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UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF FLORIDA TAMPA DIVISION

ELI LILLY AND COMPANY,

Case No.

Plaintiff,

JURY TRIAL DEMANDED

v.

PHTB LLC D/B/A PRECISION HEALTH TAMPA BAY,

Defendant.

COMPLAINT FOR TRADEMARK INFRINGEMENT, FALSE ADVERTISING, FALSE DESIGNATION OF ORIGIN AND DECEPTIVE AND UNFAIR TRADE PRACTICES

INTRODUCTION

1. This is an action to protect patients from unstudied, unapproved, and unsafe drugs masquerading as Plaintiff Eli Lilly and Company's ("Lilly") FDAapproved medicines for adults with type 2 diabetes, obesity, or excess weight and weight-related medical problems. Defendant PHTB LLC d/b/a Precision Health Tampa Bay has designed its websites, social media, and advertising materials to deceive patients into thinking Defendant offers a way to obtain Lilly's clinically studied medicines, when in reality Defendant offers no such thing.¹ Lilly therefore brings this action under federal and state law to protect patients from Defendant's dangerous, deceptive, and unlawful practices.

2. For nearly 150 years, Lilly has worked tirelessly to develop and deliver trusted and innovative medicines that meet critical and unmet patient needs. Lilly's proprietary MOUNJARO[®] and ZEPBOUND[®] are two such first-of-their-kind medicines, which are indicated for the serious conditions afflicting many tens of millions of Americans. To advance treatment of these chronic conditions, Lilly used its extensive experience with world-class medicines to develop the brand-new class of GLP-1 (glucagon-like peptide-1) and GIP (glucose-dependent insulinotropic polypeptide) dual-receptor agonists, which includes tirzepatide, the active ingredient in Lilly's MOUNJARO[®] and ZEPBOUND[®]. Lilly's MOUNJARO[®] and ZEPBOUND[®].

¹ In support of this Complaint, Lilly's allegations are upon actual knowledge with respect to itself and its own acts, and upon information and belief as to all other matters.

3. Before obtaining FDA approval, Lilly's new medicines underwent years-long clinical trials, which tested them for safety, quality, and effectiveness on thousands of patients. When approving these medicines, the FDA called Lilly's "novel" MOUNJARO[®] an "important advance" and observed that Lilly's ZEPBOUND[®] "addresses an unmet medical need."

https://web.archive.org/web/20221028212253/https://www.fda.gov/newsevents/press-announcements/fda-approves-novel-dual-targeted-treatment-type-2diabetes (archived FDA MOUNJARO[®] approval press announcement); https://www.fda.gov/news-events/press-announcements/fda-approves-newmedication-chronic-weight-management (FDA ZEPBOUND[®] approval press announcement).

4. Compounded products sold as "tirzepatide," meanwhile, are not approved or even reviewed by the FDA. Pharmacies currently offering compounded versions of tirzepatide are not required to follow the FDA's "good manufacturing practices," nor to comply with the same controls on sterility and safe storage as manufacturers of FDA-approved medicines. They are also not required to report adverse events—an important regulatory requirement imposed on manufacturers of FDA-approved medicines for patient safety. Compounded drugs are not tested for safety, quality, or efficacy in clinical trials. Accordingly, and as the FDA has warned, "compounded drugs pose a higher risk to patients than FDA-approved drugs," such as MOUNJARO[®] and ZEPBOUND[®].

https://www.fda.gov/drugs/human-drug-compounding/drug-compounding-anddrug-shortages (FDA explainer on Drug Compounding).

5. Defendant falsely and unlawfully trades on Lilly's work, reputation, and goodwill, offering unproven and unapproved compounded drugs as if they were genuine Lilly medicines or generic versions thereof. But Defendant does not offer Lilly's proprietary MOUNJARO[®] and ZEPBOUND[®] medicines, nor any FDAapproved "generic" version of them. Indeed, Defendant's drugs have undergone *none* of the rigorous studies or approval processes that Lilly's medicines have. Passing Defendant's compounded drugs off as Lilly's MOUNJARO[®] and ZEPBOUND[®] is not merely deceptive—it's dangerous.

6. Defendant's intentional deception of patients starts from the top of the "Tirzepatide" webpage on Defendant's "https://precisionhealthandweightloss.com" website, where Defendant boldly proclaims that "Tirzepatide's brand name is Mounjaro, and we offer it at Precision Health," as shown below:



7. Despite this impossible-to-miss headline, Defendant does not offer "Mounjaro" at Precision Health. Nor is Defendant's product, which purports to contain tirzepatide, produced by Eli Lilly, approved by the FDA, or tested for safety, quality, and effectiveness in any clinical trial, including Lilly's SURMOUNT[®] clinical trials, as Defendant claims elsewhere on its website.

8. Lilly therefore brings this action pursuant to the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*, and for violation of Florida statutory and common law regarding deceptive and unfair trade practices. Lilly's claims arise out of Defendant's infringement of Lilly's rights in the MOUNJARO® and ZEPBOUND® trademarks and Defendant's acts of false designation of origin, false advertising, and deceptive and unfair trade practices.

THE PARTIES

9. Plaintiff Lilly is a corporation organized and existing under the laws of Indiana and has its principal place of business in Indiana.

 Defendant is a Florida limited liability company with a principal place of business at 17523 North Dale Mabry Highway, Lutz, Florida 33548, in this District. Its registered agent is Registered Agents Inc., with registered agent address 7901 4th Street N, Suite 300, St. Petersburg, Florida 33702. Defendant PHTB LLC additionally reports two title managers: Tara Hrobowski-Blackman, located at P.O. Box 945, Odessa, Florida 33556 and Tamika Hrobowski-Houston, located at P.O. Box 366093, Atlanta, Georgia 30336.

11. Defendant also conducts business using the website"https://precisionhealthandweightloss.com," including the webpage"https://precisionhealthandweightloss.com/phtb."

JURISDICTION AND VENUE

12. The Court has subject matter jurisdiction over the Lanham Act causes of action pleaded herein pursuant to 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331 and 1338(a). The Court has supplemental jurisdiction over the state and common law causes of action pleaded herein pursuant to 28 U.S.C. §§ 1338(b) and 1367(a).

13. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Defendant operates and conducts business in this District. Defendant is subject to personal jurisdiction in this District.

LILLY'S FDA-APPROVED TIRZEPATIDE MEDICINES: MOUNJARO[®] AND ZEPBOUND[®]

14. Lilly's MOUNJARO[®] is a novel treatment for type 2 diabetes, a chronic and progressive condition facing more than 30 million Americans. As the FDA has noted, "Despite the availability of many medications to treat diabetes, many patients do not achieve the recommended blood sugar goals."

https://web.archive.org/web/20221028212253/https://www.fda.gov/news-

events/press-announcements/fda-approves-novel-dual-targeted-treatment-type-2-

diabetes (archived FDA MOUNJARO® approval press announcement).

MOUNJARO[®] targets this problem head-on using an innovative active

pharmaceutical ingredient, tirzepatide. Before it received FDA approval, Lilly's

MOUNJARO[®] was clinically proven to improve blood sugar control "more effective[ly] than the other diabetes therapies with which it was compared in clinical studies." *Id.*

15. The FDA approved MOUNJARO[®] and indicated it in addition to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. As part of the approval process, Lilly submitted data on safety, quality, and effectiveness collected through clinical trials involving thousands of patients. Lilly's MOUNJARO[®] is thus proven safe and effective when used as directed.

16. In addition to MOUNJARO[®], Lilly markets and sells ZEPBOUND[®], another proprietary, FDA-approved treatment option containing the active pharmaceutical ingredient tirzepatide. With ZEPBOUND[®], Lilly aims to help the many dozens of millions of American adults with obesity or with excess weight and weight-related medical problems lower their risks of cardiovascular disease and other leading causes of death. As the FDA has noted, ZEPBOUND[®] "addresses an unmet medical need" by targeting "chronic weight management (weight reduction and maintenance)" through a new method of hormone receptor activation. https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-chronic-weight-management (FDA ZEPBOUND[®] approval press announcement).

17. As with MOUNJARO[®], the safety, quality, and effectiveness of ZEPBOUND[®] was established through rigorous clinical trials featuring thousands of patients. The FDA recently approved ZEPBOUND[®] and indicated it for adults with

obesity (with a BMI of 30 kg/m2 or greater) or those who are overweight (with a $BMI \ge 27 \text{ kg/m2}$ or greater) and also have at least one weight-related additional condition, such as hypertension (high blood pressure), dyslipidemia (high cholesterol or fats in blood), type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease, to lose weight. It should be used with a reduced-calorie diet and increased physical activity.

18. Lilly's tirzepatide medicines are the result of billions of dollars of investments in research and development, which included dozens of studies and trials.

