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' Memorandum of Law in Support of a
Preliminary Injunction and Stay Pending Review

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Introduction

Patients throughout the nation rely on compounded versions of GLP-1 drugs, including tirzepatide, to treat serious medical conditions like diabetes and obesity. Since those drugs came on the market, surging demand has far outpaced their manufacturers' supply, prompting the Food and Drug Administration to list them as in shortage. That authorized compounded versions of those drugs to ensure patient access and satisfy unmet demand. By all indications, the tirzepatide shortage persists: wholesalers continue to list it as unavailable or restricted, patients continue to report inability to fill prescriptions, media continues to report its unavailability, and the demand satisfied by compounders rather than the manufacturer, Eli Lilly & Co., has only grown.

Yet in October, FDA abruptly declared the tirzepatide shortage over. FDA's stated basis was Lilly's representation that it could "meet the present and projected national demand." When Plaintiffs here challenged that claim, FDA abandoned any defense of this action, obtained a remand to reconsider, and declared that tirzepatide compounding could continue in the meantime.

Two months later, FDA re-took the same action on the same basis. Its decision relies solely on "information and data Lilly has provided to FDA" that FDA says "demonstrate that Lilly's supply is currently meeting or exceeding demand." Yet FDA missed that [redacted] It then cited the strength of Lilly's showing as grounds to dismiss all evidence from every party but Lilly. This is arbitrary in the extreme.

FDA could have avoided these missteps had it engaged the public with a notice-and-comment rulemaking, as the Administrative Procedure Act requires. But FDA would prefer to engage only the manufacturers of name-brand drugs in deciding whether shortages exist. A decision that

declares the law applicable to an entire industry is a rule and not, as FDA claims, an adjudication. While adjudicating a given party's rights may result in administrative stare decisis that affects similarly situated parties, FDA here declared the law going forward. That is rulemaking.

An injunction is required to protect patients and prevent irreparable injury to Plaintiffs, a compounding pharmacy and trade association of compounders whose tirzepatide products will be forced off the market by FDA's action. The Court can have no faith in FDA's decisionmaking process or ultimate decision. There are no meaningful countervailing interests. An injunction is essential to preserve the status quo pending final determination of Plaintiff's claims.

Background

A. Congress Authorizes Compounding To Ensure Patient Needs Are Met During Drug Shortages

Drug compounding, "a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication," is "a traditional component of the practice of pharmacy, and is taught as part of the standard curriculum at most pharmacy schools." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61 (2002) (citation omitted). The Federal Food, Drug, and Cosmetic Act (FDCA) regulates drug compounding in two provisions, Section 503A and Section 503B. Section 503A authorizes state-licensed pharmacies to compound from "bulk drug substances," including active ingredients of FDA-approved drugs, so long as the pharmacy "does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product." 21 U.S.C. § 353a(b)(1)(D). Section 503B separately governs "outsourcing facilities," which are larger compounding facilities subject to more stringent regulation and direct FDA oversight. *Id.* § 353b(a)(1), (b).

Congress established a system to permit compounding to help ensure patient access to drugs during drug shortages. Section 506E requires FDA to "maintain an up-to-date list of drugs that are determined by [FDA] to be in shortage in the United States." 21 U.S.C. § 356e(a). By operation of statute, the addition of a drug to the shortage list authorizes compounders to provide

additional supply. Specifically, it authorizes pharmacies to compound copies of the drug.[1] A shortage listing also authorizes outsourcing facilities to compound from that drug's active ingredient—which is generally otherwise prohibited—including by compounding drugs that are "essentially a copy" of an approved drug. 21 U.S.C. § 353b(a)(2)(A)(2), (a)(5), (d)(2)(A). To put this in plain English: pharmacies generally may compound from the active ingredients of brand-name drugs but may copy those drugs only during a shortage, and outsourcing facilities generally cannot compound from the active ingredients of brand-name drugs, except when a drug is in shortage.

B. FDA Removes Tirzepatide from the Shortage List and Then Refuses To Defend Its Decision

Tirzepatide is the active ingredient of FDA-approved prescription drugs that treat type-2 diabetes and obesity. "Obesity is the most prevalent chronic disease worldwide, affecting approximately 650 million adults," which "impose[s] a considerable economic burden and constitute major contributors to global morbidity and mortality."[2] Tirzepatide is manufactured by Eli Lilly & Co. and sold under the brand names Mounjaro for diabetes treatment and Zepbound for weight loss. ECF No. 65-1, at 4 ("Decision"). Demand for tirzepatide is exceptionally high and continues to grow rapidly. Decision 4, 15; Rosebush Decl. ¶ 4, App. 6.

On December 15, 2022, FDA added tirzepatide injection products to the shortage list. Decision 1. The listing enabled pharmacies and outsourcing facilities to satisfy patient needs through compounding. Rosebush Decl. ¶ 8, App. 7. Since then, market demand has been met in meaningful part by compounded products. Rosebush Decl. ¶ 9 (App. 7) and Exs. 36–38 (App. 224–243); *see also* Decision 23 ("We acknowledge reports of significant compounding."); *id*. at 26 ("a substantial volume"). In fact, notwithstanding the additional supply provided by compounders, some patient needs went unfulfilled or met delays. Rosebush Decl. ¶ 60, App. 14.

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[1] Food and Drug Administration, Compounding when Drugs are on FDA's Drug Shortages List (Dec. 18, 2024), *available at* https://www.fda.gov/drugs/human-drug-compounding/compounding-when-drugs-are-fdas-drug-shortages-list.

