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, and ELI LILLY AND COMPANY, Intervenor-Defendant.	Civil Action No. 4:24-cv-953-P

AMENDED COMPLAINT

Plaintiffs Outsourcing Facilities Association ("OFA") and North American Custom Laboratories, LLC, doing business as FarmaKeio Custom Compounding ("FarmaKeio"), by and through undersigned counsel, allege as follows:

Nature of the Action

1. At issue in this case is a reckless and arbitrary decision—lacking any semblance of lawful process—by the Food and Drug Administration ("FDA") to deprive patients of a vital treatment for type 2 diabetes and obesity, two of the most common and harmful medical conditions in existence. Tirzepatide, an active ingredient that treats those conditions, has been provided to patients in large part through lawful drug compounding under the Federal Food, Drug, and Cosmetic Act ("FDCA"). Compounding is the process by which a doctor, pharmacist, or licensed outsourcing facility combines, mixes, or alters ingredients to create medicines tailored to patient

needs. Congress determined that, when a drug is in short supply, compounding is an efficient, effective, and appropriate means to ensure that patient treatment can occur, notwithstanding the shortage. FDA placed Tirzepatide on the shortage list in December 2022, and since then, patient demand has been satisfied in precisely the manner Congress contemplated: pharmacies and outsourcing facilities—including Plaintiffs and their members—have compounded Tirzepatide to meet a large segment of market demand.

2. But on October 2, 2024, FDA changed all that with a post to its website, abruptly depriving patients of much needed treatment and artificially raising drug prices. Ignoring evidence that the shortage persists, FDA removed Tirzepatide from the shortage list without notice, without soliciting input from affected parties and the public, and without meaningful rationale. Indeed, the agency *confirmed* that there remains a Tirzepatide shortage and that it acted to benefit special interests, raise drug prices, and deprive much of the public of access to a needed medicine. The only basis FDA offered for its declaration of victory over the shortage was the "stated product availability and manufacturing capacity" of the drug's manufacturer—the company that is self-interested in monopolizing the market. The sole factual assertion FDA made concerning a shortage was that it *persists*: "Patients and prescribers may still see intermittent localized supply disruptions as the products move through the supply chain from the manufacturer and distributors to local pharmacies." Put simply, FDA knows its action will leave many patients with no effective treatment but persisted with that action anyway on an expedited basis and without warning.

3. After Plaintiffs filed this suit and sought expedited temporary injunctive relief, FDA promptly folded, and the parties jointly sought remand of the action to the agency for reconsideration. On December 19, 2024, FDA provided notice of another determination (this time

under seal in a confidential order) that Tirzepatide is not in shortage. This second decision cured none of the infirmities plaguing the first.

4. If ever an agency action were arbitrary, capricious, and contrary to law, this is it. The Administrative Procedure Act (APA) secures the foundational principle that "the Government should turn square corners in dealing with the people," just as regulated parties "must turn square corners when they deal with the Government." *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 591 U.S. 1, 24 (2020) (citations omitted). Under the APA, FDA's decision to remove a drug from the shortage list is clearly a "substantive" rule, which means a rule that establishes legal rights and duties. Because of the profound impact of substantive rules, the APA demands that agencies undergo notice-and-comment rulemaking before promulgating them: an agency must propose and give notice of its action in the Federal Register, solicit comments from interested parties, and in its final decision explain its rationale and address the meaningful comments it receives in a reasoned and transparent decision. Agencies across the massive federal bureaucracy do these things every day of the week. But FDA skipped past every single requirement of reasoned rulemaking when it declared the Tirzepatide shortage resolved—thereby depriving patients of access to the compounded drug. This Court's immediate intervention is essential to protect the many patients who rely on compounded Tirzepatide and vindicate Congress's insistence on reasoned, informed rulemaking by federal agencies.

Parties

5. Plaintiff Outsourcing Facilities Association ("OFA") is a trade association representing outsourcing facilities that engage in drug compounding under federal law, including facilities that compound Tirzepatide. As explained below, all OFA's members will be prohibited from compounding Tirzepatide by the final agency action challenged in this case. OFA's mission

is to represent and advocate for the interests of outsourcing facilities and to educate the public and policymakers about the essential services and products provided by outsourcing facilities.

6. Plaintiff North American Custom Laboratories, LLC, doing business as FarmaKeio Custom Compounding ("FarmaKeio"), is a Texas limited liability company headquartered in Southlake, Texas. FarmaKeio has been compounding Tirzepatide in compliance with federal law, and its compounding activities are directly regulated by FDA. FDA's final agency action in this case restricts Tirzepatide compounding by FarmaKeio, as explained below.