19. Countless highly specialized personnel ensure Lilly medicines meet quality and safety standards. Lilly manufactures its medicines under strict controls in state-of-the-art facilities. Transforming tirzepatide API to medicine is a complex, methodical, and science-based process. Lilly follows Good Manufacturing Practices (GMP), which are regulations that "provide[] for systems that assure proper design, monitoring, and control of manufacturing processes and facilities." https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-currentgood-manufacturing-practice-cgmp (FDA explainer on GMP). GMPs include "establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories." *Id.* GMPs help "prevent instances of contamination, mix-ups, deviations, failures, and errors." *Id.*

20. Each step in Lilly's process to manufacture its tirzepatide medicines from sourcing and chemical synthesis of the API to formulation and device assembly and packaging—requires extensive testing and controls and specialized equipment. Lilly's medicines must be, and always are, accompanied with important, FDAapproved labels, instructions, and warnings.

21. Lilly now promotes, offers, and sells MOUNJARO[®] and ZEPBOUND[®] medicines in Florida and throughout the United States.

LILLY'S MOUNJARO® AND ZEPBOUND® TRADEMARKS

22. Lilly uses the trademarks MOUNJARO[®] and ZEPBOUND[®] (the "Lilly Marks") to identify and promote Lilly's proprietary, FDA-approved medicines with the active pharmaceutical ingredient tirzepatide. Lilly markets and sells MOUNJARO[®] and ZEPBOUND[®] throughout the United States using the Lilly Marks.

23. Lilly first adopted and used the MOUNJARO[®] mark at least as early as June 3, 2022, and has used the MOUNJARO[®] mark continuously since that time. Lilly has extensively promoted, advertised, and marketed its prescription-only diabetes medicine bearing the MOUNJARO[®] mark in many different channels, directed both to healthcare professionals and to patients.

24. Lilly is the owner of two federal trademark registrations for MOUNJARO[®], U.S. Reg. Nos. 6,809,369 (issued August 2, 2022) and 7,068,463 (issued May 30, 2023). True and correct copies of Plaintiff Lilly's registrations for the MOUNJARO[®] mark are attached hereto as part of **Exhibit A.** Lilly additionally

has several pending applications to register its MOUNJARO[®] mark in connection with more classes, services, and goods, including U.S. Trademark Ser. Nos. 97/596,856, 97/668,206, and 98/253,743. As a result of its use of the MOUNJARO[®] mark, Lilly also owns valuable common law and other rights in and to the MOUNJARO[®] mark.

25. Lilly first adopted and used the ZEPBOUND[®] mark at least as early as November 30, 2023, and has used the ZEPBOUND[®] mark continuously since that time. Lilly has extensively promoted, advertised, and marketed its prescription-only weight-loss medicine bearing the ZEPBOUND[®] mark in many different channels, directed both to healthcare professionals and to patients.

26. Lilly is the owner of one federal trademark registration for ZEPBOUND[®], U.S. Reg. No. 7,288,373 (issued January 23, 2024). A true and correct copy of Plaintiff Lilly's registration for the ZEPBOUND[®] mark is attached hereto as part of **Exhibit A.** Lilly additionally has several pending applications to register its ZEPBOUND[®] mark, including U.S. Trademark Ser. Nos. 97/530,451, 97/530,456, and 98/295,137. As a result of its use of the ZEPBOUND[®] mark, Lilly also owns valuable common law and other rights in and to the ZEPBOUND[®] mark.

27. Lilly conceived the Lilly Marks to stand out in the marketplace. The Lilly Marks do not describe any attributes of either medicine and are accordingly inherently distinctive.

28. Lilly promotes, advertises, and markets MOUNJARO[®] and ZEPBOUND[®] both to healthcare professionals and to patients, among others,

through various channels, including on the websites mounjaro.com, mounjaro.lilly.com, zepbound.com, and zepbound.lilly.com, in social media, in online advertisements, and on television.

29. As a result of Lilly's use, promotion, advertising, and marketing of MOUNJARO[®] and ZEPBOUND[®], the Lilly Marks are exclusively associated with Lilly, serve to identify genuine Lilly products, and are valuable assets of Lilly.

THE RISKS OF COMPOUNDING

30. Upon information and belief, Defendant markets and sells to patients compounded drug products that purport to contain tirzepatide and that are not approved by the FDA or any other global regulatory agency ("Unapproved Compounded Drugs").

31. Typically, prescription medicines must undergo a rigorous premarket approval process. Federal law creates a narrow exception for compounding, which the FDA defines as 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."

https://www.fda.gov/drugs/guidance-compliance-regulatory-information/humandrug-compounding (FDA guidance on drug compounding law compliance). This narrow exception applies, for instance, where a patient cannot safely take a commercially manufactured FDA-approved drug due to an allergy to a particular dye.

32. The Food, Drug, and Cosmetic Act (FDCA), in section 503A,

prescribes a rigid set of requirements that compounding pharmacies must meet, including a requirement that compounding occur only "on the prescription order that a compounded product is necessary for the identified patient." This restriction is important because compounding pharmacies are not required to comply with GMP, so they are only permitted to produce a small amount based on the specific needs of specific patients. The FDA has explained the importance of this requirement to ensure that compounding pharmacies "are not actually operating as conventional manufacturers":

The longer a compounded sterile drug product that has been contaminated is held by a pharmacist or physician before distribution, or held in inventory in a health care facility before administration, the greater the likelihood of microbial proliferation and increased patient harm. Because of these and other risks, the FD&C Act places conditions on compounding that must be met for compounded drugs to qualify for the exemptions in section 503A, [including that] compounding is for an identified individual patient, drugs compounded in advance of receiving prescriptions are compounded only in limited quantities, and drugs are distributed pursuant to a valid patient-specific prescription. These conditions are meant to help ensure that compounding under section 503A is based on individual patient needs, and that entities purportedly operating under section 503A are not actually operating as conventional manufacturers.

https://www.fda.gov/media/97347/download (FDA prescription requirement

compliance guidance for industry).

33. As the FDA further explained, "The *prescription requirement* under

section 503A is a critical mechanism to distinguish compounding by a licensed

pharmacist or licensed physician from conventional manufacturing, and to ensure

that drug products compounded under section 503A, which are not FDA-approved,

are not subject to the requirement that labeling bear adequate directions for use, and are not subject to []GMP requirements, are provided to a patient only based on individual patient need." *Id.* (emphasis in original).

34. Compounders are also limited in their ability to engage in a practice called anticipatory compounding, which is when, "based on a history of receiving prescriptions for a particular drug product to be compounded for an identified individual patient, and in the context of an established relationship with a particular prescriber or patient, a pharmacist or physician will compound a batch of drugs in anticipation of receiving another patient-specific prescription. The compounder then provides the drugs to a patient or health care provider when a prescription for an identified individual patient is received." *Id.* As the FDA further explained:

[A]nticipatory compounding [] has risks. For example, if a problem occurs during compounding, such as contaminating a drug product that is supposed to be sterile, or producing subpotent or superpotent sterile or non-sterile drugs, it could affect numerous patients, and not just one. Because drug products compounded in accordance with section 503A are exempt from CGMP requirements, there is an inherently greater chance of a production mistake or contamination. Restricting anticipatory compounding to limited quantities serves to limit the number of patients likely to be affected if there are drug product mix-ups or contamination. The limitations on anticipatory compounding in section 503A (i.e., compounding must be in "limited quantities" and based on an "established relationship") help to protect patients from product quality issues. These limitations on anticipatory compounding also help to distinguish licensed pharmacists or licensed physicians compounding drug products under section 503A for individual patients from conventional manufacturers, who generally produce larger quantities of drugs that are distributed without a prescription.

Id. (emphasis added).

35. According to the FDA, "[c]ompounded drugs are not FDA-approved.

This means that FDA does not review these drugs to evaluate their safety,

effectiveness, or quality before they reach patients." The FDA has warned that: "Compounded drugs . . . do not have the same safety, quality, and effectiveness assurances as approved drugs. Unnecessary use of compounded drugs unnecessarily exposes patients to potentially serious health risks. Because compounded drugs are not FDA-approved, FDA does not verify their safety, effectiveness, or quality before they are marketed." https://www.fda.gov/drugs/human-drugcompounding/compounding-and-fda-questions-and-answers (FDA drug compounding FAQ).

36. Health risks from compounded drugs are serious. In 2021, a pharmacist pled guilty to providing adulterated compounded drugs to cataract surgery patients. The adulterated compounds contained "an excessive amount of an inactive ingredient" that can damage sensitive eye tissue. https://www.fda.gov/inspectionscompliance-enforcement-and-criminal-investigations/press-releases/texaspharmacist-pleads-guilty-adulterating-drug-used-cataract-surgeries (FDA press announcement reguilty plea). At least 68 patients were injected with the adulterated compounds, at two different surgery centers, over a period of months, even though patients suffered near-immediate adverse events, including permanent blindness. https://www.wfaa.com/article/news/do-not-publish-yet/287-5f002ed3-e110-4063-9959-a2e5f54b5097 (WFAA article re outbreak). One patient had believed "every pill you take, every shot you take is tested" and was surprised to learn that compounded drugs were neither fully tested nor deemed safe or otherwise approved by the FDA. *Id.*

37. There are countless other examples of people experiencing serious injury from taking unregulated medicines. Inappropriate drug compounding caused at least 73 reported compounding errors between 2001 and 2019. These errors led to more than 1,562 adverse events and at least 116 deaths.

https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2020/usillnesses-and-deaths-associated-with-compounded-or-repackaged-medications-2001-19 (U.S. Illnesses and Deaths Associated With Compounded or Repackaged Medications, 2001–19).

