UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

OUTSOURCING FACILITIES ASSOCIATION and NORTH AMERICAN CUSTOM LABORATORIES, LLC d/b/a FARMAKEIO CUSTOM COMPOUNDING, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION and DR. ROBERT M. CALIFF, Defendants.	CASE NO. 4:24-cv-953-P

ELI LILLY AND COMPANY'S BRIEF
IN SUPPORT OF ITS MOTION TO INTERVENE

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I. INTRODUCTION

Mounjaro® and Zepbound® are groundbreaking medicines that treat patients with type 2 diabetes and those with obesity or overweight with weight-related conditions. Eli Lilly and Company ("Lilly") conducted more than thirty-seven pre-clinical and clinical trials and invested billions of dollars before the U.S. Food and Drug Administration ("FDA") approved these medicines as safe and effective for the American public. Mounjaro® and Zepbound® meet critical patient needs and, as a result, both medicines faced unprecedented demand that exceeded supply for periods of time. When FDA placed both medicines on the agency's "drug shortage" list, a cast of so-called "compounders" and telehealth start-ups began mass-manufacturing and mass-marketing their own untested, unapproved knock-off versions of Lilly's medicines. FDA has cautioned that such knock-off, non-FDA-approved compounded drugs are "risky for patients" because they "do not undergo FDA's review for safety, effectiveness and quality before they are marketed."[1] The American Diabetes Association likewise "recommends against using" these knock-offs "due to uncertainty about their content, safety, quality, and effectiveness."[2]

Compounders cite FDA's shortage designation as the sole basis for their risky practices. Fortunately, the shortage is over. As a result of Lilly's historic $23 billion manufacturing investment, all doses of Mounjaro® and Zepbound® have been available since August 2024, and FDA formally determined the shortage of both medicines was resolved in October 2024. After compounders filed this lawsuit, FDA then voluntarily and carefully reconsidered its decision, including by receiving evidence from Plaintiffs and similar entities, and correctly reaffirmed the

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[1] FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss.

[2] Press Release, The American Diabetes Association Announces Statement on Compounded Incretin Products, AM. DIABETES ASS'N (Dec. 2, 2024), https://diabetes.org/newsroom/press-releases/american-diabetes-association-announces-statement-compounded-incretin#.

lack of a shortage on December 19, 2024. FDA reviewed "detailed information and data" from Lilly and determined that "Lilly's supply is currently meeting or exceeding demand for [tirzepatide] drug products." ECF No. 32-1, at 2-3. FDA also "considered potentially relevant information . . . from patients, healthcare providers, and others, including compounders," and determined this unscientific and anecdotal evidence—unexplained and generalized reports of patients "having trouble" obtaining Mounjaro® or Zepbound®, screenshots of a pharmacy's order on a particular day, and generic commentary about anti-obesity medicines not specific to Lilly's medicines—did "not undermine or outweigh the evidence demonstrating that Lilly's supply is currently meeting or exceeding demand." *Id*. at 3.

Against this backdrop, Lilly seeks to intervene as a defendant in this case to protect its interests and help bring this suit to a swift end. Plaintiffs seek to reverse FDA's determination that Mounjaro® and Zepbound® are not in shortage, so Plaintiffs can claim entitlement to continue to mass-selling and (illegally) mass-marketing unapproved (and, all too often, unsafe) copies of Lilly's medicines. The motive for their suit is transparent: in their words, FDA's shortage determination "will . . . cause [them] to fail to capitalize on their investment" and "destroy their revenues," Compl. ¶¶ 51-52—revenues to which they are not entitled under the law and that come at the expense of the patients who take their unapproved knockoff products. To state the obvious, Plaintiffs' position not only poses significant patient safety risks and challenges the integrity of FDA's regulatory framework that ensures patients receive only safe and effective medicines, but it also directly affects Lilly's interests in preserving its exclusive right to sell its FDA-approved medicines.

Lilly satisfies each of Rule 24(a)(2)'s requirements for intervention. Lilly's motion is timely—before any responsive pleadings—and Lilly agrees to observe any schedule for pleadings

and preliminary injunction briefing the Court enters. *See* FED. R. CIV. P. 24(a)(2). Lilly has a clear and substantial interest "relating to the property or transaction that is the subject of the action," *id.*, since Plaintiffs ask the Court to undo FDA's determination that the shortage is resolved. This action threatens to "impair or impede [Lilly's] . . . interest" in two ways: first, it challenges a regulatory scheme and determination that directly govern Lilly and ensure (when enforced) that patients receive medicines FDA has determined are safe and effective, and second, it impairs Lilly's statutory right to an exclusive market for FDA-approved medicines. *Id.* And while Lilly has no doubt that FDA will defend its declaratory order, FDA has different interests than Lilly as FDA is a government agency tasked with administering the policy goals and objectives of the federal government, creating a reasonable possibility that FDA will not "adequately represent [Lilly's] interest[s]." *Id.*

Finally, in the alternative, Lilly satisfies Rule 24(b)'s criteria for permissive intervention: This motion is timely; Lilly will defend common questions of law and fact with the main action (that FDA's determination that the shortage is resolved was legally and factually sound); and Lilly's participation will not delay the resolution of the action.