7. Defendant FDA is a federal agency of the United States Government headquartered in Silver Spring, Maryland. It is an agency for purposes of the APA and is subject to its requirements.

8. Defendant Sara Brenner is the Acting Commissioner of Food and Drugs, is named in her official capacity only, and was automatically substituted as a party pursuant to Fed. R. Civ. P. 25(d).

Jurisdiction and Venue

9. This Court has jurisdiction over Plaintiffs' APA causes of action under 28 U.S.C. § 1331. Through the APA, the United States has waived sovereign immunity from this lawsuit. *See* 5 U.S.C. § 702.

10. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(e) because Plaintiff FarmaKeio resides in this district, as do certain members of Plaintiff OFA, and a substantial part of the events or omissions giving rise to the claim occurred in this district, where FDA's final action is directly regulating Plaintiff FarmaKeio and OFA members and prohibiting activity that was theretofore lawful.

Factual and Legal Background

Congress Identifies Compounding as an Effective, Efficient, and Appropriate Means of Meeting Patient Need and Market Demand During Drug Shortages

11. "Drug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication," typically one that is "not commercially available, such as medication for a patient who is allergic to an ingredient in a mass-produced product." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61 (2002). Compounding "is a traditional component of the practice of pharmacy, and is taught as part of the standard curriculum at most pharmacy schools." *Id.* at 361 (internal citation omitted). "Many States specifically regulate compounding practices as part of their regulation of pharmacies," and "[s]ome require all licensed pharmacies to offer compounding services." *Id.*

12. Congress regulated drug compounding in two provisions of the Federal Food, Drug, and Cosmetic Act (FDCA), Section 503A, 21 U.S.C. § 353a, and Section 503B, 21 U.S.C. § 353b.

13. Section 503A regulates pharmacy compounding. Compounding that meets the requirements of this section is exempted from the FDCA's new-drug approval requirement, as well as certain drug-adulteration and branding standards. 21 U.S.C. § 353a(a). To qualify for Section 503A treatment, a drug must, *inter alia*, be compounded "on the prescription order for [an] individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs" or, if it occurs "before the receipt of a valid prescription order for such individual patient," it must be "based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product." *Id.* § 353a(a)(2)(A) and (B).

14. Section 503A authorizes compounding from "bulk drug substances," which are active ingredients typically 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." *Id.* § 353a(b)(1)(D).

15. Section 503B establishes a separate regime governing "outsourcing facilities" that may compound drug products not based on existing prescriptions or a history of prescriptions if numerous requirements are satisfied. *Id.* § 353b. Section 503B subjects outsourcing facilities to registration, inspection, and reporting requirements and other regulations, *see id.* § 353b(a)(1) and (b), and exempts from the new-drug approval process and other FDCA requirements "a drug compounded…in a facility that elects to register as an outsourcing facility if each of" 11 conditions are met, *id.* § 353b(a).

16. Central to the compounding regulations of Sections 503A and 503B is the drug shortage list required by Section 506E. That section requires FDA to "maintain an up-to-date list of drugs that are determined by the Secretary to be in shortage in the United States." 21 U.S.C. § 356e(a). The provision requires that FDA identify for "each drug on such list" "[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 Secretary." *Id.* § 356e(b)(1)–(4).

17. A separate provision of the FDCA defines the term "drug shortage" to mean "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). However, this definition does not apply by its own terms to Section 506E and does not purport to restrict the scenarios of shortage cognizable under Section 506E to those where a manufacturer's own supply does not meet national demand for an identified time period. To the contrary, Section 506E identifies various scenarios of shortage, including based

on "[d]elay in shipping of the drug," *id.* § 356e(b)(3)(F), that do not turn on manufacturer supply or national demand.

18. Section 506E does not identify procedures FDA must comply with in removing a drug from the shortage list and does not displace default provisions of the APA governing FDA action in removing drugs from the shortage list.

19. When a drug is on the shortage list, Section 503A pharmacies and Section 503B outsourcing facilities are permitted to engage in compounding from its active ingredients that is unlawful if the drug is not listed on the shortage list.