[2] *See* Ania M. Jastreboff, et al., Tirzepatide Once Weekly for the Treatment of Obesity, New England Journal of Medicine, https://www.nejm.org/doi/full/10.1056/NEJMoa2206038 (June 4, 2022).

On October 2, 2024, FDA abruptly declared the shortage over by posting a declaration to that effect on its website. The agency's scant explanation indicated that the decision was premised entirely on Lilly's representation that its "stated product availability and manufacturing capacity can meet the present and projected national demand." ECF 1-2 (Exhibit A). Nonetheless, FDA's notice warned of continuing "intermittent localized supply disruptions," ECF 1-2, and stated in tirzepatide entries in its database: "Even When A Medication Is Available, Patients May Not Always Be Able To Immediately Fill Their Prescription At A Particular Pharmacy." ECF 1-3.

Plaintiffs brought suit and moved for a temporary restraining order and preliminary injunction. ECF 1, 7–8. Rather than defend its action, FDA sought a voluntary remand to "reevaluate the challenged decision." ECF 27 at 1–2. The agency represented that it would exercise "enforcement discretion" to allow Plaintiffs and their members to continue compounding dependent on tirzepatide's shortage status through the remand and adjudication of a preliminary injunction motion challenging a new decision delisting the drug. *Id*. at 3. The Court granted FDA's request. ECF 28.

Meanwhile, the shortage did not abate. In late 2024, industry participants presented FDA information showing surging demand for tirzepatide, inability of its manufacturer to keep up, scarcity in various regions and at the national level, and delays in filling prescriptions. Rosebush Decl. ¶¶ 59–61, App. 13–14. News media reported that tirzepatide "shortages have become more common" due to a "surge in demand," Ex. 5, App. 71, and a "Big Three" pharmacy wholesaler's CEO reported "a lot of volatility in terms of strong demand, supply that does not meet that demand," on an earnings call, Ex. 6, App. 87. Grassroots petitions reflect the complaints of thousands of patients unable to fill prescriptions for tirzepatide. Ex. 17, App. 179.

C. FDA Again Declares the Shortage Over, Relying on Lilly's Representations While Waving Away All Other Evidence

On December 19, 2024, FDA again declared the tirzepatide shortage over. This "**Delisting Action**" is memorialized in two documents. The "**Decision**" presents the agency's evidence and reasoning for the Act. ECF No. 64-1 (unredacted); Ex. 1, App. 18 (redacted). And the "**Order**" summarizes the agency's rationale, argues that the agency properly acted through "informal

adjudication" instead of notice-and-comment rulemaking, and provides enforcement discretion for compounding of tirzepatide products by pharmacies and outsourcing facilities of, respectively, 60 and 90 days. Ex. 2, App. 51.

Like its predecessor, the Delisting Action rests on Lilly's representations. FDA "conclude[d] that the information and data Lilly has provided to FDA demonstrate that Lilly's supply is currently meeting or exceeding demand for these drug products." Decision 1. The Decision recites data FDA received from Lilly, [redacted]

FDA gave zero weight to all evidence that it received from parties other than Lilly. It concluded that each separate category of this evidence "does not undermine or outweigh the information submitted by Lilly." Decision 16–17; *see also id*. at 18, 19, 20, 21, 22, 23 (substantially similar). It rejected all survey data submitted to the agency as insufficiently detailed. Decision 17–18. It rejected all evidence of pharmacy-wholesaler ordering portals showing tirzepatide products as unavailable or in restricted supply, dismissing some based on where submitters identified the date and ultimately accepting Lilly's explanation that pharmacies' inability to order products is not reflective of a shortage. Decision 19–21. It rejected all media reports of tirzepatide unavailability in one fell swoop, stating that "FDA did not find them to contain probative evidence." Decision 21. It rejected "[t]housands of individual comments" by patients, stating that they "do not provide

reliable evidence that could be probative." Decision 22. And it rejected all evidence that compounded products are satisfying demand that will fall on Lilly when the shortage is declared over, deeming it categorically irrelevant. Decision 22–23.

D. FDA's Delisting Action Prohibits Plaintiffs and Their Members from Compounding Tirzepatide, Putting Patient Access at Risk

Plaintiff North American Custom Laboratories, LLC, doing business as FarmaKeio Custom Compounding ("FarmaKeio"), is Section 503A compounding pharmacy located in Richardson, Texas. Declaration of Dan DeNeui ("DeNeui Decl.") ¶ 3, App. 1. FarmaKeio compounds tirzepatide in reliance on tirzepatide's drug-shortage status. DeNeui Decl. ¶ 10, App. 2. Plaintiff Outsourcing Facilities Association (OFA) is a trade association representing outsourcing facilities registered under Section 503B. Rosebush Decl. ¶ 2, App. 5. OFA members compound tirzepatide in reliance on tirzepatide's drug-shortage status. Rosebush Decl. ¶ 3, App. 6. FDA's Delisting Action will prevent FarmaKeio from compounding drugs that are essentially copies of branded tirzepatide products and OFA's members from compounding any drugs containing tirzepatide. DeNeui Decl. ¶ 18, App. 3; Rosebush Decl. ¶ 68, App. 15.

The Delisting Action shuts down what FDA acknowledges to be a "significant" and "substantial" source of market supply, Decision 23, 26, at a time when pharmacies and patients are unable to obtain branded tirzepatide products, demand is surging, and [redacted], *see* Argument § I.B.1, *infra*. OFA members produced millions of doses of compounded tirzepatide from June 1, 2024 to November 30, 2024, and pharmacies produced a comparable amount. Rosebush Decl. ¶¶ 15, 69, App. 8, 15. Current survey data shows that large numbers of patients remain unable to access branded forms of tirzepatide. Rosebush Decl. ¶ 62, App. 14. Cutting off supply through compounding will leave patient needs unfilled. Rosebush Decl. ¶ 70, App. 15.

Argument

The Court should enjoin and stay the Delisting Action because it is unlawful on the merits and the equities are clear-cut in favor of relief pending final judgment. FDA violated the

Administrative Procedure Act in failing to undertake notice-and-comment rulemaking, irrationally relying on data and representations by Lilly [redacted], and waving away extensive evidence of shortage [redacted] Absent an injunction, FarmaKeio and OFA's members will be unable to continuing filling patient needs with safe and effective medicines, and the ultimate losers will be innumerable patients with serious medical conditions that compounded tirzepatide can treat.

Plaintiffs seeking a preliminary injunction "must establish (1) a likelihood of success on the merits; (2) a substantial threat of irreparable injury; (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted; and (4) that the grant of an injunction will not disserve the public interest." *Ladd v. Livingston*, 777 F.3d 286, 288 (5th Cir. 2015) (quotation marks omitted). The standards for securing a stay under 5 U.S.C. § 705 are substantially the same. *Airlines for America v. Dep't of Trans.*, 110 F.4th 672, 674 (5th Cir. 2024).

I. Plaintiffs Are Likely To Succeed on the Merits

A. FDA Unlawfully Promulgated the Delisting Action by Failing To Undertake Notice and Comment

FDA's failure to follow the APA's notice-and-comment procedures is unlawful. The Delisting Action is a substantive rule—it makes previously lawful conduct unlawful—and is therefore subject to the APA's notice-and-comment mandate. FDA's insistence that the Action is instead the product of an "adjudication" exempt from notice and comment defies both law and reality.

1. The Delisting Action is a substantive rule subject to the APA's notice-and-comment mandate. The APA defines "rule" to include "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4). Substantive rules (also called "legislative rules") "are those which create law" by "affect[ing] individual rights and obligations." *Shell Offshore Inc. v. Babbitt*, 238 F.3d 622, 628 (5th Cir. 2001) (quotation marks omitted); *see also Mann Constr., Inc. v. United States*, 27 F.4th 1138, 1143 (6th Cir. 2022) ("impose[s] new rights or duties and change[s] the legal status of regulated parties"). For the promulgation of substantive rules, the APA prescribes a "three-

step procedure": notice, solicitation and consideration of comments, and explanation of the final rule's "basis and purpose." *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 96 (2015).

The Delisting Action creates law by prohibiting all compounding of tirzepatide by Section 503B outsourcing facilities and compounding drugs that are essentially copies of branded tirzepatide products by Section 503A pharmacies. This affected the rights of compounders by making a previously lawful activity (compounding tirzepatide) unlawful, no different in its force and effect than if Congress had enacted a statute prohibiting that activity. That is a substantive rule.

Courts have consistently held that agency listing decisions that trigger legal consequences are substantive rules. For example, the Sixth and Eleventh Circuits each recently held that IRS actions adding items to a list of presumptively abusive transactions, which in turn triggered reporting requirements, were substantive rules and therefore invalid because the agency failed to undertake notice and comment. *Green Rock LLC v. Internal Revenue Service*, 104 F.4th 220 (11th Cir. 2024); *Mann Constr*, 27 F.4th at 1138. EPA's adding a site to the CERCLA "national priorities list," which triggers various remedial obligations, is a substantive rule. *See generally Anne Arundel Cnty. v. U.S. EPA*, 963 F.2d 412 (D.C. Cir. 1992). So too are actions adding species to lists under the Endangered Species Act. *See Idaho Farm Bureau Federation v. Babbitt*, 58 F.3d 1392, 1401–04 (9th Cir. 1995); *Center for Biological Diversity v. U.S. Fish and Wildlife Service*, 698 F.Supp.3d 39 (D.D.C. 2023); *Center for Biological Diversity v. Everson*, 435 F.Supp.3d 69 (D.D.C. 2020).

Such actions are substantive rules because there is no difference between, for example, a rule providing that "compounding of tirzepatide is prohibited" and removing tirzepatide from the shortage list. Either way, the agency has changed the law by establishing a new prohibition. To change the law, an agency must follow notice-and-comment procedures. FDA's failure to do so here is fatal. *See W & T Offshore, Inc. v. Bernhardt*, 946 F.3d 227, 237 (5th Cir. 2019) ("Substantive rules not subjected to notice and comment may not be enforced against a party.").

2. Unwilling to conduct a public rulemaking, FDA insists that its Delisting Action is not a rule at all but "the product of an informal adjudication." Order 5. That is not so. For many of

the reasons that it qualifies as a substantive rule, the Delisting Action "bear[s] all the hallmarks…of rulemaking, not adjudication." *City of Arlington, Tex. v. F.C.C.,* 668 F.3d 229, 242 (5th Cir. 2012).