II. BACKGROUND

A. Lilly engages in extensive research and development to create important medicines, which it then manufactures under strict controls.

Lilly is a medicine company. Throughout its nearly 150-year existence, Lilly has pioneered countless life-changing discoveries. Lilly has developed over 100 medicines across some of the most challenging diseases, has 50 new medicine candidates currently in clinical development or under regulatory review, and launched 23 medicines in the last decade, including path-breaking therapies for diabetes, obesity, and Alzheimer's disease. Creating life-saving and life-changing medicines requires tremendous investments of time, talent, and money, and those costs have only

grown over time. Today, bringing a new medicine all the way from inception to development through the rigorous FDA approval process costs many billions of dollars. Every year, Lilly re-invests 25% of its revenue into research and development of future medical breakthroughs, including more than $9.3 billion in 2023 alone. These costs are the result of a simple reality: Medicines that secure FDA approval represent only a fraction of a fraction of the therapies developed and put into preclinical testing. Across the board, a mere 0.02% of potential treatments that go into preclinical testing end up receiving FDA approval for therapeutic use—and only one in three of that tiny subset will ever recoup its development costs.[3]

For those medicines that FDA approves, Lilly then utilizes strict controls for manufacturing its medicines in state-of-the-art facilities, which employ thousands of highly specialized personnel to ensure that its medicines meet its rigorous quality and safety standards. Transforming active pharmaceutical ingredients, or API, into medicine is a complex, methodical, and science-based process. Lilly follows current Good Manufacturing Practices ("cGMP") across the design, monitoring, and control of its manufacturing processes and facilities—from establishing robust quality management systems to obtaining quality raw materials and detecting and investigating product quality deviations. Each step—from synthesizing the API to formulation, device assembly, and packaging of the final product—requires extensive testing and controls and specialized equipment.

[3] *See* Sandra Kraljevic et. al., *Accelerating Drug Discovery*, 5 Eur. Molecular Biology Org. Reps., no. 9, 2004, at 837, https://tinyurl.com/525p87tp; John A. Vernon & Joseph H. Golec, *Pharmaceutical Price Regulation: Public Perceptions, Economic Realities, and Empirical Evidence* 7 (2008), https://tinyurl.com/2k3hfyw5; U.S. Food & Drug Admin., *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective* (Nov. 24, 2017), https://tinyurl.com/32xnaus2.

B. Lilly manufactures Mounjaro® and Zepbound®—the only FDA-approved tirzepatide medicines.

Mounjaro® and Zepbound® contain a complex molecule called tirzepatide, which targets hormone receptors (called GIP and GLP-1). FDA approved Mounjaro® and Zepbound® in 2022 and 2023, respectively, pursuant to Lilly's marketing application, itself the culmination of a lengthy clinical trial process designed to develop, study, and bring safe medicines to patients so that—in FDA's words—"American consumers benefit from having access to the safest and most advanced pharmaceutical system in the world."[4] Mounjaro® is approved to improve glycemic control in adults with type 2 diabetes mellitus. Zepbound® is approved to help the millions of American adults with obesity or who are overweight and have weight-related medical problems. In December 2024, FDA also approved Zepbound® for the treatment of moderate to severe obstructive sleep apnea in adults with obesity. This additional indication was the product of years of additional clinical trials that Lilly conducted.

Mounjaro® and Zepbound® remain protected by statutory exclusivity. Because Mounjaro® was a "new chemical entity" when it received FDA approval, FDA is prohibited by law from even accepting any New Drug Application ("NDA") or abbreviated new drug application ("ANDA") for any tirzepatide product from any company other than Lilly for years to come. *See* 21 U.S.C. § 355(c)(3)(E)(ii), (j)(5)(F)(ii); 21 C.F.R. § 314.108(b)(2), (b)(3). And, of course, no person is permitted to introduce any new drug into interstate commerce without an approved application. *See* 21 U.S.C. § 355(a). Those prohibitions reflect Congress's decision that patients should receive medicine only from a manufacturer that proved to FDA that its medicine is safe and effective, and Congress's judgment that the manufacturers of innovative medicines are entitled

[4] *Development & Approval Process | Drugs*, U.S. FOOD & DRUG ADMIN. (Aug. 8, 2022) https://www.fda.gov/drugs/development-approval-process-drugs.

to a reward of market exclusivity, irrespective of patent or other considerations, for their often-herculean efforts bringing new, life-changing medicines to market.

Both Mounjaro® and Zepbound® have been commercially available in the United States since their commercial launches in 2022 and 2023. Lilly has experienced significant demand for both medicines, reflecting their value to patients and their importance to healthcare providers. As a result of increasing demand, FDA placed Mounjaro®, and later Zepbound®, on the statutory drug shortage list in December 2022 and April 2024, respectively.