20. Under Section 503B, compounding from bulk drug substances (i.e., active ingredients) is impermissible unless "the drug compounded from such bulk drug substance appears on the drug shortage list…at the time of compounding, distribution, and dispensing" or, alternatively, the bulk drug substance appears on a separate list of ingredients for which there is a "clinical need." *Id.* § 353b(a)(2)(A)(ii). FDA has narrowly construed the "clinical need" path to bulk-drug compounding, such that an FDA-approved drug not in shortage will virtually never meet the clinical-need standard. *See Athenex Inc. v. Azar*, 397 F. Supp. 3d 56 (D.D.C. 2019). As a result, FDA will typically consider bulk drug compounding from the active ingredients of an FDA-approved drug unlawful, unless the drug is listed on the shortage list.

21. A drug's listing on the shortage list carries a second, independent consequence under Section 503B. That section bars compounding of any kind of a drug that is "essentially a copy of one or more approved drugs." *Id.* § 353b(a)(5). But the statutory definition exempts from the definition of "essentially a copy of an approved drug" any drug that "appears on the drug shortage list…at the time of compounding, distribution, and dispensing." *Id.* § 353b(d)(2)(A). Consequently, if a drug appears on the shortage list, compounding of the drug will be permitted,

even if it results in a drug that is essentially a copy of the FDA-approved drug. Otherwise, essential-copy compounding is unlawful, even if the active ingredient appears on the clinical-need list.

22. The effect of a drug-shortage listing is similar under Section 503A. As noted, compounding "in inordinate amounts" of "any drug products that are essentially copies of a commercially available drug product" does not qualify for protection under Section 503A. *Id.* § 353a(b)(1)(D). But FDA reads the term "commercially available drug product" not to include drugs listed on the shortage list, since such drugs are by definition not commercially available. *See* Food and Drug Administration, Compounding when Drugs are on FDA's Drug Shortages List, https://www.fda.gov/drugs/human-drug-compounding/compounding-when-drugs-are-fdas-drug-shortages-list. As a result, Section 503A pharmacies may compound essential copies of FDA-approved drugs that are on the shortage list.

23. FDA treats drug compounding that does not meet the standards of Section 503A or 503B as a violation of the FDCA. Violations are subject to penalties. *See* 21 U.S.C. § 331(d) (prohibited acts); 21 U.S.C. § 332(1) (injunctions); 21 U.S.C. § 333 (penalties); 21 U.S.C. § 335a (debarment). Accordingly, listing of a drug on the shortage list marks the difference between a lawful business enterprise and a federal-law violation.

24. This scheme reflects a decidedly patient-focused orientation of compounding restrictions under the FDCA and, specifically, Congress's considered judgment that compounding by pharmacies and outsourcing facilities is an efficient and effective means of ensuring patient needs are satisfied when an FDA-approved drug is in shortage.

FDA Abruptly Declares Victory Over a Drug Shortage That Manifestly Persists Without Notice, Opportunity to Comment, or a Reasoned Decision

25. Tirzepatide is the active ingredient an FDA-approved prescription drug used for the treatment of type 2 diabetes and for obesity, which is recognized in the medical field as a chronic disease that results in substantial global morbidity and mortality. Tirzepatide is administered via subcutaneous (i.e., under-the-skin) injections and is sold under the brand names Mounjaro for diabetes treatment and Zepbound for weight loss.

26. Tirzepatide has been proven effective in treating weight loss in particular, and, given the prevalence of this condition nationwide, the drug is in exceptionally high demand.

27. On or about December 15, 2022, FDA listed Tirzepatide injection on the Section 506E shortage list, noting 10 forms of Mounjaro and Zepbound injections that are in shortage.

28. The drug listing enabled pharmacies and outsourcing facilities to satisfy demand and patient needs through drug compounding, including compounding of drugs that are essentially copies of FDA-approved versions of Tirzepatide.

29. Numerous pharmacies and outsourcing facilities, including the compounder Plaintiffs, compounded Tirzepatide under Sections 503A and 503B. From that point, a large portion of market demand and patient need nationwide was satisfied by compounded forms of Tirzepatide lawfully produced as Congress envisioned.

30. In fact, notwithstanding this effort, even after the FDA listing, demand for Tirzepatide continued to go unsatisfied or saw delays in satisfaction. Patient needs have in this entire timeframe gone unmet due to an ongoing shortage.

31. Various industry participants communicated with FDA, providing updates with evidence of extremely high demand for Tirzepatide, scarcity in various regions and at the national level, and delays in filling prescriptions. For the entire period during which FDA announced a

shortage of Tirzepatide, and at least through December 19, 2024, the agency was in actual or constructive receipt of information demonstrating that supply continued to lag behind demand, even at stark levels. On information and belief, additional information was available to FDA demonstrating that supply continued to lag behind demand but was not considered because FDA failed to engage in a meaningful inquiry.