38. Lilly has seen problems first-hand for compounded tirzepatide. Lilly has discovered compounded drugs advertised as tirzepatide with safety, sterility, and efficacy problems. Some contain bacteria, high impurity levels, different colors (pink, instead of colorless), or a chemical structure different from the tirzepatide in Lilly's FDA-approved medicines. In at least one instance, Lilly saw nothing more than sugar alcohol. Lilly also has received reports of patients experiencing significant adverse events after being injected with non-Lilly tirzepatide, including a patient who experienced a seizure and was admitted to the Intensive Care Unit and other patients who experienced severe allergic reactions. According to the FDA's Adverse Events Reporting System (FAERS), to date, over 150 adverse events associated with compounded or so-called (but not actually) "generic" tirzepatide have been reported, including over 100 "serious cases" and at least 5 deaths.

39. Consequences from compounded drugs may be deadly. In October2012, compounded drugs contaminated with a fungus were shipped throughout the

country and later injected into patients' spines and joints. After these contaminated

products were injected into nearly 14,000 patients, more than 60 people died of

fungal meningitis. Id. Regarding this outbreak, the FDA has written:

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.

https://www.fda.gov/media/102493/download (FDA Compounding

Progress Report).

WIDESPREAD SAFETY CONCERNS ABOUT COMPOUNDED TIRZEPATIDE

40. Regulators and law enforcement across the United States and abroad have recognized the safety concerns with compounded tirzepatide and other incretins. They have issued warnings, and in at least one instance, banned incretin compounding.

41. The FDA, for example, has consistently and repeatedly raised its concerns with compounding generally and compounded incretins more specifically. https://www.fda.gov/media/97347/download (FDA prescription requirement compliance guidance for industry). The FDA specifically has targeted compounded tirzepatide as a threat to consumer safety. The Director of the FDA's Office of Unapproved Drugs and Labeling Compliance has issued multiple warning letters to compounding pharmacies purportedly selling compounded tirzepatide products

because they are not safe or effective. https://www.fda.gov/inspections-complianceenforcement-and-criminal-investigations/warning-letters/us-chem-labs-669074-02072024 (FDA warning letter re US Chem Labs);

https://www.fda.gov/inspections-compliance-enforcement-and-criminalinvestigations/warning-letters/synthetix-inc-dba-helix-chemical-supply-668918-02072024 (FDA warning letter re Synthetix Inc. DBA Helix Chemical Supply).

42. Across the country, at least nine state pharmacy boards, along with several state poison centers, have issued guidance and warnings regarding the risks to patients of compounded incretins. The Alabama Board of Pharmacy notified all licensed pharmacists and pharmacies that "even when compounding of [incretins] is allowable under [federal law], ... the use of any non-pharmaceutical grade active pharmaceutical ingredient (API), or one not produced by an FDA-registered establishment, is prohibited." https://www.albme.gov/press-release/concerns-withsemaglutide-and-other-glp-1-receptor-agonists (Alabama Board of Medical Examiners press release). And the Maryland Poison Control Center warned that buying compounded incretins "online puts people at risk due to the medicine not being regulated and/or being sold from a source that is not licensed," including because those compounded products "have not been evaluated for safety and effectiveness by the FDA." https://blog.mdpoison.com/2024/03/semaglutide (Blog of the Maryland Poison Center).

43. The issue of unsafe compounded drugs purporting to contain tirzepatide has also received international attention. Australia recently banned the development

and sale of compounded anti-obesity medications because of "increasing community concern" and "increasing reports of patients coming to harm from" compounded incretin drugs. The ban—effective October 2024—targets compounded drugs that are "being misrepresented and sold as replica [] Mounjaro®."

https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/protectingaustralians-from-unsafe-compounding-of-replica-weight-loss-products (Australia Minister for Health and Aged Care press release). As Mark Butler, Australia's Minister for Health, said, "Australians should be able to have faith in the medications they use, including compounded medicines," and the ban "will protect Australians from harm and save lives." *Id.*

44. Doctors and patient groups recognize the problems with compounded incretins, and they are sharing their concerns, too. The Obesity Society, Obesity Action Coalition, and Obesity Medicine Association, for example, issued a joint statement warning that when people use incretin "alternatives, you may not be getting what you hoped for. You may also get something you did not want (other active substances have been found in some compounded versions)." https://www.obesityaction.org/wp-content/uploads/GLP-1-Compounded-Alternative-Statement_Final_Logos-1.pdf (joint statement from leading obesity expert organizations).

45. Lilly itself has issued multiple public warnings about compounded tirzepatide, including by publishing an open letter.

DEFENDANT'S FALSE ADVERTISING AND TRADEMARK INFRINGEMENT

46. Lilly does not sell MOUNJARO[®] or ZEPBOUND[®] to Defendant for resale or redistribution. Nor has Lilly authorized Defendant to use the Lilly Marks in connection with any of Defendant's offered goods or services. On information and belief, therefore, the Unapproved Compounded Drugs sold by Defendant are made by compounding pharmacies, which deliver them to Defendant for prescription, administration, or other dispensing to patients.

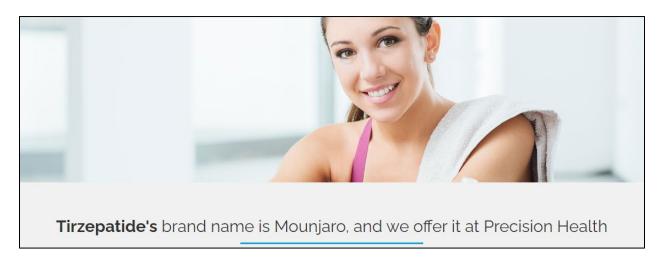
47. On information and belief, Defendant does not sell Lilly's MOUNJARO[®] and ZEPBOUND[®] and have no association with Lilly. Yet Defendant boldly and falsely appropriates the Lilly Marks to market and sell Unapproved Compounded Drugs purporting to contain tirzepatide. These drugs are *not* MOUNJARO[®] or ZEPBOUND[®]. Rather, Defendant passes off Unapproved Compounded Drugs as MOUNJARO[®] or ZEPBOUND[®]. Defendant's unlawful use of the Lilly Marks can only be intended to deceptively lure in patients in pursuit of revenues and profits.

48. Because Defendant is not offering genuine MOUNJARO[®] or ZEPBOUND[®], Lilly has no control over the safety, quality, or effectiveness of the Unapproved Compounded Drugs sold by Defendant.

49. Examples of Defendant's trademark infringement and false advertising are shown below and are attached hereto as **Exhibit B**.

50. An example of Defendant's unauthorized use of the Lilly Marks, on the "Tirzepatide" page of Defendant's website

(precisionhealthandweightloss.com/tirzepatide/), is shown below.



51. As the image shows, Defendant promotes its Unapproved Compounded Drugs by noting the "brand name is Mounjaro, and we offer it at Precision Health." Defendant's Unapproved Compounded Drugs are *not* sold under the brand name "Mounjaro," because they are not MOUNJARO[®]. Nor does Defendant offer MOUNJARO[®].

52. Also on this "Tirzepatide" webpage, which Defendant uses to advertise, promote, and market its Unapproved Compounded Drugs, Defendant uses Lilly's coined term MOUNJARO[®] repeatedly, despite the fact that Defendant does not offer this Lilly medicine.

53. Defendant refers to MOUNJARO[®] and ZEPBOUND[®] on its social media accounts as well. For example, and as shown below, on February 15, 2023, Defendant posted a graphic to Instagram that reads in large font "The BENEFITS

OF TIRZEPATIDE (MOUNJARO GENERIC)," as shown below. This post is also

precisionweightlosscent (\mathcal{L}) Follow ••• er Precision Health and Weight Loss Centers precisionweightlosscenter Mouniaro THE BENEFITS OF is the first product in a new class of medication, which acts on both GLP-1 and GIP receptors (mimicking hormones we naturally produce in the TIRZEPATIC gut) to produce a reduced appetite, earlier fullness, and improved blood sugar regulation. (MOUNJARO GENERIC) Check out our website via Link in Bio ☆ 🏠 1 It helps the body release insulin when blood sugar is high 2 It helps the body remove excess sugar from the blood 3 It stops the liver from releasing and making too much sugar #tirzepatide #weightloss #nutrition Reduce the amount of food consumed #healthyliving #weightlosshelp #fit \triangleleft 5 Mimics hormones we naturally produce in the gut for earlier fullness Liked by shearfame17 and others February 15, 2023 www.precisionhealthandweightloss.com Log in to like or comment.