C. Compounders prepare untested and potentially dangerous copies of FDA-approved medicine, exposing patients to serious risks.

While Mounjaro® and Zepbound® have been on the drug shortage list, untested—and potentially unsafe—"compounded" versions of tirzepatide have proliferated. Compounding is a "practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes or alters ingredients of a drug to create a medication tailored to the needs of an individual patient."[5] Importantly, "[c]ompounded drugs are not FDA-approved,"[6] meaning that FDA does not review compounded drugs to evaluate their safety, effectiveness, or quality before they reach patients. Compounding pharmacies—in stark contrast to commercial manufacturers of FDA-approved medicines—are not subject to labeling requirements, need not comply with cGMP regulations, need not subject their facilities to inspections by regulatory authorities, and have no reporting requirements for adverse events. FDA has warned that "[c]ompounded drugs . . . do not have the same safety, quality, and effectiveness assurances as approved drugs. Unnecessary use of

[5] *Human Drug Compounding*, U.S. FOOD & DRUG. ADMIN. (Dec. 18, 2024), https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding.

[6] *Id.*

compounded drugs . . . exposes patients to potentially serious health risks."[7] And Congress has limited legally permissible compounding activities to a very narrow set of circumstances outlined in Sections 503A and 503B of the Food, Drug and Cosmetic Act. *See* 21 U.S.C. §§ 353a, 353b.

The risks compounded products pose are not hypothetical. In 2012, the New England Compounding Center shipped compounded products contaminated with a fungus throughout the country for injection into nearly 14,000 patients' spines and joints. More than 100 people died of fungal meningitis. Afterwards, FDA commented:

> The 2012 fungal meningitis outbreak was not an isolated event. It was the most serious in a long history of serious adverse events associated with contaminated, super-potent, mislabeled, or otherwise poor quality compounded drugs. In addition, many serious adverse events linked to poor quality compounded drugs, including outbreaks of infections and deaths have occurred since then. And, because most compounders do not report adverse events to FDA, the agency may not be aware of adverse events associated with compounded drugs unless a health care provider submits an adverse event report regarding his or her patients or a state official notifies FDA.[8]

Company executives were convicted and received sentences of up to 14 years in prison.[9] In 2021, a different compounding pharmacist pled guilty to providing adulterated compounded drugs to cataract surgery patients that contained "an excessive amount of an inactive ingredient" that can damage sensitive eye tissue.[10] At least 68 patients were injected with the adulterated compounds,

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7 *Compounding and the FDA: Questions and Answers*, U.S. FOOD & DRUG. ADMIN. (June 29, 2022), https://web.archive.org/web/20240803214713/https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers.

8 FDA HUMAN DRUG COMPOUNDING PROGRESS REPORT: THREE YEARS AFTER ENACTMENT OF THE DRUG QUALITY AND SECURITY ACT 5 (2017), https://www.fda.gov/media/102493/download.

9 Press Release, *Former Owner of Defunct New England Compounding Center Resentenced to 14 Years in Prison in Connection with 2012 Fungal Meningitis Outbreak*, U.S. DEP'T OF JUSTICE (July 7, 2021), https://www.justice.gov/usao-ma/pr/former-owner-defunct-new-england-compounding-center-resentenced-14-years-prison.

10 Press Release, *Texas Pharmacist Pleads Guilty to Adulterating Drug Used in Cataract Surgeries*, U.S. FOOD & DRUG. ADMIN. & U.S. DEP'T OF JUSTICE (Oct. 13, 2021), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/texas-pharmacist-pleads-guilty-adulterating-drug-used-cataract-surgeries.

at two different surgery centers, over a period of months, and patients suffered near-immediate adverse events, including permanent blindness.[11]

These risks are present for compounded tirzepatide too. On November 1, 2024, FDA issued a warning about drugs compounded by Fullerton Wellness LLC of California after a patient noticed a black particulate in a vial of compounded semaglutide, and a joint FDA-California investigation uncovered conditions at Fullerton that could cause its drugs, including tirzepatide, to become contaminated.[12] Similarly, in March 2022, FDA inspected Plaintiff FarmaKeio and found that it "routinely use[d] non-pharmaceutical grade components for compounding drug products" and "[n]on-sterilized equipment . . . in sterile drug production,"[13] and issued a warning letter—that appears to be unresolved—for "serious deficiencies in . . . practices for producing drug products intended or expected to be sterile, which put patients at risk."[14] Critically—and concerningly—tirzepatide is also a sterile injectable.

Indeed, as tirzepatide compounding became more prevalent, government agencies began to warn the public about the risks these products pose. In July 2024, FDA sent a letter to compounding advocacy organizations warning that it had received "reports describing patients

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[11] Charlotte Huffman & Mark Smith, Dozens say they lost eyesight after routine surgery using compounded pharmacy drugs, WFAA (Feb. 9, 2019), https://www.wfaa.com/article/news/do-not-publish-yet/287-5f002ed3-e110-4063-9959-a2e5f54b5097 (last updated Feb. 13, 2019).