32. Despite the ongoing shortage, FDA abruptly announced on October 2, 2024, that "the shortage of tirzepatide injection, a glucagon-like peptide 1 (GLP-1) medication, has been resolved."

33. FDA first made this announcement around close of business Eastern Time, as the Jewish holiday Rosh Hashanah began, through a posting on its website.

34. FDA provided no notice of this announcement before it took legal effect (i.e., before the effectuation of delisting occurred). Market participants did not know before that moment that compounding activities they were currently undertaking in reliance on the listing would immediately become unlawful.

35. FDA provided no opportunity for public comment on whether to delist Tirzepatide.

36. By foregoing the public notice-and-comment process, FDA deprived regulated parties and other interested persons of the opportunity to comment on the proposed delisting of Tirzepatide and to provide probative information concerning the drug's availability. At the same time, FDA deprived itself of valuable information that would have been made available to it had the agency solicited public comment.

37. In addition, FDA's failure to follow the APA's procedures deprived all interested persons of a reasonable explanation for its decision. Among other things, FDA never addressed the voluminous evidence that demand for Tirzepatide exceeds supply and that compounding

authorized by Sections 503A and 503B remains necessary for patient needs to be met and for market demand to be satisfied.

38. In its public notice, FDA supported its decision on the merits with only a single statement: "FDA confirmed with the drug's manufacturer that their stated product availability and manufacturing capacity can meet the present and projected national demand." Ex. A at 1. From this statement, it is clear that FDA's sole consideration in deciding the shortage had ended was information provided by the manufacturer of Tirzepatide.

39. While the FDCA requires FDA to consider information provided by a drug's manufacturer in addressing a shortage, it does not *limit* FDA to that information. To the contrary, an agency required by law to engage in informed decision-making must consider *all* relevant information at its disposal, not only information supplied by a self-interested market participant whose production failings caused the shortage in the first instance and which has an overriding incentive to make a one-sided presentation to the agency.

40. Further down in its notice, FDA offered a generic assertion that it typically "considers a variety of factors, including the company's ability to meet current and historical demand, the amount in a manufacturer's stock, affected market share, ability of alternate manufacturers to cover the demand, and confirmed market stabilization." Ex A at 2. But the notice says nothing of FDA's findings (even at a high level) under any of those criteria (or any others) concerning Tirzepatide. As noted, the sole case-specific assertion in the notice references FDA's singular reliance on communications with Tirzepatide's manufacturer. This notice leaves the public in the dark as to why FDA disregarded the overriding evidence of continued gap between demand and that manufacturer's supply or whether FDA even considered such evidence at all.

41. In fact, in the very next sentence, FDA refuted its own finding that the drug shortage ended with the contrary warning: "Patients and prescribers may still see intermittent localized supply disruptions as the products move through the supply chain from the manufacturer and distributors to local pharmacies." Ex. A at 1.

42. For each of the 10 Tirzepatide injections on the shortage list (and now removed), FDA made the following finding (or a substantial equivalent):

> Even When A Medication Is Available, Patients May Not Always Be Able To Immediately Fill Their Prescription At A Particular Pharmacy. That Is Especially True For Refrigerated Products And Products With Multiple Dose Strengths, Due To Factors Like Ordering Practices And Incentives, Cold Chain Logistical Considerations, And Retailer Capacity Constraints. Patients May Experience Variability At A Particular Pharmacy Location Regardless Of Whether A Drug Is In Shortage.

Ex. B.

43. FDA's express recognition that "supply disruptions" will continue to thwart patient needs and leave market demand unsatisfied, and that patients may not always be able to immediately fill their prescription, is a confirmation on the face of FDA's notice that its determination was arbitrary, capricious, and unsupported by anything but the self-interested assertions of a market participant. FDA's finding that "Factors Like Ordering Practices And Incentives, Cold Chain Logistical Considerations, And Retailer Capacity Constraints" continue to prevent supply from meeting demand confirms there is remains a shortage: those are the very factors FDA claims to consider in deciding whether a shortage exists, so its findings that those factors are preventing patient needs from being met is a finding that the shortage is ongoing.

44. FDA's notice also reflects no consideration of the large segments of the market for Tirzepatide that are served by compounded versions of the drug. FDA's notice does not provide

any reason for it to conclude that supply will match or exceed demand after compounded forms of the drug are taken off the market.