"tagged" #mounjaro.

54. The caption on this post, however, does not refer to any so-called "MOUNJARO GENERIC" but instead refers simply to "Mounjaro"—a product Defendant does not offer for sale.

55. Defendant's website and social media convey the unmistakable impression that Defendant is offering for sale Lilly's MOUNJARO[®] and ZEPBOUND[®], and/or an FDA-approved "generic" version thereof. But Lilly is the only approved source of MOUNJARO[®] and ZEPBOUND[®] in the United States, and Lilly does not sell either medicine to Defendant for resale or redistribution. Moreover, there are *no* generic versions of either MOUNJARO[®] and ZEPBOUND[®]. 56. Defendant first started using the Lilly Marks to advertise its Unapproved Compounded Drugs long after Lilly had adopted them. Defendant's use can only have been intended to benefit from the goodwill Lilly generated around the Lilly Marks.

57. Defendant also falsely advertises its Unapproved Compounded Drugs on its websites and social media by making statements that claim or imply that its Unapproved Compounded Drugs are FDA-approved and have been proven to achieve certain therapeutic outcomes. These statements rely on the FDA's approval of *Lilly's* medicines and clinical trials for *Lilly's* medicines. These studies and approvals have no bearing on, and cannot substantiate claims about, Defendant's Unapproved Compounded Drugs, which upon information and belief are sold without having undergone any clinical trials on safety and effectiveness.

58. For example, as shown below, Defendant's same Tirzepatide webpage includes an entire section devoted to relaying the results of Lilly's "SURMOUNT-1 clinical trial," proclaiming that "For people struggling with obesity without diabetes, the SURMOUNT-1 trial showed that the highest dose of TIRZEPATIDE/Mounjaro produced an impressive 20.9% weight loss in 72 weeks, or an average of 52 pounds lost! In addition, more than one third of participants on the highest dose lost over 25% of their body weight, a weight loss range that gets close to the amount of weight loss seen after bariatric surgery and not previously seen with other anti-obesity medications."

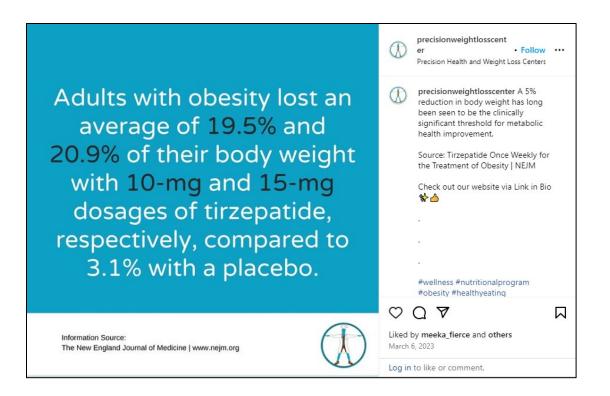
WHAT DOES THE DATA SHOW ABOUT TIRZEPATIDE/MOUNJARO FOR WEIGHT LOSS?

For people struggling with obesity without diabetes, the SURMOUNT-1 trial showed that the highest dose of TIRZEPATIDE/Mounjaro produced an impressive 20.9% weight loss in 72 weeks, or an average of 52 pounds lost! In addition, more than one third of participants on the highest dose lost over 25% of their body weight, a weight loss range that gets close to the amount of weight loss seen after bariatric surgery and not previously seen with other anti-obesity medications. For comparison, the placebo-controlled group lost an average of only 3.1% with diet and lifestyle changes alone over the same time frame. While it is difficult to compare results across different studies, prior studies showed the next most impressive medication, Wegovy (generic: semaglutide), producing an average of 14.9% weight loss over a slightly shorter time frame.

Additional benefits in overall health were seen in this study as well. Over 95% of participants with prediabetes at the start of the study achieved normal blood sugar levels by the end of the study, compared with around 62% achieved by the placebo group with diet and exercise alone. There were also significant improvements in cholesterol levels, blood pressure and overall reported physical function for those on TIRZEPATIDE/Mounjaro compared to placebo.

For people with Type 2 Diabetes, the SURPASS-1 trial showed that the highest dose of TIRZEPATIDE/Mounjaro produced an average weight loss of 11%, or about 25 pounds, with an average alc reduction of 2.3% over a 40 week period! While not a perfect comparison, prior studies on the highest dose of Wegovy (generic: semaglutide) showed that Wegovy produced an average of 9.6% weight loss and 1.6% reduction in Alc over 68 weeks in people with diabetes.

59. As with Defendant's trademark infringement, Defendant's false and/or misleading advertising extends to Defendant's social media pages as well. For example, in a March 6, 2023 Instagram post, Defendant reported on the results of a clinical trial for *Lilly's* medicine, even citing to a New England Journal of Medicine article analyzing Lilly's SURMOUNT[®] trials. This post was tagged "#mounjaro."



60. Defendant, however, does not offer the medicine studied in those trials; rather, they offer Unapproved Compounded Drugs.

61. Moreover, as noted above, Defendant refers to its Unapproved Compounded Drugs as "MOUNJARO GENERIC," even though there is *no such thing* as a "generic" form of MOUNJARO[®] available.

62. Defendant's false advertising is all the more concerning given the patient-safety messages Defendant conveys. For example, on its tirzepatide webpage, Defendant states that "Tirzepatide has demonstrated a favorable safety profile in clinical trials." Defendant's Unapproved Compounded Drugs, however, have not been studied in clinical trials, let alone demonstrated any results. Instead, Defendant relies on the clinical trials that supported the development of *Lilly's* medicines to sell Unapproved Compounded Drugs instead.

63. Upon information and belief, these statements are false and/or misleading as to Defendant's Unapproved Compounded Drugs, which are *not* FDA approved, were *not* the subject of Lilly's SURMOUNT[®] trials, were not the subject of any other clinical trials, are *not* clinically proven to achieve any results, and are not described on Lilly's zepbound.lilly.com website.

64. Defendant continues to use the Lilly Marks, including in advertising and promotion on its websites and social media, to deceive patients who, upon information and belief, are seeking to buy but are in fact not buying genuine FDAapproved MOUNJARO[®] and/or ZEPBOUND[®] to treat their serious health conditions.

65. Defendant's prominent and misleading use of the Lilly Marks is likely to cause consumers to falsely believe that they are purchasing MOUNJARO[®] and/or ZEPBOUND[®], that Defendant is a source for Lilly's FDA-approved treatment options MOUNJARO[®] and/or ZEPBOUND[®], that Defendant's Unapproved Compound Drugs are as safe and effective as Lilly's FDA-approved treatment options MOUNJARO[®] and ZEPBOUND[®], and/or that Defendant's services are provided, licensed, sponsored, authorized, or approved by, or otherwise associated or affiliated with, Lilly.

66. Defendant's use of the Lilly Marks is without the permission, consent, or authorization of Lilly. Defendant has no right to use, and Defendant knows that it has no right to use, the Lilly Marks in connection with Defendant's Unapproved Compounded Drugs or otherwise. Defendant's advertising and promotional

materials are false and misleading where they suggest and/or state an association with Lilly's FDA-approved MOUNJARO[®] and ZEPBOUND[®], because no such association exists.

67. There is no need for Defendant to use the Lilly Marks to advertise or promote its Unapproved Compounded Drugs purporting to contain tirzepatide, other than to trade upon Lilly's reputation and to create confusion in the marketplace and/or mislead patients with serious health conditions regarding the origin, identity, or source of Defendant's Unapproved Compounded Drugs.

68. Defendant's unauthorized use of the Lilly Marks is intended—and likely—to cause confusion, to cause mistake, or to deceive, and infringes Lilly's established exclusive rights in the Lilly Marks.

69. Upon information and belief, unless enjoined by this Court, Defendant will continue to use the Lilly Marks and/or otherwise falsely advertise its Unapproved Compounded Drugs as associated with or being MOUNJARO[®] and ZEPBOUND[®], all in violation of Lilly's rights.

HARM TO THE PEOPLE OF FLORIDA AND LILLY

70. Lilly's FDA-approved MOUNJARO[®] and ZEPBOUND[®] medications have undergone extensive clinical trials and approval processes. But these clinical studies and FDA approvals only apply to genuine Lilly MOUNJARO[®] and ZEPBOUND[®] used as directed by a prescribing physician. The clinical trials and approval processes do not inform the safety, quality, or effectiveness of Defendant's Unapproved Compounded Drugs.

71. Defendant's unlawful, misleading business model may expose patients to the serious risks described above. Critically, because Defendant falsely advertises and, without Lilly's consent, uses the Lilly Marks in connection with its Unapproved Compounded Drugs, patients are unlikely to know the unique risks associated with Defendant's untested, unapproved drugs.