[12] FDA warns patients and health care professionals not to use compounded drugs from Fullerton Wellness, U.S. FOOD & DRUG. ADMIN. (Nov. 1, 2024), https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-patients-and-health-care-professionals-not-use-compounded-drugs-fullerton-wellness.

[13] Form FDA 483 to N. Am. Custom Labs., LLC d/b/a FarmaKeio Superior Custom Compounding, 6 (Mar. 10, 2022), https://www.fda.gov/media/160771/download.

[14] *E.g.*, Warning Letter from Div. of Pharma. Quality Op. II to J. Graves, Vice President, N. Am. Custom Labs., LLC d/b/a FarmaKeio Superior Custom Compounding (Nov. 18, 2022), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/north-american-custom-laboratories-llc-dba-farmakeio-superior-custom-compounding-642792-11182022.

who experienced adverse events following the administration of compounded . . . tirzepatide."[15] FDA reiterated that "compounded drug products, including compounded . . . tirzepatide products, are not FDA-approved. They do not undergo premarket review by FDA for safety, effectiveness, or quality."[16] FDA later advised the public of "multiple reports of adverse events, some requiring hospitalization, that may be related to dosing errors" associated with compounded GLP-1 drugs.[17] Poison control centers across the United States have also reported a troubling trend, seeing "a nearly 1,500% increase in calls since 2019 related to overdose or side effects of injectable weight-loss drugs."[18]

Leading organizations have also expressed concern. Last month, the American Diabetes Association "recommend[ed] against using non-Food & Drug Administration (FDA)-approved compounded GLP-1 and dual GIP/GLP-1 RA products due to uncertainty about their content, safety, quality, and effectiveness."[19] The Obesity Society, Obesity Action Coalition, and Obesity Medicine likewise issued a joint statement cautioning that "[u]nfortunately, many of the available alternatives [to GLP-1 therapies], like compounded versions of semaglutide and tirzepatide, are not what they are advertised to be."[20] Foreign governments have taken action. The Government

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15 Letter from S. Glueck, Pharm.D., FDA to P. Dickison, PhD, RN, Nat'l Council of State Bds. of Nursing (July 16, 2024), https://www.pa.gov/content/dam/copapwp-pagov/en/dos/department-and-offices/bpoa/nursing/fda-safety-alert.pdf.

16 *Id.*

17 *FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss*, U.S. FOOD & DRUG. ADMIN. (Dec. 18, 2024, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss.

18 Glucagon-like Peptide-1 (GLP-1) Agonists, AM.'S POISON CTRS., https://poisoncenters.org/track/GLP-1.

19 https://diabetes.org/newsroom/press-releases/american-diabetes-association-announces-statement-compounded-incretin#:~:text=The%20statement%20recommends%20against%20using,safety%2C%20quality%2C%20and%20effectiveness.

20 *Leading Obesity Expert Organizations Release Statement to Patients on Compounded GLP-1 Alternatives*, OBESITY MED. ASS'N (Jan. 8, 2024), https://obesitymedicine.org/blog/leading-obesity-expert-organizations-release-statement-to-patients-on-glp-1-compounded-alternatives/.

of Australia banned the development and sale of compounded anti-obesity drugs because of "increasing community concern" and "increasing reports of patients coming to harm from" compounded drugs promoted to aid with weight loss.[21] And the South African Health Products Regulatory Authority explained that these drugs "pose[] a public health and safety risk" due to "the unknown nature and safety of ingredients used in compounding."[22]

D. Lilly invested substantial funds and resources to resolve the tirzepatide shortage, but this action seeks to declare the shortage ongoing.

Over the past four years, Lilly has made the most significant manufacturing investment in its nearly 150-year history—committing more than $23 billion to build, expand, acquire, or obtain internal and external manufacturing facilities in the United States and Europe. Lilly employs thousands of manufacturing employees to run its manufacturing facilities 24 hours, 7 days per week, to ensure it continues to maximize its production. Lilly also obtained supplemental FDA approvals authorizing the sale of Mounjaro® and Zepbound® in single-use vials—both were originally approved in auto-injector devices—providing additional supply capacity and access to patients who need Lilly's medicines. As a result of Lilly's efforts, FDA updated its drug shortage database in August 2024 to reflect that "[a]ll doses of Mounjaro and Zepbound [were] available."[23] Two months later, on October 2, 2024, FDA determined the tirzepatide shortage was resolved,

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[21] Press Release, *Protecting Australians from unsafe compounding of replica weight loss products*, DEP'T OF HEALTH & AGED CARE (May 22, 2024), https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/protecting-australians-from-unsafe-compounding-of-replica-weight-loss-products.

[22] Press Release, *SAHPRA's Position On GLP1 And GIP-GLP1 Products That Are Compounded, Substandard And Falsified*, S. AFRICAN HEALTH PRODS. REGULATORY AUTH. (Nov. 8, 2024), https://www.sahpra.org.za/news-and-updates/sahpras-position-on-glp1-and-gip-glp1-products-that-are-compounded-substandard-and-falsifiedas/.