45. FDA's decision came one day after port workers across the eastern seaboard and beyond—from Maine to Texas—commenced a labor strike that was projected to threaten imports and raise prices of goods across economic sectors. An FDA representative involved in the decision to delist Tirzepatide acknowledged to an OFA representative knowledge of the strike and of press coverage stating that the strike threatened supply of critical drug components for manufacturers of weight-loss drugs, including Tirzepatide. FDA's notice, however, neither reflects consideration of the strike nor provides a basis for the agency to believe the strike would not impact supply. Although the strike has been resolved for the time being, FDA had no way to know the length of the strike when it made its decision, and even a short strike is predicted to create continued supply chain disruptions. Its failure to address this issue reflects lack of reasoned decision-making and recklessness as to the true state of supply and demand in the market for Tirzepatide.

46. FDA's notice contains no finding or even assertion establishing that patient needs and market demand for Tirzepatide will be fulfilled beginning October 2, 2024.

47. FDA's notice cites no evidence establishing that patient needs and market demand for Tirzepatide will be fulfilled beginning October 2, 2024.

48. The very limited fact-related assertions related to Tirzepatide all suggest there is no basis for FDA's action deeming the shortage at an end, other than FDA's black-box reliance on manufacturer representation.

FDA Abandons Defense of Its Decision but Reissues the Decision Without Notice, Opportunity to Comment, or a Reasoned Decision

49. After Plaintiffs filed the initial complaint in this lawsuit and sought a temporary restraining order and preliminary injunction, FDA promptly abandoned its defense of the October

2 action and sought remand to the agency for reconsideration. *See* ECF No. 27. This action by FDA implicitly acknowledged that the October 2 delisting action could not fairly be defended under the APA.

50. On December 19, 2024, FDA issued another decision (the "Delisting Action") declaring the shortage resolved. Exs. C, D. The December 19 decision stands on no firmer ground than the October 2, 2024 decision.

51. The Delisting Action was not the product of notice-and-comment rulemaking. FDA again provided no notice of the decision before it was issued. Market participants did not know before that moment that compounding activities they were currently undertaking in reliance on the listing would become unlawful.

52. FDA contends that the Delisting Action is not a substantive rule but the product of informal adjudication. That is not so. The Delisting Action is generally applicable and affects the rights of thousands of compounding pharmacies and outsourcing facilities. None of those persons were "parties" to FDA's supposed adjudication. The Delisting Action is prospective, not retrospective, in nature: it declares rights and prohibitions going forward and does not make findings as to the lawfulness of action already taken. FDA therefore had no prerogative to employ information adjudication when the APA demands notice-and-comment rulemaking.

53. Even if the Delisting Action was the product of an adjudication, it is still invalid. 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. And FDA's reliance on adjudication

instead of rulemaking constitutes an abuse of discretion because the Delisting Action bears all the hallmarks of a rulemaking.

54. The Delisting Action is also arbitrary and capricious and divorced from reasoned analysis.

55. The Delisting Action relied on information provided by the manufacturer that was presented in arbitrary and erratic ways to obfuscate evidence of ongoing shortage. FDA failed to apprehend or at least address the many ways in which the data indicate an ongoing shortage, and it made findings incompatible with the very data presented.

56. The Delisting Action does not address basic parameters and premises necessarily to interpret and organize data from the manufacturer, including the time period FDA believed relevant, the supply available for that time period under a consistent reporting basis, or the demand for that time period under a consistent reporting basis.

57. The Delisting Action irrationally fails to follow the legal standard for determining shortage status it identifies as applicable.

58. Meanwhile, FDA arbitrarily disregarded the weighty evidence that pharmacies and patients across the nation lack access to tirzepatide products. Its various explanations do not justify its treatment of the evidence but rather betray a lack of evenhandedness and effort to achieve a predetermined outcome.

59. FDA also discounted evidence that compounded Tirzepatide is meeting market demand to a degree that the manufacture likely could not sustain if compounded products are banned and/or restricted. FDA erroneously treated this demand as legally irrelevant and made plain factual errors in assessing the degree of compounding at issue.

Plaintiffs Are Stifled in Their Efforts to Ensure Patients Receive Important Treatments at Reasonable Prices

60. Plaintiff FarmaKeio is a compounding pharmacy in Southlake, Texas that operates under Section 503A.

61. FarmaKeio compounds Tirzepatide pursuant to Section 503A and in reliance on Tirzepatide's drug-shortage status. With Tirzepatide removed from the shortage list, FarmaKeio will be unable to continue accepting prescriptions for Tirzepatide and filling them with compounded Tirzepatide. FarmaKeio would continue accepting prescriptions and filling them with compounded Tirzepatide but for FDA's action.