"An agency may not escape the requirements of § 553 by labeling its rule an 'adjudication.'" *Safari Club Int'l v. Zinke*, 878 F.3d 316, 332 (D.C. Cir. 2017). An "agency's characterization of its own [action]" is due "minimal" deference; instead, "courts focus primarily on the actual characteristics of the agency action." *W & T Offshore*, 946 F.3d at 237 (cleaned up).

Issuance of a generally applicable legal prohibition "is classic rulemaking" and not the proper subject of an adjudication. *City of Arlington*, 668 F.3d at 243. "Adjudications typically "resolve disputes among specific individuals in specific cases, whereas rulemaking affects the rights of broad classes of unspecified individuals." *Id*. at 242 (quotation marks omitted). The Delisting Action is generally applicable and affects the rights of thousands of compounding pharmacies and outsourcing facilities. The American Pharmacists Association reports that "about 7,500 pharmacies specialize in compounding," not including compounding pharmacies in hospitals and other health care facilities.[3] FDA identifies 88 outsourcing facilities,[4] including large facilities engaged in "high-volume" production.[5] This was not an adjudication of "the rights of a small number of parties properly before [the agency]." *Id*.

In fact, *none* of the pharmacies and facilities whose rights were the object of this so-called "adjudication" were party to it. Lilly was also not a party to this "adjudication," and neither the Decision nor Order identify it as one.[6] The Decision and Order identify no parties and do not apply any legal rule or determination to any person. There was no adjudication here at all. Instead, FDA simply announced a new legal restriction applicable to an entire industry. That is a rule. *Compare NLRB v. Wyman-Gordon Co*., 394 U.S. 759,765–66 (1969) (plurality op.) (holding agency was

[3] APHA, Frequently Asked Questions About Pharmaceutical Compounding (last visited Jan. 28, 2025), *available at* https://www.pharmacist.com/Practice/Patient-Care-Services/Compounding/Compounding-FAQs.
[4] Food and Drug Administration, Registered Outsourcing Facilities (Jan. 16, 2025), *available at* https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities.
[5] Food and Drug Administration, Compounding Outsourcing Facilities Annual Study (Aug. 18, 2020), *available at* https://www.fda.gov/media/163704/download.
[6] As relevant to Lilly's exclusion, the legal prohibitions triggered by a delisting apply only to compounders, not a manufacturer like Lilly.

required to proceed through APA rulemaking when it "purported to make a rule"—that is, "exercise its quasi-legislative power"—through adjudication).[7]

Confirming as much is the Delisting Action's prospective nature. "[R]ules generally have only 'future effect' while adjudications immediately bind parties by retroactively applying law to their past actions." *Safari Club*, 878 F.3d at 333; *see also City of Arlington*, 668 F.3d at 243 (emphasizing that FCC order "would apply prospectively"). As Justice Scalia put it, "Adjudication deals with what the law was; rulemaking deals with what the law will be." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 221 (1988) (Scalia, J., concurring). The Delisting rule's effect is, as FDA recognizes, purely prospective. Order at 9–10 (addressing the "Status of Compounding Following this Decision").

In these respects, the Delisting Action is indistinguishable from the *faux* adjudicatory orders *Safari Club* held to be rules. At issue were two Fish and Wildlife Service "findings" determining that the agency lacked sufficient information to conclude that sport-hunting of Zimbabwean elephants enhanced the species' survival, triggering an import-ban on trophies. 878 F.3d at 323–24. These findings, the court concluded, "had all of the qualities of a legislative rule" requiring notice and comment. *Id*. at 332. First, they "applied to all potential imports of sport-hunted elephant trophies from Zimbabwe, not to any individual parties." *Id*. Indeed, they "did not adjudicate any dispute between specific parties." *Id*. Second, the resulting import-ban applied only "in future permitting adjudications and enforcement actions" regarding conduct "going forward," with no "retroactive" effect on completed conduct. *Id*. Third, the agency had not "made its findings in the course of" adjudicating a party's rights, but "simply established a standard binding on the agency—a negative enhancement finding and ban on imports—to be applied to future [proceedings], until such time as the Service decides to issue a new rule based on different information." *Id*. at 334. FDA's Delisting Action shares all of these features.

[7] *See also id*. at 777 (Douglas, dissenting) (agreeing with holding); *id*. at 780 (Harlan, J., dissenting) (same).

FDA's contrary arguments lack merit. Its suggestion that the Delisting Action "do[es] not create new law," Order 6, is belied by its express acknowledgement that the Action makes certain compounding illegal, Order 9. Its italicized claim that the Delisting Action "*serves only to clarify and state an agency's interpretation of an existing statute or regulation,*" Order 6 (quotation marks omitted), makes no sense: the shortage status of tirzepatide products and lawfulness of compounding copies is not a matter of interpretation. If the agency believed its task here was to interpret some unidentified statute or regulation, then the Delisting Action is *per se* arbitrary and capricious and contrary to law. And no authority supports FDA's view that the possible "temporary nature" of an agency action transforms it from a rule into an adjudication. *See* Order 6. The APA permits agencies to dispense with notice and comment for "good cause," 5 U.S.C. § 553(b)(B), and agencies regularly employ that authority to address temporary or urgent needs through, for example, interim final rules. *E.g.*, 85 Fed. Reg. 19230 (Apr. 6, 2020) (interim final rule by FDA's sister agency making temporary changes to Medicare and Medicaid rules during pandemic). There is no additional "adjudication" exception. Anyway, actions regarding the shortage list need not be temporary; tirzepatide was listed for nearly two years, which is much longer than many of the Biden Administration's notice-and-comment rules from this past year will remain on the books.

FDA is also wrong to argue that Section 506E's "public health exception" to disclosure of a shortage and protection of "trade secrets and confidential information, 21 U.S.C. § 356e(c)(2), (3), weigh against following the APA's notice-and-comment provisions. *See* Order 7–8. This argument errs from the beginning by failing to identify the applicable legal standard. Congress prescribed that another statute supersedes APA procedures only "to the extent that it does so expressly." 5 U.S.C. § 559. "Before an agency may regulate without the protections of the notice-and-comment process, it must show that Congress 'expressly' carved out the exception." *Mann Constr.*, 27 F.4th at 1144. Such exemptions "are not lightly to be presumed," *Marcello v. Bonds*, 349 U.S. 302, 310 (1955); instead, "Congress's intent to make a substantive change [must] be clear," *Ass'n of Data Processing Serv. Orgs. v. Bd. of Governors of Fed. Rsrv. Sys.*, 745 F.2d 677, 686 (D.C. Cir. 1984). While it would be enough here to conclude that FDA's failure to engage the

proper standard dooms its argument, *see SEC v. Chenery Corp*., 318 U.S. 80, 87 (1943), the agency also cannot satisfy that standard. Nothing in Section 506E "expressly" displaces the APA's rulemaking procedures. Moreover, the "public health exception" to disclosure of a shortage is not inconsistent with the APA, which specifically authorizes agencies to forgo notice and comment for "good cause" and to refrain from publishing rules "exempted from disclosure by statute." 5 U.S.C. §§ 553(b)(B), 552(b)(3). So too for Section 356e's treatment of confidential business information. Agencies routinely accept, consider, and protect confidential materials in APA notice-and-comment rulemakings. *See generally* Heather Kilgore, Signed, Sealed, Protected: Solutions to Agency Handling of Confidential Business Information in Informal Rulemaking, 56 Admin. L. Rev. 519 (2004). FDA's preparation and issuance of the non-confidential Order and a redacted version of the Decision mirror the way agencies accommodate confidential information in rulemakings.

3. To the extent it matters, FDA's failure prejudiced Plaintiffs. (It should not matter, because FDA's failure deprives the Delisting Action of all legal force. *W & T Offshore*, 946 F.3d at 237.) First, the agency never provided notice to the public, even as it considered a matter implicating supply, demand, and availability across the entire nation. While some parties like Plaintiffs were aware of FDA's consideration, not all of the patients, providers, insurers, telehealth operators, pharmacy chains, etc., with pertinent information regularly visit "FDA's website," Order 8—or, to be precise, an obscure page buried on its website.[8] That matters because most public evidence of a shortage is additive: more reports of unavailability, across more places, showing consistency or growth over time carry greater weight. Those who were able to provide evidence are prejudiced by the agency's refusal to provide notice to and solicit information from everyone else.

Second, without notice members of the public had no way of knowing what kinds of information the agency would consider and no ability to address the agency's restrictions on the information for consideration. The prejudice in this is plain: FDA's Decision either ignores or dismisses

[8] Food and Drug Administration, FDA clarifies policies for compounders as national GLP-1 supply begins to stabilize (Dec. 19, 2024), *available at* https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.

the probative value of every single submission the agency received from every single party (including Plaintiffs) but Lilly. *See* § I.B.2, *infra*. FDA knew that parties other than Lilly would provide evidence of actual unavailability in the form of wholesaler information, survey data, media coverage, patient reports, and so forth. But it never disclosed its intention to hold these categories of evidence to the idiosyncratic standards that it applied in the Decision, which led it to disregard all this evidence in the final calculus. Had FDA done that, parties could have attempted to satisfy its standards or explain how they arbitrarily deprive the agency of highly probative information. FDA's failure to do so violated its "obligation to make its views known to the public in a concrete and focused form so as to make criticism or formulation of alternatives possible." *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 36 (D.C. Cir. 1977).

4. Even if the Delisting Action was the product of an adjudication, it is still invalid. First, FDA's creation and application of a "new methodology" to assess shortage status—disregarding all demand satisfied by compounded supply, dismissing all evidence of unavailability, and accepting the manufacturer's representations without verification or cross-checking—"is not an adjudicatory application of an existing rule to the facts of a specific case." *W & T Offshore*, 946 at 239. FDA may "not cloak its development—and industry-wide application—of a new [] methodology in the guise of simple adjudicative orders." *Id*. Second, at a minimum FDA's "reliance on adjudication instead of rulemaking constitutes an abuse of discretion" because the Delisting Action "bears all the hallmarks of [a] rulemaking." *City of Arlington*, 668 F.3d at 241–42.

B. The Delisting Action Is Arbitrary and Lacks a Reasoned Basis

Plaintiffs are likely to succeed in showing that the Delisting Action is arbitrary and capricious and divorced from "reasoned analysis." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). "[I]n order to permit meaningful judicial review, an agency must 'disclose the basis" of its action.'" *Dep't of Commerce v. New York*, 588 U.S. 752, 780 (2019) (citation omitted). Courts, in turn, "must 'consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.'" *State Farm*, 463 U.S. at 43. Review under this standard of "the factual basis for an agency's

conclusions…is functionally the same as the 'substantial evidence' test used to evaluate formal agency action under 5 U.S.C. § 706(2)(E)." *Amin v. Mayorkas*, 24 F.4th 383, 393 (5th Cir. 2022).