[23] Ned Pagliarulo, *Zepbound, Mounjaro back in supply as Lilly resolves shortage*, BIOPHARMA DIVE (Aug. 5, 2024), https://www.biopharmadive.com/news/eli-lilly-tirzepatide-supply-fda-doses-shortage/723269/.

explaining it "confirmed with [Lilly] that [its] stated product availability and manufacturing capacity can meet the present and projected national demand."[24]

Five days later, on October 7, 2024, Plaintiffs filed this suit challenging FDA's decision. The case was then stayed on FDA's unopposed motion on October 11, 2024. *See* ECF Nos. 27-28. As part of the stay, FDA asked for the Court to remand the matter to FDA so the agency could "reevaluate the decision at issue in this case." ECF No. 27, at 1. This stay remains in effect to date.[25]

E. FDA affirms its shortage determination, stating that it will take action against compounders beginning in February 2025.

On December 19, 2024, FDA issued a declaratory order with a supporting memorandum, confirming based on a thorough analysis that Lilly's tirzepatide medicines are not in shortage. *See* ECF No. 32, at 1; ECF No. 32-1. In that order and memorandum, FDA considered "detailed information" Lilly provided "regarding its production and inventory of [Mounjaro® and Zepbound®] at various points in time, including stock reports that show quantities supplied and demanded, and inventory held in stock, for all strengths of [Mounjaro® and Zepbound®]; cumulative quantities supplied to and demanded by its customers in the year 2024; projected demand and supply in future months; and wholesaler inventory data, among other information." ECF No. 32-1, at 3.

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[24] *FDA clarifies policies for compounders as national GLP-1 supply begins to stabilize*, U.S. FOOD & DRUG ADMIN. (Oct. 2, 2024), https://web.archive.org/web/20241003040400/https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.

[25] In noting their opposition to Lilly's intervention, Plaintiffs raised the fact that this case was administratively closed as a "procedural issue" to Lilly's motion. However, "administratively closing a case is merely a case-management tool" that does not prevent individuals from seeking relief from the court. *See CitiFinancial Corp. v. Harrison*, 453 F.3d 245, 250-51 & n.12 (5th Cir. 2006) (holding that it is not a final, appealable order); *Mire v. Full Spectrum Lending Inc.*, 389 F.3d 163, 167 (5th Cir. 2004) ("[Administrative closure] is the functional equivalent of a stay."). Indeed, despite the case being administratively closed, the parties filed two joint reports, one of which included a motion to extend the stay, and the Court ruled on that motion. *See* ECF Nos. 30-32. Plaintiffs are thus mistaken that the Court cannot hear Lilly's motion at this time.

On the flip side, FDA considered a range of purported evidence of shortage submitted by Plaintiffs and related entities. For example, "FDA received reports that some patients and pharmacists are not able to obtain the approved drugs," *id.* at 2, mostly via so-called "surveys" compounders conducted asking patients to report if they had "trouble"—whatever that could mean—buying brand-name obesity medicine. Compounders also submitted misleading "screenshots" from pharmacy order forms purporting to show low wholesaler inventory of tirzepatide on isolated days.[26] But, these screenshots represented a cherry-picked, isolated view that misses the larger supply picture; a wholesaler could have thousands of doses in stock in a different distribution center or have thousands coming, and any intermittent disruption in supply does not indicate a shortage. FDA considered this information and determined that these reports had "important limitations" and did "not demonstrate that Lilly will be unable to meet projected demand, especially when weighed against the Lilly-provided data." *Id.* at 3. FDA correctly noted that its shortage determinations are based on nationwide supply and demand, *see* 21 U.S.C. § 356c(h)(2)-(3); 80 Fed. Reg. 38915, 38921 (July 8. 2015), observing that it is not surprising "that patients and prescribers may still see intermittent localized supply disruptions as the products move through the supply chain from the manufacturer to wholesale distributors and pharmacies," ECF No. 32-1, at 2 n.5. FDA advised the Court of its declaratory order on the same day it was published.

While the stay continues, the December 19, 2024, joint status report indicates that the action will resume and proceed to preliminary injunction briefing. *See* ECF No. 32, at 2. Given the serious implications this action may have on Lilly's interests—including the timing of preliminary injunction briefing—Lilly now moves to intervene.

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[26] *See* Comment from The Alliance for Pharmacy Compounding to FDA Docket No. 2015-N-0030-0001 (Nov. 20, 2024), https://www.regulations.gov/comment/FDA-2015-N-0030-12242; Comment from The Alliance for Pharmacy Compounding to FDA Docket No. 2015-N-0030-0001 (Nov. 15, 2024), https://www.regulations.gov/comment/FDA-2015-N-0030-10384.