62. Plaintiff OFA is a trade association representing outsourcing facilities registered under Section 503B, including in this judicial district. All members of OFA are outsourcing facilities that compound drugs within the Section 503B framework. Because FDA removed Tirzepatide from the shortage list, and because Tirzepatide is not on the clinical need list, bulk compounding of Tirzepatide will be categorically unavailable under Section 503B and thus prohibited to all OFA's members.

63. The compounded drugs produced by FarmaKeio and OFA's members help meet patient needs, fulfill market demand, and keep prices down.

64. Compounding by an outsourcing facility under Section 503B is expensive. OFA's members spent significant sums in sunk costs to support compounding operations. It can cost hundreds of thousands of dollars and takes months of lead-in effort to begin compounding in compliance with Section 503B. Additionally, an outsourcing facility experiences opportunity cost from compounding operations, as manufacturing lines are devoted to compound a drug (here, Tirzepatide) that can no longer be put to that use after the drug is removed from the list. It takes additional investment and time before the same manufacturing lines can be converted to other uses.

65. FDA's delisting of Tirzepatide will (if it stands) cause OFA's members to fail to capitalize on their investment. It will destroy their revenues, and those of FarmaKeio, from the sale of compounded drugs that are in acute demand. Even if Plaintiffs prevail in this action, they will be unable to recoup lost revenues or profits from the federal government.

66. OFA's members and FarmaKeio intend to continue compounding Tirzepatide on a prospective basis to continue meeting patient needs and market demand and would do so but for FDA's arbitrary and unlawful removal of Tirzepatide from the shortage list.

67. OFA's members invested in technology, equipment, space, human resources, and other assets in order to facilitate compounding Tirzepatide. Without court intervention or further action by FDA, these investments will be wholly or partially impaired or adversely impacted.

68. The shortage of Tirzepatide continues. Without lawful compounding under Sections 503A and 503B, patient needs will not be fulfilled and market demand will not be satisfied. Conditions treated by Tirzepatide will go untreated, resulting in further disease and increased mortality rates.

FIRST CAUSE OF ACTION
(Agency Rulemaking Without Requisite Notice, Comment, and Explained Decision)

69. The above paragraphs are hereby incorporated by reference as if set forth fully herein.

70. The APA establishes a notice-and-comment rulemaking requirement that applies to all agency rulemaking, with limited exceptions that do not apply here. 5 U.S.C. § 553.

71. Under the notice-and-comment process, an agency must issue a notice of proposed rulemaking in the Federal Register with specified information (e.g., legal authority for the rule, description of the rule), solicit public comments for a period not less than 30 days, and review those comments. An agency must also respond to meaningful comments in its final rulemaking.

72. FDA's decision to remove Tirzepatide from the shortage list is final agency action that qualifies as an agency rule. A "rule" is defined 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). "[T]he APA defines the term 'rule' broadly enough to include virtually every statement an agency may make." *Apter v. Dep't of Health & Hum. Servs.*, 80 F.4th 579, 590 (5th Cir. 2023). FDA's Delisting Action meets this definition.

73. FDA's Delisting Action is a "legislative" rule that is subject to the notice-and-comment requirement because it "has the force and effect of law." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015). Listing and removal mark the difference between a lawful compounding business enterprise and one FDA considers unlawful and subject to severe penalties. Accordingly, a delisting decision is a rule "affecting individual rights and obligations." *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979).

74. FDA's Delisting Action is not eligible for the exemption from notice-and-comment requirements applicable to "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." 5 U.S.C. § 553(b)(A). FDA's Delisting Action is not interpreting a legal provision, making a generic policy statement, or governing the agency's internal process. Rather, a delisting decision declares previously lawful activity, regarded by Congress's as beneficial, to be unlawful.

75. No provision of the FDCA "expressly" exempts FDA from the APA's notice-and-comment requirement, as is necessary for an organic statute to eliminate such a requirement. 5 U.S.C. § 559.

76. FDA's Delisting Action is not the product of adjudication. Even if the delisting action is regarded as adjudication, FDA abused its discretion in utilizing adjudication for a matter subject to the notice-and-comment-rulemaking requirement.

77. FDA did not engage in notice-and-comment rulemaking before issuing its final decision removing Tirzepatide from the shortage list.

78. FDA's final decision removing Tirzepatide from the shortage list is therefore "contrary to law" and "without observance of procedure required by law" under the APA and must be "set aside." 5 U.S.C. § 706(2)(A), (D). FDA's unlawful action entitles Plaintiffs to the relief requested below.

SECOND CAUSE OF ACTION
(Lack of Reasoned Decisionmaking by Omission of Rationale Sufficient to Explain Final Agency Action)

79. The above paragraphs are hereby incorporated by reference as if set forth fully herein.

80. The APA obligates agencies to engage in reasoned decisionmaking and directs that their actions be set aside if arbitrary and capricious. *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 591 U.S. 1, 16 (2020). This includes requirements that agencies consider relevant factors and provide an explanation for their final actions. *Id.* at 16, 20–24. This standard obligates an agency to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Because the agency's disclosed bases for a final action supply the sole grounds on which it may be upheld in litigation, a failure to provide sufficient grounds for the decision, standing alone, requires vacatur of the decision and remand. *Regents of the Univ. of California*, 591 U.S. at 16.

81. FDA's sole basis for final action removing Tirzepatide from the shortage list was its reliance on data provided by the manufacturer of brand-name Tirzepatide products. But that data was presented in an arbitrary fashion that obfuscated evidence of a shortage.

82. FDA's decision—the sole basis on which the Delisting Action could be upheld—says nothing of key parameters necessary to determine whether supply satisfies demand for any given time period. The decision does not identify what time period it considers relevant or how supply and demand are properly reported. Nor does FDA provide any comparison between the time period for which the shortage was declared resolved and the time period when the shortage was first declared.

83. FDA's failings to address the most basic parameters of its analysis enabled the manufacturer to manipulate the analysis through inconsistent reporting and data lacking a consistent baseline and presentation. FDA appears to have misunderstood the data at times.

84. FDA's final decision removing Tirzepatide from the shortage list is therefore "arbitrary and capricious" under the APA and must be "set aside." 5 U.S.C. § 706(2)(A). FDA's unlawful action entitles Plaintiffs to the relief requested below.

THIRD CAUSE OF ACTION
(Lack of Reasoned Decisionmaking by Arbitrary and Facially Contradictory Findings That Refute or Undermine the Basis of Final Agency Action)

85. The above paragraphs are hereby incorporated by reference as if set forth fully herein.

86. The APA obligates agencies to engage in reasoned decisionmaking and directs that their actions be set aside if arbitrary and capricious. *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 591 U.S. 1, 16 (2020). This includes requirements that agencies consider relevant factors and provide an explanation for their final actions. *Id.* at 16, 20–24. Because the agency's disclosed bases for a final action supply the sole grounds on which it may be upheld in litigation,

a failure to provide sufficient grounds for the decision, standing alone, requires vacatur of the decision and remand. *Id.* at 20–24.

87. A corollary of these principles demands that agency determinations be founded on findings that are not themselves arbitrary and capricious. This principle forbids agencies to predicate their actions on determinations that are facially incoherent or inconsistent.

88. Here, FDA's decision is facially incoherent and inconsistent. Its findings of supply contradict the data on which it purported to rely, and its finding that the shortage ended contradict evidence of ongoing shortage, including in the manufacturer's own data (properly construed). FDA acted arbitrarily in discounting evidence presented by persons other than the manufacturer of ongoing shortage.

89. FDA's final decision removing Tirzepatide from the shortage list is therefore "arbitrary and capricious" under the APA and must be "set aside." 5 U.S.C. § 706(2)(A). FDA's unlawful action entitles Plaintiffs to the relief requested below.

FOURTH CAUSE OF ACTION
(Arbitrary and Capricious Determination That Tirzepatide Shortage Ended)

90. The above paragraphs are hereby incorporated by reference as if set forth fully herein.

91. The APA forbids arbitrary and capricious agency action.

92. FDA acted arbitrarily and capriciously in determining that the drug shortage has ended in the face of overriding evidence that supply of Tirzepatide—including supply made possible by compounding—cannot keep pace with demand.

93. Market participants presented FDA evidence that patient needs and market demand for Tirzepatide is not satisfied by current supply, including supply made possible by compounding. Additional evidence was available to FDA that patient needs and market demand for Tirzepatide

is not satisfied by current supply, including supply made possible by compounding, had it engaged in appropriate investigation. Information provided by the manufacturer, properly interpreted, lent further support to evidence showing an ongoing shortage.

94. FDA, however, rushed out a decision declaring the shortage had ended based solely (or primarily) on statements by the manufacturer that it can meet demand, despite substantial probative evidence proving to the contrary, including the manufacturer's own evidence.