1. The Delisting Action Fails on Its Own Terms and Evidence

The Delisting Action fails under these principles. FDA stated that it was analyzing whether there exists "a period of time when the demand or projected demand for" injection tirzepatide "within the United States exceeds the supply of the drug." Decision 3 (quoting 21 U.S.C. § 356c(h)(2)). This required determinations on three elements: (1) time period, (2) supply, and (3) demand. FDA failed at each step. First, the Decision identifies no time period for analysis, and that failing prevented FDA from understanding [redacted]. Second, with no evidentiary basis, the Decision finds [redacted]. Third, the Decision makes no finding of demand for any time period [redacted]

a. Time Period. The Decision does not disclose what "period of time" FDA chose to analyze. Decision 3 (quoting 21 U.S.C. § 356c(h)(2)). Assuming FDA had discretion to select a time period, the Supreme Court has "frequently reiterated that an agency must cogently explain why it has exercised its discretion in a given manner." *State Farm*, 463 U.S. at 48. The Decision fails in this basic matter. This omission blinded FDA to [redacted]

[redacted]

[redacted] "Illogic and internal inconsistency are characteristic of arbitrary and unreasonable agency action." *Chamber of Com. of United States of Am. v. United States Dep't of Lab.*, 885 F.3d 360, 382 (5th Cir. 2018). By misunderstanding of Lilly's approach, FDA failed to scrutinize Lilly's specific choices implementing that approach.

[redacted]

FDA should have known better. [redacted]

[9] *E.g.*, cumulative demand of 10 in March and 14 in April means April demand was 14 – 10, or 4.

[redacted]

[redacted] FDA missed this entirely.

[redacted]

[redacted]

b. Supply. FDA's determination turns on the finding [redacted] The Decision does not justify accepting this self-serving assertion.

c. Demand. The final component is demand. But FDA made no finding of demand under any consistently defined time period. [redacted] In any event, "if there is an explanation" as to FDA's view of monthly demand, "it does not appear in the final" action. *Ohio v. EPA*, 144 S. Ct. 2040, 2054 (2024), which is fatal.

[redacted] An accounting of inventory for a monthly period should contain: (1) beginning inventory, (2) purchases during the month, (3) ending inventory, and (4) cost of goods sold. *See* Penn State University, Financial and Managerial Accounting, 2.6 Accounting for Inventory.[11] The Decision does not report that information. [redacted]

[11] *Available at* https://psu.pb.unizin.org/acctg211/chapter/periodic-v-perpetual-inventory/

[redacted]

2. FDA Arbitrarily Waved Away All Evidence of Shortage

FDA received weighty evidence that pharmacies and patients across the nation lack access to tirzepatide products. Rather than take that seriously, FDA "treated conflicting evidence here with an almost breathtaking lack of evenhandedness." *Sutter E. Bay Hosps. v. N.L.R.B.*, 687 F.3d 424, 437 (D.C. Cir. 2012). FDA's indulgence of Lilly is matched by its hyper-skepticism of all contrary evidence, to the point one doubts that any showing could satisfy the agency.

a. Pharmacy Wholesaler Unavailability. On a weekly basis, FDA received screenshots of wholesalers' webpages showing no supply or restricted supply of brand-name tirzepatide products. *See* Exs. 7, 14, 17, 18, 21–33. The Decision acknowledges that this evidence "show[s] a wholesaler's website listing" tirzepatide products "as unavailable." Decision 19. It is hard to imagine more probative evidence than a drug's regular unavailability from the "Big Three" wholesalers that control 90% of the national market.[13]

FDA rejected this evidence based on "the information provided by Lilly" on "availability of product." Decision 20. But FDA failed in its assessment of Lilly's data, as shown above.

The Decision also cites "limitations of the screenshot evidence," i.e., that screenshots were "undated and do[] not include information about the length of time that the product is or was out of stock." Decision 19–20. But FDA admitted that cover emails identified the dates, *id.* at 19, and ignored that representatives of submitters met with FDA officials and agreed to provide weekly submissions with current information, Rosebush Decl. ¶ 16, App. 9. Meanwhile, FDA's concern

[redacted]

[13] *See* Russ Britt, MarketWatch, 'Big Three' pharma distributors post sharp gain (9/15/2010), https://www.marketwatch.com/story/big-3-pharma-distributors-post-sharp-gains-2010-09-15

about dates misses the sheer force of this evidence. If shortages were intermittent or localized, the consistent stream of screenshots from "Big Three" national wholesalers would not be possible.

The Decision also hypothesizes the problem is "that the forward distribution center has temporarily run out of product, but that does not necessarily mean that the wholesaler *itself* has run out of product." Decision 20–21. But it is a *national* problem if *national* wholesalers must pick between local distributors for shipments. Anyway, FDA misses that—wherever the bottleneck is—*patients cannot get the product*. That is a shortage. Indeed, the statute identifies "[d]elay in shipping of the drug" as a possible cause of a shortage. 21 U.S.C. § 356e(b)(3)(F).

b. Patient Reports. FDA acknowledged reports that patients cannot obtain tirzepatide products, "reported weekly and cumulatively." Decision 17. This survey data presents tens of thousands of reports of individuals across the nation. Ex. 7, 14. FDA's principal basis for rejecting this showing yet again was the "information submitted by Lilly." Decision 16.

FDA also complained of "limitations" in this data. Decision 18. But FDA met with individuals involved with the submissions, was fully informed about them, was asked for input, and declined to provide feedback or ask questions. Rosebush Decl. ¶ 16, App. 9. This approach stands in stark contrast to FDA's collaborative arrangement with Lilly, where the agency provided information to Lilly and accepted Lilly's explanations. *See, e.g.*, Decision 21 & nn.95–98. FDA's treatment of other parties reflects an active disinterest in their information.

Besides, the limitations FDA complained of are overblown. FDA did not meaningfully address OFA's time-stamped reports of unavailability, which include zip codes and report only incidents where a patient "attempted to have a [tirzepatide] prescription filled at more than one pharmacy." Ex. 35. FDA complains that this "does not include details of the reported individual experiences," Decision 18, but inability to get a prescription filled at *two* pharmacies is as detailed as descriptions get on this scale. The suggestion that the information may not reflect a "national" problem, Decision 18, is belied by the vast diversity of zip codes, covering dozens of states, if not all of them. Ex. 35. Likewise, FDA's rejection of data from a national telehealth company ignores the national market it serves and valuable information it can provide.

c. Press, Industry, and Patient Reports. The Decision acknowledges "news coverage" on "the shortage situation." Decision 21. FDA addressed none of it on the merits. It ignored the December 10, 2024 announcement that a national retail pharmacy "is no longer taking new GLP-1 patients" because of "market demand." Ex. 12. It ignored a November 1, 2024 earnings call where the CEO of Cardinal Health—a "Big Three" wholesaler—discussed "strong demand, supply that does not meet demand" and explained that "we have seen very static levels of inventory, relatively low levels of inventory that have not fluctuated much at all of the last several quarters." Ex. 6 at 14. It ignored that the nation's leading association of pharmacists, American Society of Health-System Pharmacists, lists tirzepatide on its shortage list.[14] And FDA ignored other reporting. Exs. 4, 5, 9, 10, 11, 13, 16. FDA simply stated this evidence does "not undermine or outweigh" Lilly's data. Decision 22. This finding is arbitrary where FDA' misconstrued Lilly's data. The same is true of FDA's disregard of "[t]housands of individual comments" it received from individuals indicating they cannot obtain GLP-1 products. Decision 22.

d. Tirzepatide Compounding. FDA erred as a matter of law and fact in disregarding the "the sales volume of compounded tirzepatide" as evidence of demand. Decision 22.

First, FDA erroneously deemed compounded products irrelevant, reasoning that "[t]he relevant demand here is the demand for the approved drug product," not "for a different drug." Decision 22. That is wrong. A shortage listing authorizes compounding of drugs that are "essentially a copy" of approved drugs. 21 U.S.C. § 353b(a)(5); *see also* 21 U.S.C. § 353a(b)(1)(D). The point of allowing essentially-a-copy compounding during shortages is to enable compounded drugs to fill the demand the manufacturer is not satisfying. To redefine that same demand as not part of the demand would redefine shortages out of existence as soon as they are declared.

Second, FDA erred in disregarding demand for compounded products because they beat Lilly's on price. Decision 26. FDA reasoned that customers who cannot afford Lilly's products will drop out of the market once compounding is banned, which reduces future demand from

[14] ASHP, Tirzepatide Injection (Jan. 9, 2025), *available at* https://www.ashp.org/drug-shortages/current-shortages/drug-shortage-detail.aspx?id=972.

current demand. *Id.* This announces in startling terms that, insofar as FDA is concerned, the way to end a shortage is to declare that only rich Americans may access GLP-1 products. That rule of law would enable Lilly to end shortages simply by raising prices or limiting supply (or both). Because supply and demand always meet at price, this approach redefines demand as coterminous with Lilly's supply. This would defeat the purpose of a supply-demand inquiry.

Third, FDA acted arbitrarily in dismissing the role of compounders as too small to matter. *See* Decision 23–28. It acknowledged "significant compounding" with "some effect," but dismissed this because there is no "reliable basis to project the scope of this effect." *Id.* at 23. But the difficulty in knowing the precise degree of a "significant" factor does not justify zeroing it out. Moreover, FDA made arbitrary choices and factual errors. It looked at outsourcing facility compounding only for the "**first six months of 2024**," Decision 24, even as it focused [redacted] This missed substantial compounding increases in the latter six months of 2024. Rosebush Decl. ¶ 69, App. 15. Additionally, FDA apparently miscalculated the doses per "package" and arrived at the absurd conclusion that a single pharmacy (Plaintiff FarmaKeio, which FDA erroneously referred to as an outsourcing facility) [redacted] Decision 24. And FDA's own numbers belie its finding. Given that just *one* pharmacy can provide [redacted], Decision 24, and given the thousands of pharmacies authorized to compound during a shortage, the supply from pharmacies makes a material difference, especially when combined with supply from outsourcing facilities. Indeed, FDA had evidence as of December 17 that 37 specifically identified pharmacies were providing at least 503,260 doses per month. *See* Ex. 40.[15] That is a *low* number, given that other pharmacy compounding is not necessarily disclosed. FDA ignored this evidence, which—at a minimum—should have prompted the agency to investigate.