III. ARGUMENT

Lilly has a right to intervene under Rule 24(a)(2). This motion is timely; Lilly has an interest "relating to the property or transaction" at issue in the action; Lilly's ability to protect its interest would be impaired or impeded by the disposition of this action; and the existing parties do not adequately represent Lilly's interests. Independently, the Court should permit Lilly to intervene under Rule 24(b) so it can protect its valuable interests in its FDA-approved medicines.

A. Lilly has the right to intervene under Rule 24(a).

A party has a right to intervene where: (1) "the application for intervention [is] timely"; (2) the party has "an interest relating to the property or transaction which is the subject of the action"; (3) the party is "so situated that the disposition of the action may, as a practical matter, impair or impede his ability to protect that interest"; (4) the party's "interest [is] inadequately represented by the existing parties to the suit." *Texas v. United States*, 805 F.3d 653, 657 (5th Cir. 2015). Lilly meets all four requirements.

1. Lilly's motion is timely.

Courts consider a variety of factors when assessing whether a motion to intervene is timely, including "the length of time during which the would-be intervenor actually knew" of its interest before intervening and the "extent of the prejudice . . . to the litigation" from any delay. *See Edwards v. City of Houston*, 78 F.3d 983, 1000 (5th Cir. 1996). All these factors support Lilly's motion.

First, Lilly moved quickly to intervene. This case was filed on October 7, 2024, but it was stayed by unopposed motion just four days later. *See* ECF Nos. 27-28. During the stay, FDA reevaluated its decision, and the case was dormant; there was no certainty that the case would proceed at all. *E.g.*, ECF No. 30 (Nov. 21, 2024 Joint Status Report 1-2). FDA reaffirmed its shortage determination by a declaratory order on December 19, 2024, *see* ECF No. 32-1, and, on

the same day, the parties filed a joint status report indicating that Plaintiffs intend to file a preliminary injunction motion. *See* ECF No. 32 (noting, *inter alia*, that the "parties will confer regarding a preliminary injunction briefing schedule"). This report was the first indication that the litigation would continue post-remand and implicate Lilly's interests.

Lilly moved quickly to intervene after the December 19, 2024, status report, filing this motion within 13 days. Lilly's motion thus comes much faster than in other cases where courts found a motion to intervene to be timely. *See, e.g.*, *Sierra Club v. Espy*, 18 F.3d 1202, 1205-07 (5th Cir. 1994) (motion found timely when made within two months of becoming aware that interests were affected); *Pam Int'l, Inc. v. Kam Coach, LLC*, 2008 WL 2037302, at *2 (E.D. Tex. May 8, 2008) (finding timely a motion filed within a month of being put on notice of indemnification and two months after a defendant answered); *Ass'n of Pro. Flight Attendants v. Gibbs*, 804 F.2d 318 (5th Cir. 1986) (five month lapse found not unreasonable). Indeed, "most of [the Fifth Circuit's] case law rejecting petitions for intervention as untimely concern motions filed after judgment was entered in the litigation." *Edwards*, 78 F.3d at 1001.

Lilly's intervention will not prejudice the other parties. This "factor [concerns] only . . . the prejudice caused by the applicants' delay, not that prejudice which may result if intervention is allowed." *Id*. at 1002. Here, there has been no delay, given Lilly had no reason to intervene while FDA was reconsidering its shortage decision and the case was stayed. Nor has there been extensive completed motion practice or proceedings that would be undermined by Lilly's intervention. Once FDA issued its declaratory order and the case appeared likely to proceed, Lilly moved quickly.

2. Lilly has a legally protected interest.

Lilly has a protected interest as the exclusive manufacturer of FDA-approved tirzepatide. Indeed, Lilly's NDA for Mounjaro® and Zepbound® itself is a transferable asset and thus

property—and a "property interest . . . almost always" satisfies the "protectable interest" requirement of Rule 24(a)(2). *Texas*, 805 F.3d at 657-58. Moreover, courts routinely find that "organizations that successfully petition for adoption of" a regulatory scheme and its "'intended beneficiar[ies]" "ha[ve] a legally protected interest in a case challenging that system." *NextEra Energy Cap. Hldgs., Inc. v. D'Andrea*, 2022 WL 17492273, at *3 (5th Cir. Dec. 7, 2022) (holding that parties granted a contractual right by a statute have a right to intervene in an action challenging the statute's constitutionality); *City of Houston v. Am. Traffic Solutions, Inc.*, 668 F.3d 291, 293-94 (5th Cir. 2012) (holding that an organization that led the effort in passing "a city charter amendment" had "a particular interest in cementing their electoral victory and defending the charter amendment itself"). Here, not only does Lilly have interests in its FDA-approved medicines, but Congress has also granted it market exclusivity for tirzepatide drug products for its innovative breakthrough. 21 U.S.C. § 355(c)(3)(E)(ii), (j)(5)(F)(ii); 21 C.F.R. § 314.108(b)(2). Thus, Lilly has a "direct, substantial, legally protectable interest in the proceedings," *Texas*, 805 F.3d at 657, including because it affects Lilly's right to exclusivity. *Alamo Brewing Co. v. Old 300 Brewing, LLC*, 2014 WL 12876370, at *4 (W.D. Tex. May 21, 2014) (permitting intervention by party holding the right to use and license a trademark in an action about the fair use of that trademark); *see also Mova Pharma. Corp. v. Shalala*, 140 F.3d 1060, 1074 (D.C. Cir. 1998) ("Upjohn was entitled to intervene as of right" as it "was in danger of losing market share to Mylan if the district court denied the injunction and allowed Mylan's product on the market."); *Mylan Pharms. Inc. v. FDA*, 789 F. Supp. 2d 1, 8 (D.D.C. 2011) ("[A]n ANDA applicant has a legally protected interest in the FDA's consideration of its own ANDA, and it might suffer harm as a result of the FDA's denial or neglect.").

