinguish the abusive-transactions cases recognizing as much on the basis that the actions there "'create[d] new substantive duties,'" FDA.Opp.21, because that is exactly what the Delisting Action did. And it does not attempt to distinguish all the other statutory listing schemes. The point is not, as FDA misconstrues it (at 19–20), that any action triggering

legal consequences must go through rulemaking; rather, it is that a listing decision made outside of a case involving specific parties is not an adjudication. That is the difference between FDA's deciding a manufacturer's new-drug application and its removing a drug from the shortage list. *See Safari Club*, 878 F.3d at 334.

3. FDA does not show that Congress "expressly," 5 U.S.C. § 559, displaced the APA's notice-and-comment provisions in Section 506E, *see* FDA.Opp.17–18. First, the directive to keep the shortage list "up-to-date" certainly did not, especially where the APA's "good cause" exception contemplates circumstances requiring expedition. Second, the statute's incorporation of generally applicable confidentiality provisions does not make "meaningful notice-and-comment" impossible, as shown by FDA's disclosure of extensive factual information and reasoning in its Order and the redacted Decision here. Moreover, the statutory default is to make listing information "publicly available." 21 U.S.C. § 356e(c)(1). That some drug manufacturers might seek to maintain the confidentiality of their own business information—as businesses may do in any FDA proceeding, 21 C.F.R. § 20.61—does not justify shutting the public out completely and in all instances. Third, the same goes for FDA's limited discretion to withhold information from the public, which the agency has never sought to exercise here. FDA has zero authority for its position that provisions authorizing confidentiality in limited circumstances evince any intent to override the APA. Overall, FDA's argument for displacement is far weaker than the one rejected by *Mann Construction, Inc. v. United States*, 27 F.4th 1138, 1145–48 (6th Cir. 2022), where the statute cross-referenced rules of practice permitting the agency to act without notice and comment. And FDA concedes (at 17) the statute here does not prescribe any "new procedure" in place of the APA's generally applicable one. *Id*.

4. Both FDA and Lilly ignore the Fifth Circuit's holding that no showing of prejudice is necessary when agencies fail to subject substantive rules to notice and comment. *W & T Offshore, Inc. v. Bernhardt*, 946 F.3d 227, 237 (5th Cir. 2019). In any event, the prejudice here is plain. FDA insists (at 23) that a post buried on its website and some newspaper articles were practically as good as full-fledged *Federal Register* notice. But it overlooks that a notice has both reach and substance. Not only was the interested public never informed that the agency was contemplating

ending shortage-based compounding, but the agency never told anyone what information it was looking for or how it would evaluate it. Aside from Lilly with its direct line to FDA decisionmakers, not a single party was able to guess what FDA might consider. FDA essentially admits (at 23) that all it was willing to consider was the sort of "detailed nationwide supply-and-demand data" potentially only available to the manufacturer. Had FDA provided notice of that, Plaintiffs and others could have attempted to meet the agency's standard or explained to the agency why that was wrongheaded and would disregard much probative evidence.[1]

B. The Delisting Action Is Arbitrary, Without Basis, and Contrary to Law

The opposition briefs fail to identify (1) a level of supply (2) that exceeds demand (3) over some set time period. *See* Lilly.Opp.10–13; FDA.Opp.6–12. If "a wealth of information" truly "spoke directly to [the] comprehensive nationwide inquiry," Lilly.Opp.10, then it should have been easy for FDA and Lilly to state, for example, that Lilly's monthly supply is X million doses and its monthly demand is Y million doses. [redacted] Without an apples-to-apples comparison of supply and demand over a set time period, the Delisting Action cannot stand.