Fourth, FDA erred in assuming this market demand was for unapproved uses of tirzepatide. Decision 27. But all pharmacies and outsourcing facilities that filled demand are regulated by state

[15] The exhibit shows 125,815 patients being served per month, and each patient receives four doses per month (125,815 patients x 4 doses per patient = 503,260 doses).

and federal law, and dissemination to patients required lawful prescriptions. The Decision cites incidents of bad actors apparently not acting in compliance with law. *See* Decision 27 & nn. 118–119. It was arbitrary for FDA to view these incidents as indicative of lawful compounding.

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

The equities are clear-cut in favor of a preliminary injunction, which would afford substantial benefit for no cognizable harm. "Preliminary injunctions commonly favor the status quo and seek to maintain things in their initial condition so far as possible until after a full hearing permits final relief to be fashioned." *Wenner v. Tex. Lottery Comm'n*, 123 F.3d 321, 326 (5th Cir. 1997). Here, patient needs have been satisfied for two years by compounding, as Congress contemplated. To permit compounding for the short duration of this lawsuit will secure access to needed medication and avoid irreparable harm. An injunction would impose no countervailing harms.

A. Absent immediate relief, FarmaKeio and OFA members will be irreparably harmed. *See Wages & White Lion Invs., LLC v. United States Food & Drug Admin.*, 16 F.4th 1130, 1142 (5th Cir. 2021) (finding irreparable harm in FDA's action forbidding plaintiff's product manufacturing and marketing). FarmaKeio and OFA members have met patient needs since December 2022 and will suffer substantial financial loss without an injunction, which is "sufficient to show irreparable injury." *Texas v. EPA*, 829 F.3d 405, 433 (5th Cir. 2016). The Delisting Action prohibits FarmaKeio's compounding of copies of FDA-approved tirzepatide products and OFA members' compounding of all tirzepatide products. FarmaKeio will suffer approximately $1,750,000 to $2,000,000 in lost revenue per month because of the Delisting Action, DeNeui Decl. ¶ 19, App. 3, which will cause FarmaKeio to lay off from 6 to 9 employees, and the patients FarmaKeio has been serving will be unable to get their tirzepatide prescriptions filled by FarmaKeio, DeNeui Decl. ¶¶ 20–21, App. 3. OFA members will suffer materially identical harms. Rosebush Decl. ¶¶ 67–270, App. 15. Financial losses like these constitute irreparable harm "because federal agencies generally enjoy sovereign immunity for any monetary damages." *Wages & White Lion*, 16 F.4th at 1142.

B. The balance of harms and public interest also favor an injunction. These factors "'merge when the Government is the opposing party,'" *Texas v. Becerra*, 577 F.Supp.3d 527, 561 (N.D. Tex. 2021) (quoting *Nken v. Holder*, 556 U.S. 418, 435 (2009)), and present no contest here.

First, the public has a substantial interest in continued access to compounded tirzepatide. Tirzepatide treats serious conditions, and patient need has been supplied for two years in meaningful part through compounding. The "access to…medical treatments is unquestionably in the public interest." *Dumanian v. Schwartz*, 2022 WL 2714994, at *15 (N.D. Ill. July 13, 2022); *see also Med-Cert Home Care, LLC v. Azar*, 365 F.Supp.3d 742, 758 (N.D. Tex. 2019) (granting injunctive relief because of the public's strong interest in access to health care); *Benson v. St. Joseph Reg'l Health Ctr.*, 2005 WL 6459109, at *2 (S.D. Tex. Dec. 22, 2005) (noting "the important public interest in open and fair competition for health services"); *Bos. Heart Diagnostics Corp. v. Health Diagnostics Lab'y, Inc.*, 2014 WL 2048436, at *2 (D. Mass. May 16, 2014) (recognizing the "public's interest in having access to medical treatment"). Without an injunction, FDA's unlawful action will deprive an untold number of patients of access to provider-prescribed treatment.

Second, the public also has a "substantial public interest in having governmental agencies abide by the federal laws that govern their existence and operations." *Texas v. United States*, 40 F.4th 205, 229 (5th Cir. 2022). It is "not in the public interest to suspend notice and comment," which "are basic to our system of administrative law." *Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 115 (2d Cir. 2018). "Notice requirements are designed (1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review." *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005). FDA's rejection of notice-and-comment rulemaking disserves the public's interests in safe and effective medicine and in transparent government and informed decisionmaking.

No cognizable harms weigh on the other side of the scale. FDA cannot plausibly claim injury from following congressional dictates and making a reasonably informed—rather than

arbitrary—decision or from a continuation of the state of affairs that begun in December 2022. Nor can FDA credibly allege a public-safety risk, especially given its extension of enforcement discretion to authorize compounding for months following the Delisting Action. Order 9. The drug-shortage element of Section 503A and 503B relates to public need and is not a mechanism of regulating safety. Nor is there evidence of a safety risk. Lilly could drum up evidence of only 215 reported adverse-incident events related to tirzepatide compounding, *see* ECF No. 59 at 4, but its own tirzepatide products caused more than 28,000 adverse-incident events in 2024 alone.[16]

Finally, any harm to Lilly is far outweighed by that facing Plaintiffs and the patients. By Lilly's own account, it is not losing out on sales. According to Lilly, [redacted] Decision 14. In any instance, [redacted] *See* § I.B.1, *supra*. Any cost to Lilly would be de minimis in light of its $45 billion annual revenues.

Conclusion

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

[16] Food and Drug Administration, FDA Adverse Events Reporting System (FAERS) Public Dashboard (last visited Jan. 28, 2025), *available at* https://www.fda.gov/drugs/fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard (search "mounjaro" and "zepbound").

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