72. Defendant advertises itself as providing MOUNJARO[®] and ZEPBOUND[®] (or their supposed "generic" equivalents), when in reality Defendant provides untested Unapproved Compounded Drugs. Defendant's promotional tactics are *intended* to mislead patients into believing that Unapproved Compounded Drugs are backed by clinical trials and have been approved by the FDA, when no such studies have been conducted, and neither the FDA nor any other regulatory body has approved them. Patients who take Defendant's Unapproved Compounded Drugs and suffer harm will have had no forewarning.

73. Not only does this deceitful content expose the people of Florida to serious health risks, but Defendant's unlawful tactics undermine the name, goodwill, and reputation that Lilly has invested heavily in developing. Moreover, Defendant's unfair methods allow it and its suppliers of Unapproved Compounded Drugs to unjustly profit from sales to patients looking for MOUNJARO[®] and ZEPBOUND[®].

FIRST CAUSE OF ACTION Trademark Infringement in Violation of 15 U.S.C. § 1114

74. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

75. Lilly is the owner of all right, title, and interest in federal trademark registrations for the inherently distinctive Lilly Marks and has standing to maintain an action for trademark infringement under 15 U.S.C. § 1114.

76. Without Lilly's consent, Defendant has used and continues to use in commerce the Lilly Marks in connection with the offering, sale, and advertising of its Unapproved Compounded Drugs purporting to contain tirzepatide. Consumers who encounter Defendant's unauthorized use of the Lilly Marks in connection with Defendant's Unapproved Compounded Drugs and related goods and services are likely to think that they are provided, licensed, sponsored, authorized, or approved by, or otherwise associated or affiliated with, Lilly.

77. Defendant's actions are likely to cause confusion, or to cause mistake, or to deceive, and thus constitute trademark infringement of the registered Lilly Marks, in violation of Section 32 of the Lanham Act, 15 U.S.C. § 1114.

78. Defendant had actual and/or constructive knowledge of Lilly's rights prior to its infringing use of the Lilly Marks. The actions of Defendant alleged above have at all times relevant to this action been willful.

79. As a direct and proximate result of the actions of Defendant alleged above, Lilly has been damaged and will continue to be damaged. Defendant's

conduct, unless enjoined by the Court, will further impair the value of the Lilly Marks' name, reputation, and goodwill. This harm constitutes an injury for which Lilly has no adequate remedy at law.

80. This is an exceptional case under 15 U.S.C. § 1117.

81. Based on such conduct, Lilly is entitled to injunctive relief as well as monetary damages, and other remedies provided by Sections 1116, 1117, and 1118, including Defendant's profits, treble damages, reasonable attorneys' fees, costs, and prejudgment interest.

SECOND CAUSE OF ACTION Trademark Infringement, False Designation of Origin and Unfair Competition in Violation of 15 U.S.C. § 1125

82. Lilly repeats and realleges the allegations in paragraphs 1 through 73 above as if fully set forth herein.

83. Lilly is the owner of all right, title, and interest in the inherently distinctive Lilly Marks and has standing to maintain an action for trademark infringement, false designation of origin, and unfair competition under 15 U.S.C. § 1125.

84. Without Lilly's consent, Defendant has used and continues to use in commerce the Lilly Marks in connection with the offering, sale, and advertising of its Unapproved Compounded Drugs purporting to contain tirzepatide. Consumers who encounter Defendant's unauthorized use of the Lilly Marks in connection with Defendant's Unapproved Compounded Drugs and related goods and services are

likely to think that they are provided, licensed, sponsored, authorized, or approved by, or otherwise associated or affiliated with, Lilly.

85. Defendant's actions are likely to cause confusion, or to cause mistake, or to deceive as to the origin, sponsorship, or approval of the products and services and commercial activities of Defendant, and thus constitute trademark infringement, false designation of origin, and unfair competition with respect to the Lilly Marks, in violation of Section 43(a)(1)(A) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(A).

86. Defendant had actual and/or constructive knowledge of Lilly's rights prior to its infringing use of the Lilly Marks. The actions of Defendant alleged above have at all times relevant to this action been willful.

87. As a direct and proximate result of the actions of Defendant alleged above, Lilly has been damaged and will continue to be damaged. Defendant's conduct, unless enjoined by the Court, will further impair the value of the Lilly Marks' name, reputation, and goodwill. This harm constitutes an injury for which Lilly has no adequate remedy at law.

88. This is an exceptional case under 15 U.S.C. § 1117.

89. Based on such conduct, Lilly is entitled to injunctive relief as well as monetary damages, and other remedies provided by Sections 1116, 1117, and 1118, including Defendant's profits, treble damages, reasonable attorneys' fees, costs, and prejudgment interest.

THIRD CAUSE OF ACTION False and Misleading Advertising and Promotion in Violation of 15 U.S.C. § 1125(a)(1)(B)

90. Lilly repeats and realleges the allegations in paragraphs 1 through 73 above as if fully set forth herein.

91. Defendant's commercial advertising claims described herein are false and misleading in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

92. Defendant has knowingly and willfully made material false and misleading statements in its commercial advertisements for its Unapproved Compounded Drugs, and these statements regarding Unapproved Compounded Drugs' safety, quality, effectiveness, and regulatory status have influenced and are likely to continue to influence consumers' purchasing decisions.

93. Defendant's statements—including its various literally false claims have the tendency to deceive a substantial segment of consumers, who have relied or likely will rely on Defendant's false statements in making their tirzepatide-based medicine purchase decisions.

94. Defendant has caused its false statements to enter interstate trade or commerce.

95. As a direct and proximate result of Defendant's false and deceptive campaign, Lilly is suffering immediate and continuing irreparable injury for which there is no adequate remedy at law.

96. As a direct and proximate result of Defendant's false and deceptive campaign, Lilly has suffered and will continue to suffer significant monetary damages and discernible competitive injury by the direct diversion of sales from Lilly to Defendant and Defendant's suppliers and by a loss of goodwill associated with Lilly's MOUNJARO[®] and ZEPBOUND[®] and the Lilly Marks.

97. This is an exceptional case under 15 U.S.C. § 1117.

98. Lilly is entitled to injunctive relief as well as monetary damages, and other remedies provided by Sections 1116, 1117, and 1118, including Defendant's profits, treble damages, reasonable attorneys' fees, costs, and prejudgment interest.

FOURTH CAUSE OF ACTION Deceptive and Unfair Practices in Violation of Fla. Stat. § 501.201 *et seq.*

99. Lilly repeats and realleges the allegations in paragraphs 1 through 73 above as if fully set forth herein.

100. Defendant's acts constitute unfair methods of competition, in violation of the laws of the State of Florida, including Fla. Stat. § 501.201, *et seq.*

101. Fla. Stat. § 501.204(1) states that "Unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."

102. Lilly is an "interested party or person" within the meaning of Fla. Stat. § 501.203(6) and has standing to bring an action based on unfair and deceptive trade practices.

103. Defendant's acts unethically exploit the Lilly Marks in a material manner likely to deceive and mislead, and therefore be substantially injurious to, the public, including a substantial portion of consumers. These acts therefore offend the established public policy of the State of Florida.

104. Defendant's acts include making false or misleading representations in its advertising and promotional materials in a material manner likely to deceive and mislead, and therefore be substantially injurious to, the public, including a substantial portion of consumers. These acts therefore offend the established public policy of the State of Florida.

105. Defendant's Unapproved Compounded Drugs do not have the same safety, quality, and effectiveness as MOUNJARO[®] or ZEPBOUND[®]. Defendant's deceptive conduct and regulatory non-compliance therefore enabled it to obtain an unfair and illegal business advantage over Lilly.

106. As a direct and proximate result of Defendant's unfair and deceptive trade practices, Lilly has suffered and will continue to suffer significant monetary damages and discernible injury to its business, including by a loss of goodwill associated with Lilly's MOUNJARO[®] and ZEPBOUND[®] medicines and the Lilly Marks. Defendant therefore has unfairly profited from the actions alleged.

107. By reason of Defendant's acts, Lilly's remedy at law is not adequate to compensate for the injuries inflicted by Defendant. Accordingly, Lilly is entitled to entry of preliminary and permanent injunctive relief, in addition to actual damages, attorneys' fees, and costs.

FIFTH CAUSE OF ACTION Trademark Infringement and Unfair Competition in Violation of Florida Common Law

108. Lilly repeats and realleges the allegations in paragraphs 1 through 73 above as if fully set forth herein.

109. The above-described acts of Defendant constitute unfair competition in violation of Florida common law.

110. Without Lilly's consent, Defendant has used and continues to use in commerce the Lilly Marks to pass off its Unapproved Compounded Drugs purporting to contain tirzepatide as genuine MOUNJARO[®] and ZEPBOUND[®].

111. Defendant's unauthorized use of the Lilly Marks in connection with Defendant's Unapproved Compounded Drugs and related goods and services is likely to cause confusion, or to cause mistake, or to deceive as to the origin, sponsorship, or approval of the products and services and commercial activities of Defendant.