1. FDA denies (at 12) that it needed to analyze over a set time period,[2] but it claims to have implemented a statute defining shortage as "*a* period of time" where demand exceeds supply. Decision 3 (quoting 21 U.S.C. § 356c(h)(2)) (emphasis added). This required "a single statutorily compliant" time period. *Niz-Chavez v. Garland*, 593 U.S. 155, 163 (2021). Because FDA applied the wrong legal test, the Decision is "not in accordance with law." 5 U.S.C. § 706(2)(A). It is also arbitrary. A shortage analysis requires a choice of time period because orders

[1] Lilly takes out of context the statement in *Perez v. Mortgage Bankers Association* about agencies using "the same procedures when they amend or repeal a rule as they used to issue the rule." 575 U.S. 92, 101 (2015). The court's point was that there's no difference in the procedures "required" at each stage, *id*., not that whatever the agency did at issuance necessarily applies to amendments or repeal. It could not have meant that: agencies like the Internal Revenue Service long eschewed notice and comment for substantive rules, Kristin Hickman, It's Time To Let Go: Treasury Regulations Are Not Interpretative Rules, *Tax Notes* (June 16, 2022), while other agencies regularly undertake notice and comment where it's not required, such as for guidance documents, *see* Nicholas Parillo, Should the Public Get To Participate Before Federal Agencies Issue Guidance?, 71 Admin. L. Rev. 57 (2019).

[2] Oddly, Lilly contends (at 13) that FDA did analyze "a given period" but is unable to state what that was.

and product are constantly coming and going and inconsistent use of time periods can obfuscate whether product is available to satisfy orders. [redacted]

2. [redacted] Did FDA even notice?

[redacted]

[redacted]

3. [redacted]

[3] [redacted]

[redacted] Inventory works like a checking account, where a snapshot conveys little: an account statement listing a $4,000 balance on December 15 may conceal a shortfall if there's a $4,500 mortgage payment due to be debited on December 16.

So too here. [redacted] Lilly easily could have presented a proper inventory accounting showing opening inventory, closing inventory, and total orders for a series of months or quarters. Mot.18. That it didn't should speak volumes—at least, to an agency seeking to listen.

[redacted]

[redacted]

4. FDA relied on Lilly's presentation to discredit what it admits (at 8) is "a variety of other sources" showing "that Mounjaro or Zepbound products were out of stock or limited in the amount that could be ordered." Notably, *all* information other than Lilly's secret submissions point to a shortage, and FDA and Lilly cite no corroborative evidence that the shortage is resolved. FDA credited Lilly's showing over all other evidence, FDA.Opp.9, but missed that [redacted] Lilly contends (at 14) that everyone else's information can be disregarded because Lilly's is more "comprehensive." Setting aside the limitations—and contradictions—in Lilly's showing, it would not be possible for anyone but the manufacturer to provide information like the manufacturer has, so Lilly's point is essentially that manufacturers have an absolute right to declare shortages over based on their irrebuttable say-so.

Both FDA and Lilly fail to address the breadth of evidence of wholesaler unavailability, which refutes their "localized" narrative. FDA.Opp.12. [redacted] the fact that access was unavailable in *four far-flung states* is overriding evidence of shortage on a national level. Addressing *supply* while ignoring *demand* fails yet again to get at the problem.

This evidence should have prompted FDA to investigate. FDA's response (at 15 n.7) that it need not "'conduct [its] own empirical or statistical studies'" does not excuse its "failure to adduce empirical data that can readily be obtained," *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 519 (2009), such as from Big Three wholesalers, national providers, and trade associations. And

there is no excuse for FDA's "decision to ask for—and then ignore—already-existing data it did not want to consider." *Chamber of Com. of U.S. v. SEC*, 85 F.4th 760, 776 (5th Cir. 2023).

II. The Equities Weigh Heavily in Favor of an Injunction and Stay

A preliminary injunction would continue the state of affairs that has existed since December 2022. That harms no one and benefits the public. Without an injunction, Plaintiffs and patients will suffer irreparable harm. The equitable balance here presents no contest.

A. Lilly is incorrect in denying (at 20–22) that Plaintiffs will suffer irreparable harm without an injunction. It acknowledges (at 20) that FarmaKeio "compounds tirzepatide" and does not deny that, without an injunction, FarmaKeio will suffer lost revenue that cannot be recouped due to FDA's sovereign immunity. Mot.23. Lilly's argument (at 20–22) that pharmacies like FarmaKeio are not permitted to compound essential copies of tirzepatide during a shortage has no place in this case. FDA (correctly[4]) understands that FarmaKeio has that right when tirzepatide is in shortage. FDA.Opp.4. Congress made explicit that only FDA may enforce the FDCA. 21 U.S.C. § 337(a); *see Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs., Inc.*, 48 F.4th 1040, 1050 (9th Cir. 2022) (rejecting claim of manufacturer against compounder where FDA declined to act). Without an injunction, FDA will pursue compounding of essential copies by FarmaKeio, but it will not with an injunction. That is classic irreparable harm. And Plaintiff OFA's members are outsourcing facilities that Lilly concedes may compound essential copies during a shortage, and *all* of their rights are at issue here—including those of Olympia Pharmacy and PQ Pharmacy, which compound tirzepatide, Decision 24; Rosebush Supplemental Declaration ¶ 3.[5]

B. FDA and Lilly's balance-of-equities arguments add nothing to their position on the merits. If they are wrong on the likelihood of success, then an injunction would not "give effect to

[4] Lilly's statutory argument is wrong. Section 503A prohibits compounding "essential[] copies of a commercially available drug product," 21 U.S.C. § 353a(b)(1)(D), and products in shortage are not commercially available, *see* Webster's New World College Dictionary (4th ed. 2007) ("available" means "that can be gotten, had, or reached; handy"). Lilly erroneously compares (at 21–22) language enacted in 1997 in Section 503A, PL 105–115, November 21, 1997, 111 Stat 2296, § 127(a), with language enacted in 2013 in Section 503B. *See Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 186 (1994).

[5] There is no obligation to disclose member identities in a complaint. *Hancock Cnty. Bd. of Sup'rs v. Ruhr*, 487 F. App'x 189, 198 (5th Cir. 2012).

the balance Congress struck," FDA.Opp.24, because "Congress has … authorized some compounding when a drug is in shortage," Lilly.Opp.4. Likewise, because FDA erred in declaring the shortage resolved, Lilly enjoys no "statutory exclusivity," Lilly.Opp.22, which is not in any event within the statute's zone of interests, *cf. Nexus*, 48 F.4th at 1050. FDA's point (at 24) about "safety protections" is a quarrel with Congress, which deemed the protections of Sections 503A and 503B sufficient during shortages. So is Lilly's misleading history of compounding (at 5–7), which is not germane to activities under the scheme Congress adopted. And Congress has not "tried to stop" compounding. Lilly.Opp.5. That would have been easy. Instead, Congress generally *authorized* compounding by state-regulated pharmacies in Section 503A and then enacted Section 503B to *authorize* outsourcing facilities to compound large batches of sterile drugs without individual patient prescriptions, subject to stringent regulatory requirements including the same current Good Manufacturing Practice standards that apply to Lilly.

It is unfortunate that Lilly sees the attention to this litigation as an opportunity for a press statement against its commercial competitors. Lilly.Opp.23–24. Lilly should not throw stones. Its tirzepatide products are subject to tens of thousands of adverse-incident reports. Mot.25. FDA inspections have faulted it for serious deficiencies, including in "quality control," in injectable-product manufacturing facilities.[6] Its products have been subject to recalls based on serious safety breaches and other failings.[7] The company pleaded guilty to charges for failing to inform FDA that one of its drugs caused numerous "deaths and toxic reactions."[8] By comparison, the single incident Lilly identifies (at 23–24) concerning a Plaintiff resulted in no reported patient injuries, had nothing to do with tirzepatide, and has no bearing on injunctive relief, which would not prevent FDA's enforcing safety requirements.

CONCLUSION

The Court should enter a preliminary injunction and stay FDA's Delisting Action.

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[6] *E.g.*, Eli Lilly, Press Release, FDA Issues Warning Letter After Inspection, Mar. 8, 2001.
[7] *E.g.*, FDA, Eli Lilly and Company Issues Voluntary Nationwide Recall of One Lot of GLUCAGON® Emergency Kit Due to Loss of Potency, Sept. 26, 2021.
[8] Marlene Cimons, Eli Lilly Pleads Guilty of Failure to Disclose Oraflex-Linked Deaths, L.A. Times, Aug. 22, 1985.

Dated: February 25, 2025

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