Further, Lilly has a protected interest in protecting the confidential information that it submitted to FDA that will likely be part of the administrative record. Since the declaratory order is based on Lilly's "stock reports," "inventory held in stock," and projections, *see* ECF No. 32-1, at 3, the administrative record and future briefing will likely involve these documents, threatening their disclosure to compounders and the general public. Congress recognized that manufacturers must share confidential information with FDA during shortage situations, and it specified that such confidentiality must be maintained. *See* 21 U.S.C. §§ 356c(d), 356e(c)(2). Lilly has a right to participate in this action to protect the confidentiality of that "detailed information and data."

3. This action may impair or hinder Lilly's ability to protect its interests.

Plaintiffs seek a declaration voiding the declaratory order and requiring FDA to place tirzepatide on the drug shortage list, Compl. at 22, and Plaintiffs admit that they seek to continue to sell unapproved copies of Lilly's FDA-approved medicines if they prevail, *see id.* ¶ 52, all of which would impair Lilly's interests. In considering whether the impairment prong is met, courts consider the "practical" effect of the litigation on the movant's interest. *E.g.*, *Lucid Grp. USA Inc. v. Johnson*, 2023 WL 4539846, at *2 (W.D. Tex. Mar. 20, 2023) (holding that an association of car dealers' "interest in upholding Texas's . . . car dealership statutes" could be impaired by a manufacturer's challenge to those statutes); *Cayuga Nation v. Zinke*, 324 F.R.D 277, 282 (D.D.C. 2018) (holding that an action impacting a tribe's right to federal funds and affecting its governance could impair interests of a tribe's council).

Beyond the billions it spent developing, testing, and bringing to market its revolutionary medicines, Lilly has committed over $23 billion to increase its manufacturing capacity.[27] And,

[27] Press Release, *Lilly Increases Manufacturing Investment to $9 Billion at Newest Indiana Site to Boost API Production for Tirzepatide and Pipeline Medicines*, ELI LILLY & CO. (May 24, 2024), https://investor.lilly.com/news-releases/news-release-details/lilly-increases-manufacturing-investment-9-billion-newest.

even though Lilly's FDA-approved medicines are commercially available and Lilly's supply meets or exceeds demand, *see* ECF No. 32-1, at 1-2, Plaintiffs are nevertheless trying to justify continuing to profit from Lilly's investment by undercutting the safety and efficacy standards that support Lilly's FDA-approved medicines. If Plaintiffs continue compounding, more patients will be exposed to untested, unapproved, and potentially unsafe knock-off tirzepatide drugs rather than Lilly's FDA-approved Mounjaro® and Zepbound®. Among other harms, patients may wrongly attribute their injury from these products to Lilly, harming the goodwill Lilly developed for its FDA-approved tirzepatide medicines. This case directly impairs Lilly's interests, including in circumventing Lilly's statutory exclusivity and challenging FDA's entire statutory and regulatory framework to ensure patients receive only FDA-approved tirzepatide medicine from Lilly, rather than unapproved and untested drugs from compounders. *NextEra Energy*, 2022 WL 17492273, at *4 (litigation concerning a regulatory "scheme's validity" impairs the interests of its intended beneficiaries); *City of Houston*, 668 F.3d at 293-94 (litigation concerning the constitutionality of a charter amendment impaired interests of groups that advocated for the amendment).

4. No party adequately represents Lilly's interests.

Lilly also meets Rule 24(a)(2)'s final requirement because FDA does not adequately represent Lilly's interests. A movant "need not show that the representation by existing parties will be, for certain, inadequate." *Texas*, 805 F.3d at 661. Instead, the Rule "is satisfied if the applicant shows that the representation of his interest 'may be' inadequate." *Edwards*, 78 F.3d at 1005; *Supreme Beef Processors, Inc. v. U.S. Dept. of Agriculture*, 275 F. 3d 432, 437-38 (5th Cir. 2001). Even where, as here, an intervenor shares the "same ultimate objective" as the government, this element is satisfied if the intervenor's "interests diverge from the [government's] interests in a manner germane to the case." *Texas*, 805 F.3d at 661-62. In fact, "[i]t is . . . 'axiomatic' that the interests of private [parties] 'will diverge from those' of . . . state actors." *Alliance for Hippocratic*

Med. v. FDA, 2024 WL 1260639, at *6 (N.D. Tex. Jan. 12, 2024). For example, the Fifth Circuit in *Texas* found that interests of the federal government and potential recipients of a federal immigration program diverged even though both sought to uphold the program, because the federal government also sought to "secur[e] an expansive interpretation of executive authority, efficiently enforc[e] the immigration laws, and maintain[] its working relationship with the States," whereas the recipients were concerned only with private benefits. *Texas*, 805 F.3d at 663.

Lilly's interests may not be fully represented by the government for three reasons. *First*, as in *Texas*, FDA's interests are different from Lilly's. FDA is interested not only in defending its declaratory order but also in defending its "executive authority," *id.*, "efficiently enforcing the . . . law," *id.*, and "represent[ing] the broad public interest," *Alliance for Hippocratic*, 2024 WL 1260639, at *5. The fact that FDA's "broader interests 'may diverge' from [Lilly's] 'in the future'" "'is enough' for the purposes of this factor." *Id.* at *6 (holding that the court "need not 'say for sure that the [government's] more extensive interests will *in fact* result in inadequate representation'").

Second, Lilly is concerned that FDA may not agree with it about the correct interpretation of section 503A of the FDCA. Lilly believes that the plain text of section 503A does not allow compounding pharmacies like FarmaKeio to manufacture copies of commercially available drug products—and that conclusion does not turn in any way on whether tirzepatide is currently on the shortage list. Specifically, compounding pharmacies under 503A are only permitted to make "essentially a copy" of an FDA-approved medicine in certain limited circumstances. *See* 21 U.S.C. § 353a. That drug product appearing on FDA's drug shortage list is ***not one of them***. Unlike Section 503B of the FDCA, Section 503A makes no mention of drug shortages. *Compare* 21 U.S.C. § 353b(a)(1)(2)(A)(ii), *with* 21 U.S.C. § 353a. Rather, it has a narrow exception to the

"essentially a copy" restriction when a medicine is not "commercially available." 21 U.S.C. § 353a. Commercial availability is not the same as a drug shortage, as confirmed by legislative history and statutory text. Plaintiffs have alleged that FDA disagrees and has chosen to allow compounding pharmacies to mass-manufacture copies of commercially available drugs if they are on the shortage list. *E.g.*, Compl. ¶ 20. If Plaintiffs are correct, no party in this litigation adequately represents Lilly's interest in seeing the appropriate application of section 503A for tirzepatide—a dispositive question for one of the plaintiffs here.

Third, FDA may not adequately represent Lilly's interests in the event of an appeal. While Lilly believes FDA's shortage decision is appropriate, in the event of an adverse decision, Lilly has no way of knowing if FDA would appeal. The only way Lilly can ensure its rights are protected in the event of appeal is by intervening in the lawsuit.

B. Alternatively, the Court should permit Lilly to intervene under Rule 24(b).

Independently, the Court should allow Lilly to intervene under Rule 24(b). This Rule gives the Court discretion to "permit anyone to intervene who," on a timely application, shows that it "has a claim or defense that shares with the main action a common question of law or fact" and the intervention will not "unduly delay or prejudice the adjudication" of Plaintiffs' rights. FED. R. CIV. P. 24(b); *Franciscan Alliance Inc. v. Azar*, 414 F. Supp. 3d 928, 933 (N.D. Tex. 2019); *Reid v. Gen. Motors Corp.*, 240 F.R.D. 257, 260 (E.D. Tex. 2006). Lilly meets all requirements.

First, for the reasons described above, *see supra* Part III.A.1, Lilly's motion is timely. Lilly moved quickly to join the lawsuit after FDA issued its declaratory order and the parties indicated that the litigation may continue.

Second, Lilly's defense has common questions of law and fact with the main action. Lilly will demonstrate that FDA's decision was sound, thus rebutting Plaintiffs' allegations. Among other things, Lilly's defense will show that Lilly's supply of tirzepatide exceeds demand and that

FDA's declaratory order correctly determined that any localized or intermittent patient difficulty in obtaining a specific dose of a specific medication at a specific pharmacy cannot establish a shortage under 21 U.S.C. § 356c(h)(2). Moreover, Lilly may raise additional defenses that FDA may not raise, such as unclean hands or lack of standing against FarmaKeio, as the latter's compounding of tirzepatide is unlawful regardless of whether tirzepatide were in shortage.

Finally, intervention will not unduly delay or prejudice the adjudication of this action. The case continues to be stayed and the Court has not yet entered a schedule for resolution of the matter or plaintiffs' likely forthcoming preliminary injunction motion. By intervening now, Lilly can participate in discussions with the parties on a quick resolution to the matter.

IV. CONCLUSION.

For all of these reasons, the Court should allow Lilly to intervene in this case under either Rule 24(a) or Rule 24(b).

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Respectfully submitted,

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