112. Consumers who encounter Defendant's unauthorized use of the Lilly Marks in connection with Defendant's Unapproved Compounded Drugs and related goods and services are likely to think that they are provided, licensed, sponsored, authorized, or approved by, or otherwise associated or affiliated with, Lilly.

113. Defendant's actions thereby unfairly and wrongfully exploit and infringe Lilly's trademark, goodwill, and reputation.

114. As a direct and proximate result of Defendant's unfair methods of competition, Lilly has suffered and will continue to suffer significant monetary

damages and discernible competitive injury by the direct diversion of sales from Lilly to Defendant and by a loss of goodwill associated with Lilly's MOUNJARO[®] and ZEPBOUND[®] medicines and the Lilly Marks.

115. By reason of Defendant's acts, Lilly's remedy at law is not adequate to compensate for the injuries inflicted by Defendant. Accordingly, Lilly is entitled to entry of preliminary and permanent injunctive relief.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Lilly prays that this Court enter judgment in its favor on each and every claim for relief set forth above and award it relief including, but not limited to, the following:

- 1. An Order declaring that Defendant:
 - a. Infringed the federally registered Lilly Marks, in violation of 15
 U.S.C. § 1114(1);
 - Infringed the Lilly Marks and engaged in trademark
 infringement, false designation of origin, and unfair competition,
 in violation of 15 U.S.C. § 1125(a)(1)(A);
 - c. Engaged in false and misleading advertising and promotion, in violation of 15 U.S.C. § 1125(a)(1)(B);
 - d. Engaged in deceptive and unfair practices in violation of the statutory and common law of Florida;
 - e. That each of the above acts was willful and knowing.

2. An injunction preliminarily and then permanently enjoining and restraining Defendant and its officers, agents, servants, employees, and attorneys and all persons acting in concert or participation with any of them, from:

- a. Using the Lilly Marks or any mark confusingly similar to them, in connection with the advertising, promoting, marketing, selling or offering for sale of any goods or services (including, but not limited to, Unapproved Compounded Drugs) or otherwise engaging in any activity that is likely to cause confusion, cause mistake, or deceive or otherwise infringe any rights of Plaintiff Lilly in the Lilly Marks or any similar mark;
- b. Falsely stating or suggesting that Defendant's Unapproved Compounded Drugs are genuine or generic versions of MOUNJARO® or ZEPBOUND®, that Defendant is associated or connected in any way with Plaintiff or its products, or that Defendant's Unapproved Compounded Drugs are approved by the FDA, have been the subject of clinical studies, or achieve certain therapeutic outcomes;
- c. Engaging in any unfair competition with Plaintiff Lilly; and
- d. Engaging in any deceptive or unfair acts.

3. An Order Requiring Defendant and its officers, agents, servants, employees, and attorneys and all persons acting in concert or participation with any of them, to engage in corrective advertising by informing consumers that Defendant

is not and never has been authorized by, affiliated with, sponsored by, approved by, or related to Plaintiff Lilly or MOUNJARO[®] and ZEPBOUND[®], that Defendant's Unapproved Compounded Drugs are not MOUNJARO[®] or ZEPBOUND[®], that Defendant's Unapproved Compounded Drugs are not generic MOUNJARO[®] or generic ZEPBOUND[®], that Defendant's Unapproved Compounded Drugs have never been genuine or generic versions of MOUNJARO[®] and ZEPBOUND[®], and that Defendant's Unapproved Compounded Drugs are not and have never been approved or reviewed by the FDA or tested for safety, quality, or effectiveness in clinical trials.

4. An Order directing Defendant to file with this Court and serve on Lilly's attorneys, thirty (30) days after the date of entry of any injunction, a report in writing and under oath setting forth in detail the manner and form in which they have complied with the Court's injunction.

5. An Order requiring Defendant to account for and pay to Lilly any and all profits arising from the foregoing acts of infringement, false designation of origin, false advertising, and unfair competition.

6. An Order requiring Defendant to pay Lilly compensatory damages in an amount as yet undetermined caused by the foregoing acts of infringement, false designation of origin, false advertising, and unfair competition, and trebling such compensatory damages for payment to Lilly in accordance with 15 U.S.C. § 1117 and other applicable laws.

7. An Order for pre-judgment and post-judgment interest on all damages;

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8. An Order requiring Defendant to pay Lilly all types of monetary remedies available under Florida state law in amounts as of yet undetermined caused by the foregoing acts of infringement, false designation of origin, false advertising, and unfair competition.

9. An Order requiring Defendant to pay Lilly's costs and attorney's fees in this action pursuant to 15 U.S.C. § 1117, Florida state law, and any other applicable provision of law.

10. Other relief as the Court may deem appropriate.

Dated: June 20, 2024

Respectfully submitted,

/s/ Gavin C. Gaukroger

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Attorneys for Plaintiff ELI LILLY AND COMPANY Case 8:24-cv-01488-TPB-SPF Document 1 Filed 06/20/24 Page 40 of 40 PageID 40

JURY DEMAND

Lilly hereby demands a jury trial for all issues so triable.

/s/ Gavin C. Gaukroger

Gavin C. Gaukroger BERGER SINGERMAN LLP Fla. Bar. No. 76489 Attorney for Plaintiff ELI LILLY AND COMPANY

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JS 44 (Rev. 03/24)

CIVIL COVER SHEET

 The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

 I. (a) PLAINTIFFS
 DEFENDANTS

 Eli Lilly and Company
 PHTB LLC d/b/a Precision Health Tampa Bay

 (b) County of Residence of First Listed Plaintiff
 Marion County, IN

 (EXCEPT IN U.S. PLAINTIFF CASES)
 County of Residence of First Listed Plaintiff

 (c) Attorneys (Firm Name, Address, and Telephone Number)
 Attorneys (If Known)

II. BASIS OF JURISD	ICTION (Place an "X" in	One Box Only)		TIZENSHIP OF		INCIPA				r Plaintiff
1 U.S. Government Plaintiff	▼ 3 Federal Question (U.S. Government Not a Party)			(For Diversity Cases O n of This State	Only) PTF	DEF	a Incorporated or Pri of Business In T		Defendant) PTF	DEF
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VI. CAUSE OF ACTION	VI. CAUSE OF ACTION Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 15 U.S.C. §§ 1114,1125 Brief description of cause:									
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VII. REQUESTED IN COMPLAINT:	CHECK IF THIS UNDER RULE 2	IS A CLASS ACTION 3, F.R.Cv.P.		EMAND \$ specified; Injunction	l.		CHECK YES only		n complai	
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EXHIBIT A



MOUNJARO

Reg. No. 6,809,369	Eli Lilly and Company (INDIANA CORPORATION) Lilly Corporate Center Indianapolis, INDIANA 46285			
Registered Aug. 02, 2022				
Int. Cl.: 5	CLASS 5: Pharmaceutical preparations, namely, pharmaceutical preparations for the treatment of diabetes			
Trademark				
Principal Register	FIRST USE 6-3-2022; IN COMMERCE 6-3-2022			
	THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT STYLE, SIZE OR COLOR			
	SER. NO. 88-680,946, FILED 11-05-2019			



Kathevine Kelly Vidal

Director of the United States Patent and Trademark Office



REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years* What and When to File:

- *First Filing Deadline:* You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. See 15 U.S.C. §§1058, 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.
- *Second Filing Deadline:* You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between the 9th and 10th years after the registration date.* See 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods* What and When to File:

• You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

*ATTENTION MADRID PROTOCOL REGISTRANTS: The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the United States Patent and Trademark Office (USPTO). The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. See 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. See 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

NOTE: Fees and requirements for maintaining registrations are subject to change. Please check the USPTO website for further information. With the exception of renewal applications for registered extensions of protection, you can file the registration maintenance documents referenced above online at http://www.uspto.gov.

NOTE: A courtesy e-mail reminder of USPTO maintenance filing deadlines will be sent to trademark owners/holders who authorize e-mail communication and maintain a current e-mail address with the USPTO. To ensure that e-mail is authorized and your address is current, please use the Trademark Electronic Application System (TEAS) Correspondence Address and Change of Owner Address Forms available at http://www.uspto.gov.



MOUNJARO

Reg. No. 7,068,463	Eli Lilly and Company (INDIANA CORPORATION) Lilly Corporate Center Indianapolis, INDIANA 46285			
Registered May 30, 2023				
Int. Cl.: 44	CLASS 44: Medical information services in the field of diabetes			
Service Mark	FIRST USE 6-7-2022; IN COMMERCE 6-7-2022			
Principal Register	THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT STYLE, SIZE OR COLOR			
	SER NO. 07.468.410 EILED.06.21.2022			

SER. NO. 97-468,410, FILED 06-21-2022

Kathevine Kelly Vidal

Director of the United States Patent and Trademark Office



REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years* What and When to File:

- *First Filing Deadline:* You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. See 15 U.S.C. §§1058, 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.
- *Second Filing Deadline:* You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between the 9th and 10th years after the registration date.* See 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods* What and When to File:

• You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

*ATTENTION MADRID PROTOCOL REGISTRANTS: The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the United States Patent and Trademark Office (USPTO). The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. See 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. See 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

NOTE: Fees and requirements for maintaining registrations are subject to change. Please check the USPTO website for further information. With the exception of renewal applications for registered extensions of protection, you can file the registration maintenance documents referenced above online at http://www.uspto.gov.