95. FDA's final decision removing Tirzepatide from the shortage list is therefore "arbitrary and capricious" under the APA and must be "set aside." 5 U.S.C. § 706(2)(A). FDA's unlawful action entitles Plaintiffs to the relief requested below.

FIFTH CAUSE OF ACTION
(Unlawful Interpretation and Application of Drug Shortage Statute)

96. The above paragraphs are hereby incorporated by reference as if set forth fully herein.

97. Agency action must comply with the law Congress imposed on that agency. Agency obligations under a statute are resolved through court determination of "the best reading of the statute" without deference to the agency. *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244, 2266 (2024).

98. FDA's decision rests on an erroneous reading of statutes. The FDCA requires FDA to "maintain an up-to-date list of drugs that are determined by the Secretary to be in shortage in the United States." 21 U.S.C. § 356e(a). This provision enumerates various circumstances where a shortage may arise, including a "[d]elay in shipping of the drug." *Id.* § 356e(b)(3)(F).

99. FDA, however, looked to a different provision of the FDCA, addressing manufacture shortage reporting for its definition of a shortage. *Id.* § 356c(h)(2). That section,

however, defines "drug shortage" only "[f]or purposes of this section." *Id.* § 356c(h)(2). It does not purport to define the full scope of shortages or causes of shortage.

100. FDA erred in applying this overly restrictive definition. For example, it stated that it would ignore inability of patients to obtain Tirzepatide without proof of a nationwide shortage and that it would not treat supply chain disruptions as evidence of a shortage if wholesalers had not entirely run out of Tirzepatide products. Nothing in Section 506E supports those determinations.

101. Additionally, FDA stated that it would not consider portions of the demand satisfied by ongoing compounding as part of the relevant demand on the basis that (1) only demand for the brand-name (not compounded) product qualifies and (2) recipients of compounded products may drop out of the market entirely after compounded products are banned or restricted, given the high prices of brand-name Tirzepatide products. But 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). Moreover, the point of allowing essentially-a-copy compounding during shortages is to enable compounded drugs to fill the demand the manufacture is not satisfying. 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.

102. FDA's final decision removing Tirzepatide from the shortage list is therefore "contrary to law" under the APA and must be "set aside." 5 U.S.C. § 706(2)(A). FDA's unlawful action entitles Plaintiffs to the relief requested below.

SIXTH CAUSE OF ACTION
(Unlawful Failure to Publish Decision in the Federal Register)

103. The above paragraphs are hereby incorporated by reference as if set forth fully herein.

104. The public information section of the APA obligates agencies to "publish in the Federal Register… (D) substantive rules of general applicability adopted as authorized by law." 5 U.S.C. § 552(a)(1)(D). This "was adopted to provide, inter alia, that administrative policies affecting individual rights and obligations be promulgated pursuant to certain stated procedures so as to avoid the inherently arbitrary nature of unpublished ad hoc determinations." *Morton v. Ruiz*, 415 U.S. 199, 232 (1974)

105. FDA's decision to remove Tirzepatide from the shortage list is a legislative rule: it affects the individual rights of numerous market participants in a generally applicable manner, as well as the interests of innumerable patients who need Tirzepatide for their treatment.

106. FDA did not publish its decision in the Federal Register.

107. FDA's final decision removing Tirzepatide from the shortage list is therefore "contrary to law" under the APA and must be "set aside." 5 U.S.C. § 706(2)(A). FDA's unlawful action entitles Plaintiffs to the relief requested below.

Prayer for Relief

Plaintiffs respectfully asks that this Court enter judgment in their favor and that they be granted the following relief:

A. Declare that FDA's final action removing Tirzepatide from the drug shortage list is contrary to law under the APA, which subjects that action to notice-and-comment rulemaking procedures;

B. Declare that FDA's final action removing Tirzepatide from the drug shortage list is arbitrary and capricious in violation of the APA;

C. Vacate and/or set aside FDA's final action removing Tirzepatide from the drug shortage list on the grounds stated above;

D. Permanently and temporarily enjoin FDA from taking action against Plaintiffs or their members for engaging in compounding of Tirzepatide that is lawful in circumstances where Tirzepatide is named on the drug-shortage list;

E. Award Plaintiffs their fees and costs related to this action, including reasonable attorneys' fees; and

F. Grant such other and further relief as the Court deems appropriate.

Dated: January 28, 2025

/s/ Ty Doyle

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