NOTE: A courtesy e-mail reminder of USPTO maintenance filing deadlines will be sent to trademark owners/holders who authorize e-mail communication and maintain a current e-mail address with the USPTO. To ensure that e-mail is authorized and your address is current, please use the Trademark Electronic Application System (TEAS) Correspondence Address and Change of Owner Address Forms available at http://www.uspto.gov.



ZEPBOUND

Reg. No. 7,288,373	Eli Lilly and Company (INDIANA CORPORATION) Lilly Corporate Center Indianapolis, INDIANA 46285			
Registered Jan. 23, 2024				
Int. Cl.: 5	CLASS 5: Pharmaceutical preparations, namely, pharmaceutical preparations for the treatment of obesity			
Trademark				
Principal Register	FIRST USE 11-30-2023; IN COMMERCE 11-30-2023			
	THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT STYLE, SIZE OR COLOR			
	SER. NO. 97-362,818, FILED 04-14-2022			

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EXHIBIT B

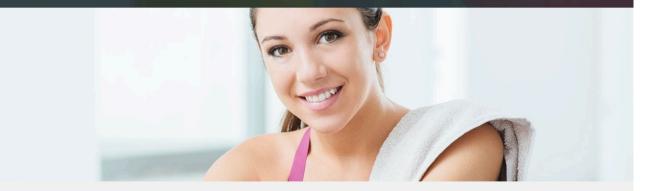


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TIRZEPATIDE PROGRAM

HELPING YOU EVOLVE INTO A HEALTHIER AND HAPPIER YOU!



Tirzepatide's brand name is Mounjaro, and we offer it at Precision Health

Welcome to Precision Health and Weight Loss Center! We are your trusted source for prescription-strength medications. Weight loss has been our specialty for over 16 years!

Introducing Tirzepatide: A Revolutionary Treatment for Health and Weight Loss

At Precision Health and Weight Loss Center, we are committed to providing cutting-edge solutions to support your journey towards a healthier and happier life. We are excited to introduce you to Tirzepatide, a breakthrough medication that has shown remarkable promise in both health management and weight loss.

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✓ WHAT DOES THE DATA SHOW ABOUT TIRZEPATIDE/MOUNJARO FOR WEIGHT LOSS?

For people struggling with obesity without diabetes, the SURMOUNT-1 trial showed that the highest dose of TIRZEPATIDE/Mounjaro produced an impressive 20.9% weight loss in 72 weeks, or an average of 52 pounds lost! In addition, more than one third of participants on the highest dose lost over 25% of their body weight, a weight loss range that gets close to the amount of weight loss seen after bariatric surgery and not previously seen with other anti-obesity medications. For comparison, the placebo-controlled group lost an average of only 3.1% with diet and lifestyle changes alone over the same time frame. While it is difficult to compare results across different studies, prior studies showed the next most impressive medication, Wegovy (generic: semaglutide), producing an average of 14.9% weight loss over a slightly shorter time frame.

Additional benefits in overall health were seen in this study as well. Over 95% of participants with prediabetes at the start of the study achieved normal blood sugar levels by the end of the study, compared with around 62% achieved by the placebo group with diet and exercise alone. There were also significant improvements in cholesterol levels, blood pressure and overall reported physical function for those on TIRZEPATIDE/Mounjaro compared to placebo.

For people with Type 2 Diabetes, the SURPASS-1 trial showed that the highest dose of TIRZEPATIDE/Mounjaro produced an average weight loss of 11%, or about 25 pounds, with an average a1c reduction of 2.3% over a 40 week period! While not a perfect comparison, prior studies on the highest dose of Wegovy (generic: semaglutide) showed that Wegovy produced an average of 9.6% weight loss and 1.6% reduction in A1c over 68 weeks in people with diabetes.

> CAN I TAKE TIRZEPATIDE/MOUNJARO IF I'VE ALREADY HAD BARIATRIC SURGERY?

> WHAT ARE THE SIDE EFFECTS OF TIRZEPATIDE/MOUNJARO?

HOW IS TIRZEPATIDE/MOUNJARO TAKEN?

> HOW MUCH DOES TIRZEPATIDE/MOUNJARO COST?

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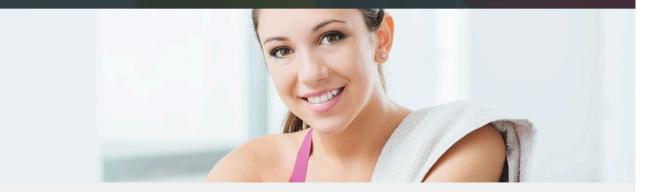


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While there are no studies yet in the use of TIRZEPATIDE/Mounjaro for weight regain or sub-optimal weight loss after bariatric surgery, there are studies that show that other GLP-1 agonists are safe and effective to use for patients after bariatric surgery. We are successfully using TIRZEPATIDE/Mounjaro and others in this class to help with sub-optimal weight loss after bariatric surgery with impressive results.

> WHAT ARE THE SIDE EFFECTS OF TIRZEPATIDE/MOUNJARO?

- > HOW IS TIRZEPATIDE/MOUNJARO TAKEN?
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6. Complete Form (link at top of Appointment Confirmation Email) prior to your initial visit, if possible

With most of our services booked in advance, we accept appointments only. Click the "Book Appointment" button at the top, if scheduling from desktop or laptop. Download the free "Precision Health" app, if scheduling from cellphone. ATTENTION: Offices may close after last scheduled client of the day! Please make an appointment. Only one guest (13 yo or older) per client is allowed. No refund policy. No outside Food/Drink. No solicitation. Holiday closure: TBA.

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As with any medication, side effects can occur on this medication. The most common side effects include nausea, diarrhea and constipation. Usually, these are mild-to-moderate and they usually improve over time. We recommend a slow escalation in dose on these medications to reduce any side effects and give your body time to adjust to the medication. We also recommend simple dietary strategies to improve side effects such as eating more slowly than you might usually, avoiding high fat, greasy foods and making sure to sip water throughout the day to stay hydrated.

While TIRZEPATIDE/Mounjaro will not cause hypoglycemia, or low blood sugar, on its own, it can cause low blood sugars when combined with medications such as insulins or sulfonylurea medications. Your healthcare provider will likely need to reduce your dose or discontinue insulins or sulfonylurea medications when you start TIRZEPATIDE/Mounjaro to avoid these risks. The great news is, insulins and sulfonylurea medications can actually cause weight gain, while TIRZEPATIDE/Mounjaro causes weight loss, so being able to reduce or eliminate the need for insulins and sulfonylurea medications is beneficial to overall health and weight control for those with Type 2 Diabetes!

In rare cases, pancreatitis has been reported with this class of medications and therefore your healthcare provider should counsel you on signs and symptoms of pancreatitis, however, this is not a typical side effect. People with a family history of medullary thyroid cancer or MEN-2 syndrome should not take this medication and those who have previously had pancreatitis should also avoid this class of medications.

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TIRZEPATIDE/Mounjaro is a once weekly subcutaneous injection taken in the thigh, abdomen or upper arm that most patients can administer themselves. It comes in a single-dose pen with the medication dose already measured out and the needle already attached to be as user-friendly as possible. The needle is very small and medication is injected just under the skin. Most people report very little pain or discomfort with this injection, most describe it as similar to a small pinch. The initial dose is 2.5 mg weekly. The second month, the dose is increased to 5 mg weekly. The third and subsequent months at Precision, the dose is either 5 mg or 10 mg weekly depending on your personal goals, results, and budget.

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At Precision Health and Weight Loss Center, we are committed to providing cutting-edge solutions to support your journey towards a healthier and happier life. We are excited to introduce you to Tirzepatide, a breakthrough medication that has shown remarkable promise in both health management and weight loss.

What is Tirzepatide?

Tirzepatide is a novel, once-weekly injectable medication developed for the treatment of type 2 diabetes and obesity. It belongs to a class of drugs called glucagon-like peptide-1 receptor agonists (GLP-1 RAs) and represents a significant advancement in this field.

How does Tirzepatide work?

Tirzepatide works by mimicking the function of the hormone GLP-1, which plays a crucial role in regulating blood sugar levels and appetite. By activating GLP-1 receptors in the body, Tirzepatide helps to lower blood sugar levels, increase insulin secretion, and reduce appetite, leading to improved diabetes control and weight loss.

Benefits of Tirzepatide:

I. Enhanced Glycemic Control: Tirzepatide has demonstrated superior efficacy in lowering blood sugar levels compared to other GLP-1 RAS. Clinical trials have shown significant reductions in HbAlc (average blood sugar levels over time) with Tirzepatide use, leading to improved diabetes management and prevention.

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2. Weight Loss: Tirzepatide has shown remarkable effectiveness in promoting weight loss. Clinical trials have demonstrated substantial reductions in body weight, making it an attractive option for individuals struggling with obesity or overweight conditions.

3. Cardiovascular Benefits: Apart from its blood sugar-lowering effects, Tirzepatide has also shown potential cardiovascular benefits. Studies have indicated a reduction in major adverse cardiovascular events, making it a comprehensive treatment option for individuals with diabetes and cardiovascular risk factors.

4. Convenience: With its once-weekly dosing schedule, Tirzepatide offers convenience and ease of use for patients. This reduces the burden of daily medication regimens and enhances treatment adherence.

5. Safety Profile: Tirzepatide has demonstrated a favorable safety profile in clinical trials, with the most common side effects being mild to moderate gastrointestinal symptoms. As with any medication, it is important to consult with your healthcare provider to assess individual risks and benefits. A physician consultation comes with our Tirzepatide program.

Is Tirzepatide right for you?

Tirzepatide can be a game-changer for individuals with type 2 diabetes and obesity who are looking for effective treatment options. It is essential to consult with our experienced health care professionals at Precision Health and Weight Loss Center to guide you in the use of Tirzepatide. Our team will evaluate your medical history, assess your specific needs, and work with you to create a personalized treatment plan that optimizes your health and weight loss goals.

Take the next step towards a healthier future:

At Precision Health and Weight Loss Center, we are dedicated to providing comprehensive and personalized care to help you achieve your health and weight loss goals. Schedule to get started with Tirzepatide and learn more about the benefits of Tirzepatide. Let us empower you on your journey towards a healthier, happier you!

Disclaimer: This web page is intended for informational purposes only and should not be considered medical advice. Please consult with a qualified healthcare professional before starting any new medication or treatment.

> WHAT DOES THE DATA SHOW ABOUT TIRZEPATIDE/MOUNJARO FOR WEIGHT LOSS?

- > CAN I TAKE TIRZEPATIDE/MOUNJARO IF I'VE ALREADY HAD BARIATRIC SURGERY?
- > WHAT ARE THE SIDE EFFECTS OF TIRZEPATIDE/MOUNJARO?
- > HOW IS TIRZEPATIDE/MOUNJARO TAKEN?

✓ HOW MUCH DOES TIRZEPATIDE/MOUNJARO COST?

Although the difficult to get brand name Mounjaro is very expensive with pricing for the low dosing at around \$1100.00, we now offer the equally effective Tirzepatide at the starting price of only \$400 (with cash discount). The second month of medication is only \$500 (with cash discount)! And at the highest dose that we offer and the one where 50% of research study participants lost at least 20% of their body weight during the study, this monthly price is only \$900! As always, we deliver superior products at a very good price so that you can achieve the results that you desire and deserve.

Steps to Get Started

- 1. Click the 'BOOK APPOINTMENT' tab or Download the free 'Precision Health' App
- 2. Complete Online Profile
- 3. Look under the category "Semaglutide" or "Tirzepatide" based on what you want

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4. Select the "Initial Visit" option

- 5. Schedule and Pay (Need help at this point? Text 404-496-6028 once profile is complete)
- 6. Complete Form (link at top of Appointment Confirmation Email) prior to your initial visit, if possible

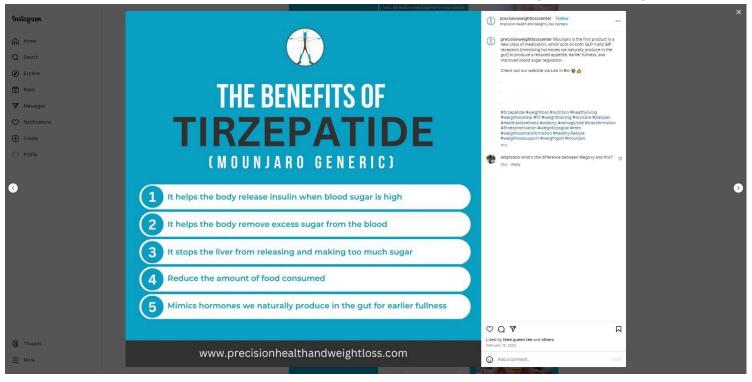
With most of our services booked in advance, we accept appointments only. Click the "Book Appointment" button at the top, if scheduling from desktop or laptop. Download the free "Precision Health" app, if scheduling from cellphone. ATTENTION: Offices may close after last scheduled client of the day! Please make an appointment. Only one guest (13 yo or older) per client is allowed. No refund policy. No outside Food/Drink. No solicitation. Holiday closure: TBA.

*Independently Operated

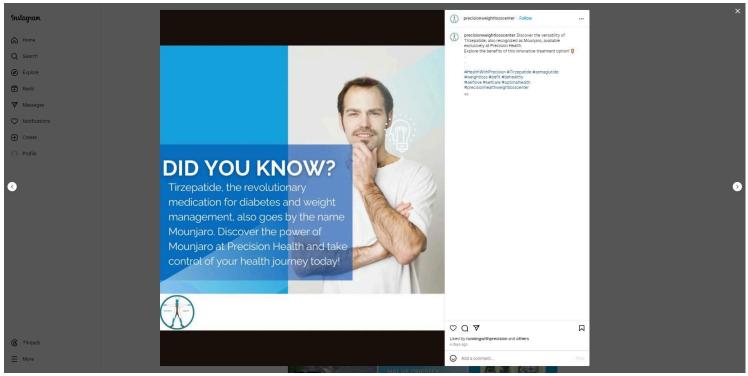
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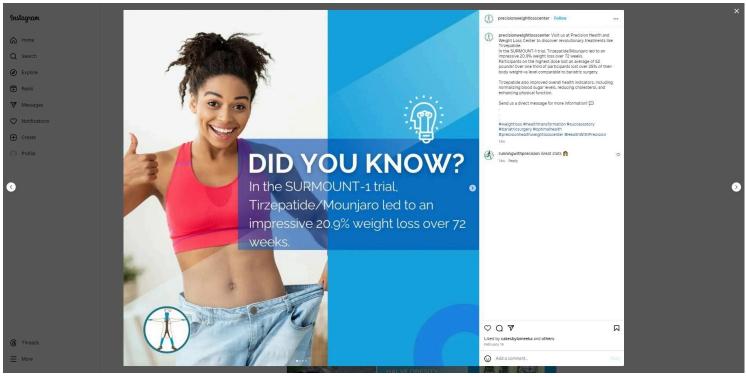
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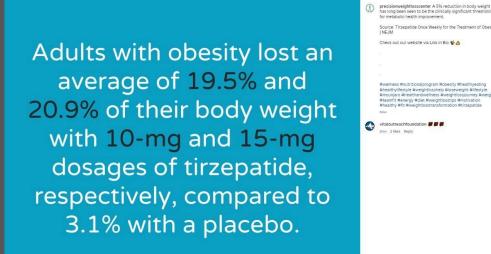
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Information Source: The New England Journal of Medicine | www.neim.org



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Source: Tirzepatide Once Weekly for the Treatment of Obesity INEJM

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AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Middle District of Florida

)

Eli Lilly and Company

Plaintiff(s)

v.

Civil Action No.

PHTB LLC d/b/a Precision Health Tampa Bay

Defendant(s)

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) PHTB LLC 17523 North Dale Mabry Highway Lutz, Florida 33548

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in <u>Fed. R. Civ.</u> <u>P. 12</u> (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Gavin C. Gaukroger, Esq. Berger Singerman LLP 201 East Las Olas Blvd., Suite 1500 Fort Lauderdale, FL 33301 ggaukroger@bergersingerman.com

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date:

Signature of Clerk or Deputy Clerk

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by <u>Fed. R. Civ. P. 4</u> (l))

	This summons for (nam	ne of individual and title, if any)						
was re	ceived by me on (date)	·						
	□ I personally served	the summons on the individua	l at (place)					
		on (date)						
	\square I left the summons	□ I left the summons at the individual's residence or usual place of abode with <i>(name)</i>						
			on of suitable age and discretion who res	sides there,				
	on (date)	, and mailed a copy to	o the individual's last known address; or					
	\Box I served the summa	□ I served the summons on (name of individual)						
	designated by law to	accept service of process on be	half of (name of organization)					
			on (date)	; or				
	\Box I returned the summ	nons unexecuted because		; or				
	□ Other (specify):							
	My fees are \$	for travel and \$	for services, for a total of \$	0.00 ·				
	I declare under penalty of perjury that this information is true.							
Date:								
			Server's signature					
			Printed name and title					

Server's address

Additional information regarding attempted service, etc: