UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

ELI LILLY AND COMPANY,

Plaintiff,

v.

J. BERGERON, M.D., P.A. D/B/A HOUSTON WEIGHT LOSS CENTER,

Defendant.

Case No. 4:24-cv-2313

JURY TRIAL DEMANDED

PLAINTIFF ELI LILLY AND COMPANY'S COMPLAINT FOR TRADEMARK INFRINGEMENT, FALSE ADVERTISING, AND FALSE DESIGNATION OF ORIGIN

INTRODUCTION

1. This is an action to protect patients from unstudied, unapproved, and unsafe drugs masquerading as Plaintiff Eli Lilly and Company's ("Lilly") FDA-approved medicines for adults with type 2 diabetes, obesity, or excess weight and weight-related medical problems. Defendant J. Bergeron, M.D., P.A. d/b/a Houston Weight Loss Center ("Defendant") has designed its website, 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® are the only FDA-approved GLP-1/GIP medicines.

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

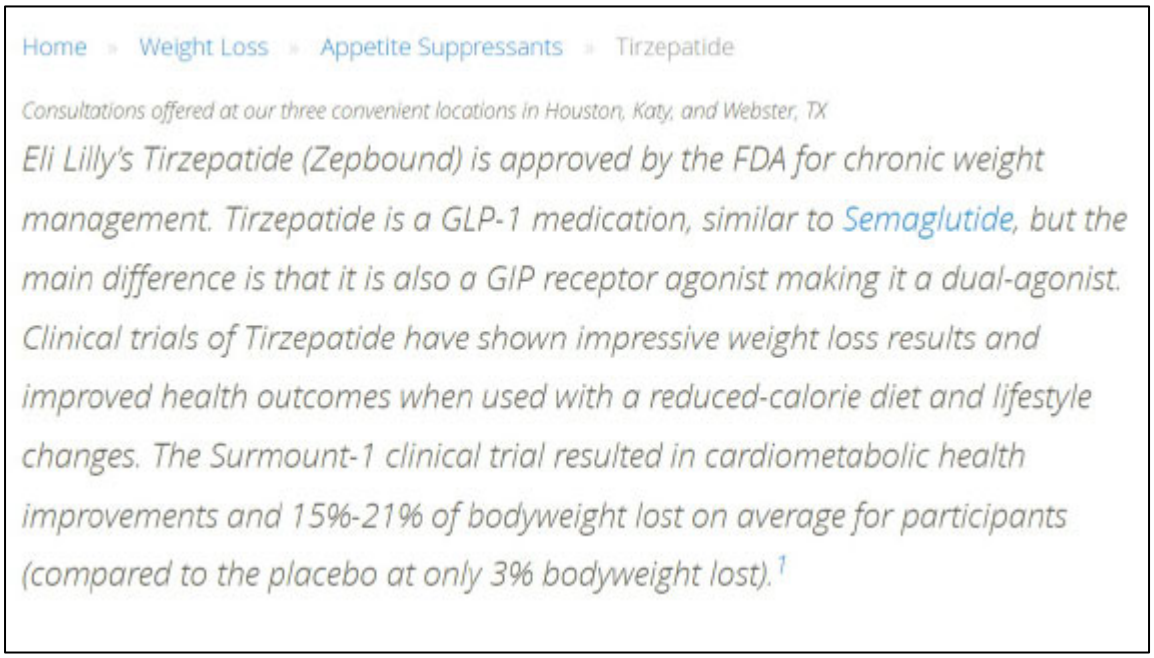
[1] In support of this Complaint, Lilly's allegations are upon actual knowledge with respect to itself and its own acts, and upon information and belief as to all other matters.

advance" and observed that Lilly's ZEPBOUND® "addresses an unmet medical need." 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); https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-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-and-drug-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. But Defendant does not offer Lilly's proprietary MOUNJARO® and ZEPBOUND® medicines. 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 its "Tirzepatide" webpage, where it boldly proclaims "Eli Lilly's Tirzepatide (Zepbound) is approved by the FDA for chronic weight management," before citing to "Clinical trials," including Lilly's SURMOUNT® clinical trials, as shown below:


Home » Weight Loss » Appetite Suppressants » Tirzepatide

Consultations offered at our three convenient locations in Houston, Katy, and Webster, TX

Eli Lilly's Tirzepatide (Zepbound) is approved by the FDA for chronic weight management. Tirzepatide is a GLP-1 medication, similar to Semaglutide, but the main difference is that it is also a GIP receptor agonist making it a dual-agonist. Clinical trials of Tirzepatide have shown impressive weight loss results and improved health outcomes when used with a reduced-calorie diet and lifestyle changes. The Surmount-1 clinical trial resulted in cardiometabolic health improvements and 15%-21% of bodyweight lost on average for participants (compared to the placebo at only 3% bodyweight lost).[1]

7. Despite this impossible-to-miss headline, Defendant does not offer ZEPBOUND®. Nor is Defendant's product purporting 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.

8. Lilly therefore brings this action pursuant to the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*, and for violation of Texas common law. 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 unfair competition.

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.

10. Defendant is a Texas professional association with a principal place of business at 1941 W T C Jester Boulevard, Houston, Texas 77008, in this District. Its president, registered agent, and sole reported director or officer is John Bergeron, with registered agent address 1941 W T C Jester Boulevard, Houston, Texas 77008.

11. Defendant additionally does business as "Houston Weight Loss Center" and at its website, "https://www.houstonweightloss.com."

12. According to Defendant's website, Defendant offers services "at our three convenient locations in Houston, Katy, and Webster, Tx." https://www.houstonweightloss.com/weight-loss/appetite-suppressant-programs/tirzepatide-for-weight-loss. These locations have addresses at:

a. 1941 W T C Jester Boulevard #101, Houston, Texas 77008

b. 23217 Red River Drive, Katy, Texas 77494

c. 17630 State Highway 3, Webster, Texas 77598

JURISDICTION AND VENUE

13. 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).

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

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

15. 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.*

16. 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.

17. 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).

18. 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 ≥ 27 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.

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

20. 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-current-good-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.*

21. 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, FDA-approved labels, instructions, and warnings.

22. Lilly now promotes, offers, and sells MOUNJARO® and ZEPBOUND® medicines in Texas and throughout the United States.

LILLY'S MOUNJARO® AND ZEPBOUND® TRADEMARKS

23. 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.

24. 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.

25. 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.

26. 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.

27. 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.

28. 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.

29. 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.

30. 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

31. 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").

32. 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/human-drug-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.

33. 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).

34. 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).

35. 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).

36. 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-drug-compounding/compounding-and-fda-questions-and-answers (FDA drug compounding FAQ).

37. 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/inspections-compliance-enforcement-and-criminal-investigations/press-releases/texas-pharmacist-pleads-guilty-adulterating-drug-used-cataract-surgeries (FDA press announcement re guilty 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.*

38. 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/us-illnesses-and-deaths-associated-with-compounded-or-repackaged-medications-2001-19 (U.S. Illnesses and Deaths Associated With Compounded or Repackaged Medications, 2001–19).

39. 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.

40. Consequences from compounded drugs may be deadly. In October 2012, 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

41. 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.

42. 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-compliance-enforcement-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-criminal-investigations/warning-letters/synthetix-inc-dba-helix-chemical-supply-668918-02072024 (FDA warning letter re Synthetix Inc. DBA Helix Chemical Supply).

43. 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-with-semaglutide-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).

44. 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/protecting-australians-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.*

45. 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).

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

DEFENDANT'S FALSE ADVERTISING AND TRADEMARK INFRINGEMENT

47. 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.

48. On information and belief, Defendant does not sell Lilly's MOUNJARO® and ZEPBOUND® and has 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.

49. 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.

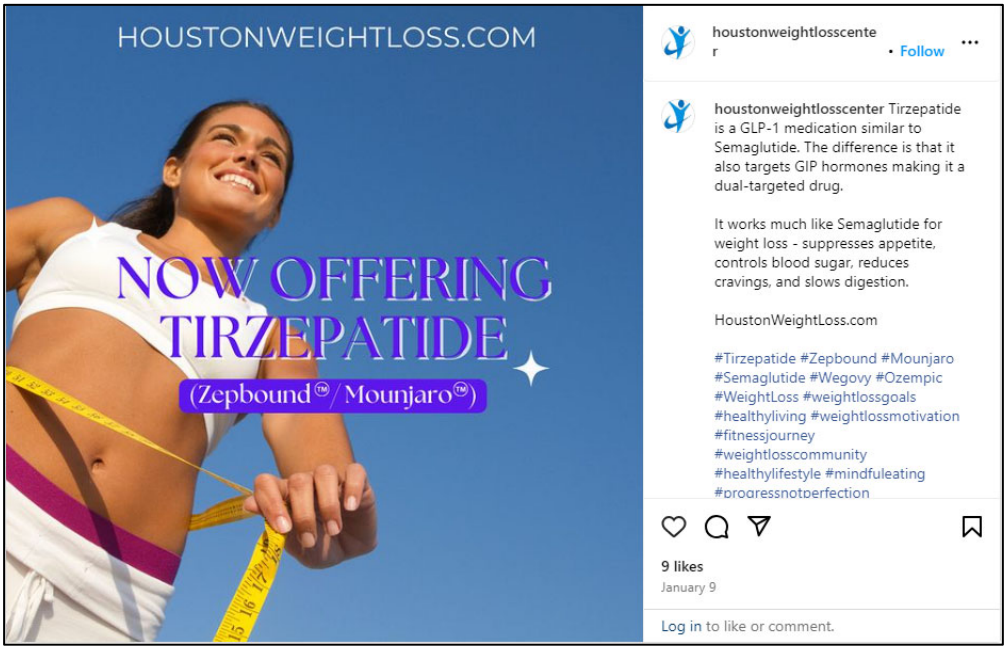
50. Examples of Defendant's trademark infringement and false advertising are shown below and are attached hereto as **Exhibit B**.

51. An example of Defendant's unauthorized use of the Lilly Marks, on the "Tirzepatide" page of Defendant's website (houstonweightloss.com/weight-loss/appetite-suppressant-programs/tirzepatide-for-weight-loss), is shown below.

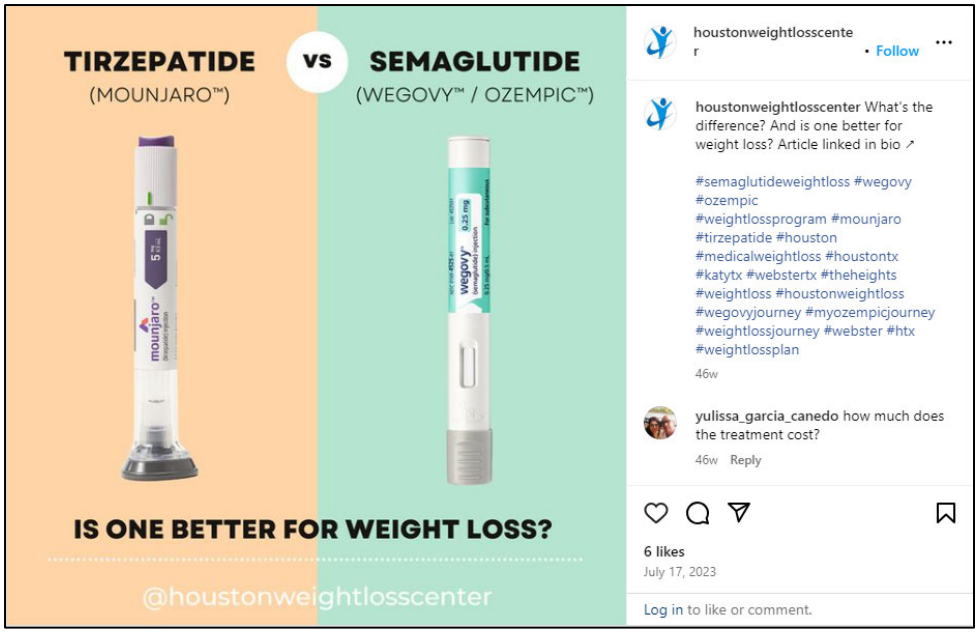
52. As the image shows, Defendant promotes its Unapproved Compounded Drugs as "approved for weight loss under the brand name Zepbound. It is also approved for Type 2 diabetes under the brand name, Mounjaro." Defendant's Unapproved Compounded Drugs are ***not*** sold under the brand name "Zepbound" or "Mounjaro," because they are not ZEPBOUND® or MOUNJARO®.

53. On this "Tirzepatide" webpage, which Defendant uses to sell its Unapproved Compounded Drugs, Defendant uses Lilly's coined terms MOUNJARO® and ZEPBOUND® repeatedly, despite the fact that Defendant does not offer either of these Lilly medicines.

54. Defendant invokes Lilly's MOUNJARO® and ZEPBOUND® trademarks on its social media accounts as well. For example, and as shown below, on January 9, 2024 Defendant posted a graphic to Instagram that reads in large font "NOW OFFERING TIRZEPATIDE (Zepbound™ / Mounjaro ™)." This post is also "tagged" #Zepbound and #Mounjaro, as shown below.



55. In another post from July 17, 2023, Defendant showed an image of Lilly's MOUNJARO® autoinjector pen under the words "TIRZEPATIDE (MOUNJARO™)." This post, too, was tagged #Mounjaro.



56. Defendant's website and social media conveys the unmistakable impression that Defendant is offering for sale Lilly's MOUNJARO® and ZEPBOUND®, a product originating from the same source as Lilly's MOUNJARO® and ZEPBOUND®. 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.

57. 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.

58. Defendant also falsely advertises its Unapproved Compounded Drugs on its website 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.

59. 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 "Tirzepatide was shown to have impressive results for weight loss and improved cardiometabolic health."

Clinical Trial Results – Tirzepatide for Weight Loss

In the Surmount 1 clinical trial, Tirzepatide was shown to have impressive results for weight loss and improved cardiometabolic health. The trial was a randomized, double blind, placebo-controlled study lasting 72 weeks that included 2,539 participants. Participants were required to have a BMI of 30 or greater, or, BMI of 27 or greater with at least one weight-related health problem.

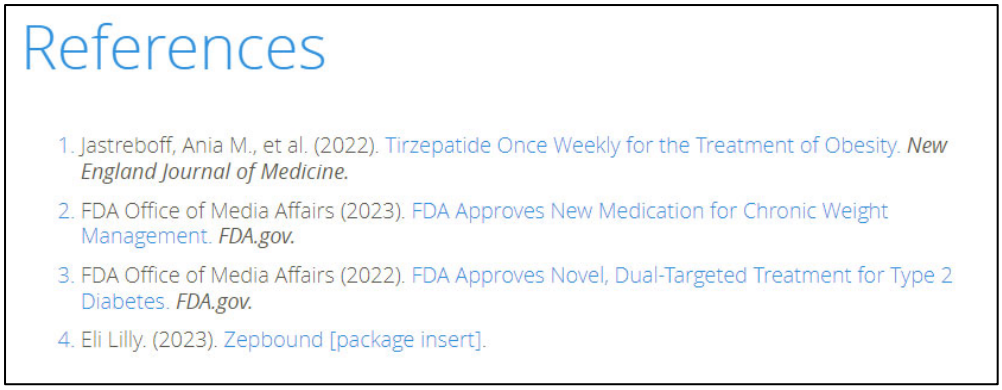
- Tirzepatide 5-mg doses – Average change in weight was -15%
- Tirzepatide 10-mg dose – Average change is weight was -19.5%
- Tirzepatide 15-mg dose – Average change in weight was -20.59%

Placebo – Average change in weight was -3%

Along with these significant weight loss results there were also improvements in all prespecified cardiometabolic measures for participants taking Tirzepatide.[1]

60. Moreover, Defendant's Unapproved Compounded Drugs are not FDA approved for any indication, despite Defendant's exclamatory "Yes!" shown above. *See* ¶50.

61. As shown below, Defendant's webpage also contains a "References" section, which cites to (1) a medical journal article discussing the results of the Lilly-funded SURMOUNT® trial, (2) ZEPBOUND®'s FDA approval announcement, (3) MOUNJARO®'s FDA approval announcement, and (4) Lilly's zepbound.lilly.com website.



References

1. Jastreboff, Ania M., et al. (2022). Tirzepatide Once Weekly for the Treatment of Obesity. *New England Journal of Medicine.*
2. FDA Office of Media Affairs (2023). FDA Approves New Medication for Chronic Weight Management. *FDA.gov.*
3. FDA Office of Media Affairs (2022). FDA Approves Novel, Dual-Targeted Treatment for Type 2 Diabetes. *FDA.gov.*
4. Eli Lilly. (2023). Zepbound [package insert].

62. As with Defendant's trademark infringement, Defendant's false and/or misleading advertising extends to Defendant's social media pages as well. For example, on May 15, 2024, Defendant posted a graphic on Instagram that, as shown below, stated that "Patients lost **up to 21% of starting body weight** on average during the clinical trial" in answer to the question "How much weight can you lose on Tirzepatide?" Defendant's caption indicates these were the results from Lilly's SURMOUNT® clinical trials.

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® clinical 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 website and social media, to deceive patients who, upon information and belief, are seeking to buy but are in fact not buying genuine FDA-approved 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 the reputation of Lilly 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 TEXAS 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®, 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 Texas 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 each and every allegation 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 each and every allegation 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 the 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
Unfair Competition
in Violation of Texas Common Law

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

100. The above-described acts of Defendant constitute unfair competition in violation of Texas common law.

101. 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®.

102. 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.

103. 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.

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

105. 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.

106. 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);

   b. 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 unfair competition in violation of the common law of Texas;

   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.

8. An Order requiring Defendant to pay Lilly all types of monetary remedies available under Texas state law in amounts as of yet undetermined caused by the foregoing acts of 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, Texas 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/ James John Lomeo

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Attorneys for Plaintiff
ELI LILLY AND COMPANY

JURY DEMAND

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

/s/ James John Lomeo

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Attorney for Plaintiff
ELI LILLY AND COMPANY

EXHIBIT A

United States of America
United States Patent and Trademark Office

MOUNJARO

Reg. No. 6,809,369

Registered Aug. 02, 2022

Int. Cl.: 5

Trademark

Principal Register

Eli Lilly and Company (INDIANA CORPORATION)
Lilly Corporate Center
Indianapolis, INDIANA 46285

CLASS 5: Pharmaceutical preparations, namely, pharmaceutical preparations for the treatment of diabetes

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

Katherine 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.

United States of America
United States Patent and Trademark Office

MOUNJARO

Reg. No. 7,068,463

Registered May 30, 2023

Int. Cl.: 44

Service Mark

Principal Register

Eli Lilly and Company (INDIANA CORPORATION)
Lilly Corporate Center
Indianapolis, INDIANA 46285

CLASS 44: Medical information services in the field of diabetes

FIRST USE 6-7-2022; IN COMMERCE 6-7-2022

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT STYLE, SIZE OR COLOR

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

Katherine 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/.

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United States of America
United States Patent and Trademark Office

ZEPBOUND

Reg. No. 7,288,373

Registered Jan. 23, 2024

Int. Cl.: 5

Trademark

Principal Register

Eli Lilly and Company (INDIANA CORPORATION)
Lilly Corporate Center
Indianapolis, INDIANA 46285

CLASS 5: Pharmaceutical preparations, namely, pharmaceutical preparations for the treatment of obesity

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

Katherine 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/.

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EXHIBIT B

TIRZEPATIDE

Appetite Suppressants

- Semaglutide
- Tirzepatide
- Phentermine

Home » Weight Loss » Appetite Suppressants » Tirzepatide

Consultations offered at our three convenient locations in Houston, Katy, and Webster, TX

Eli Lilly's Tirzepatide (Zepbound) is approved by the FDA for chronic weight management. Tirzepatide is a GLP-1 medication, similar to Semaglutide, but the main difference is that it is also a GIP receptor agonist making it a dual-agonist. Clinical trials of Tirzepatide have shown impressive weight loss results and improved health outcomes when used with a reduced-calorie diet and lifestyle changes. The Surmount-1 clinical trial resulted in cardiometabolic health improvements and 15%-21% of bodyweight lost on average for participants (compared to the placebo at only 3% bodyweight lost).[1]

Contents [HIDE]

What is Tirzepatide?

Tirzepatide is a once weekly injection that is a first-in-class medicine that activates the GLP-1 (Glucagon-like Peptide-1) and GIP (Glucose-Dependent Insulinotropic Polypeptide) receptors. These hormones regulate blood sugar levels, suppress appetite, and improve satiety (feelings of fullness).[2]

How does Tirzepatide Work?

Tirzepatide works like Semaglutide by targeting naturally occurring hormones, but Tirzepatide targets both GIP and GLP-1 pathways. Tirzepatide works well for weight loss in several ways by helping the body

regulate blood sugar, reduce cravings, reduce hunger/suppress appetite, and improving satiety by slowing down digestion.

Is Tirzepatide FDA-Approved for Weight Loss?

Yes! Tirzepatide is approved for weight loss under the brand name, Zepbound. It is also approved for Type 2 diabetes under the brand name, Mounjaro. [2,3]

Who is Tirzepatide for?

Tirzepatide (Zepbound) is indicated for adults with obesity, or, adults with excess weight who have weight-related medical problems. Tirzepatide is also approved for adults with type 2 diabetes as Mounjaro.[4]

It is not known if Tirzepatide is safe for those who have had pancreatitis, those under 18 years of age, or those who are breastfeeding. It is not used for people with Type 1 diabetes and should not be used by those that are pregnant or planning to become pregnant. It should not be used by patients if they, or any of their family, have had medullary thyroid carcinoma (MTC) or if they have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).[4]

As with most medications, Tirzepatide does have a variety of side effects and there are some patients who should not take Tirzepatide.

What are the Side Effects of Tirzepatide?

The most common side effects of taking Tirzepatide reported in clinical studies were gastrointestinal upset that were mild-to-moderate and most often occurred during a dosage increase. Common side effects include:[1]

- Nausea / Vomiting
- Diarrhea
- Stomach Pain
- Constipation
- Fatigue

Other less common but more serious side effects include severe stomach problems, kidney problems, gallbladder problems, pancreatitis. For a full list of potential side effects please see medication insert.

Clinical Trial Results – Tirzepatide for Weight Loss

In the Surmount 1 clinical trial, Tirzepatide was shown to have impressive results for weight loss and improved cardiometabolic health. The trial was a randomized, double blind, placebo-controlled study lasting 72 weeks that included 2,539 participants. Participants were required to have a BMI of 30 or greater, or, BMI of 27 or greater with at least one weight-related health problem.

- Tirzepatide 5-mg doses – Average change in weight was -15%
- Tirzepatide 10-mg dose – Average change is weight was -19.5%
- Tirzepatide 15-mg dose – Average change in weight was -20.59%

Placebo – Average change in weight was -3%

Along with these significant weight loss results there were also improvements in all prespecified cardiometabolic measures for participants taking Tirzepatide.[1]

How much does Tirzepatide cost?

Houston Weight Loss Center is proud to offer affordable Tirzepatide for our patients. Our initial consultation visit is $199, and monthly follow-ups are $89. Tirzepatide is purchased separately from the pharmacy. The cost of Tirzepatide ranges from $140-$480 per 4-week supply depending on dosage.

The brand name versions of Tirzepatide can cost up to $1,100 per 4-week supply out-of-pocket.

TOTAL COST TO YOU = COST OF OFFICE VISITS + COST OF TIRZEPATIDE

Initial Office Visit – $199 (includes exam, blood work, and lipotropic injection)

Follow-up Office Visits (required monthly) – $89

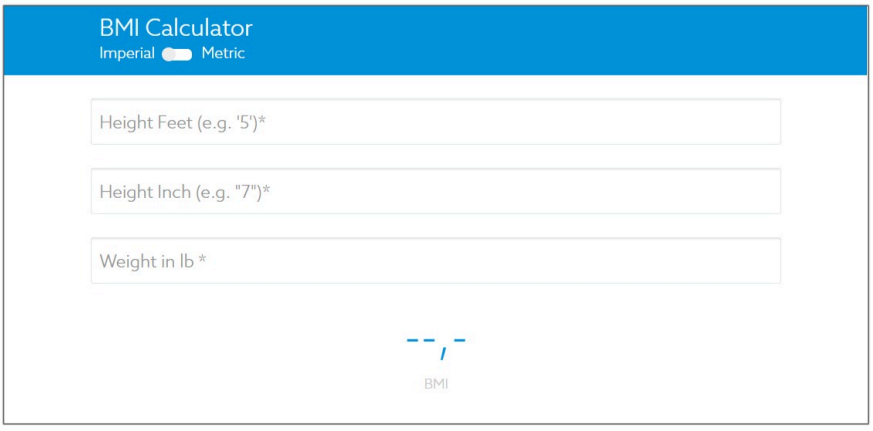
Tirzepatide – $100 to $450 (depending on dose) per 4-week supply

Do I Qualify for Tirzepatide?

Only after a visit with one of our providers can we determine whether you qualify for Tirzepatide. However, there are minimal BMI requirements:[4]

- An initial BMI of 30 or greater
- An initial BMI of 27 to 29.9 with at least one additional weight-related health issue such as high blood pressure, high cholesterol or triglycerides, diabetes, or pre-diabetes.

Check Your BMI Now



Why Choose Houston Weight Loss Center?

Health is personal and where you go matters, so it's important to find a provider you trust. **MEDICAL**

WEIGHT LOSS IS ALL WE DO! We are **a team of doctors, nurse practitioners, and medical assistants** that care about your journey. You can email, call, or schedule in-person appointments with us whenever needed, with any question.

We offer our patients an affordable Tirzepatide program that includes one-on-one coaching and weight loss support and education.

- We offer Tirzepatide injections for a fraction of the price of the brand name medications
- Our clinics specialize in medical weight loss, offering comprehensive weight loss education and clinical support (in-person)
- We have 3 convenient locations – Houston Heights, Katy, and Webster

References

1. Jastreboff, Ania M., et al. (2022). Tirzepatide Once Weekly for the Treatment of Obesity. *New England Journal of Medicine.*
2. FDA Office of Media Affairs (2023). FDA Approves New Medication for Chronic Weight Management. *FDA.gov.*
3. FDA Office of Media Affairs (2022). FDA Approves Novel, Dual-Targeted Treatment for Type 2 Diabetes. *FDA.gov.*
4. Eli Lilly. (2023). Zepbound [package insert].

*RESULTS MAY VARY

Semaglutide Weight Loss

Learn About Our Top Program

read more

Weight Loss 101

Weight Loss Tips, Recipes

read more

Testimonials

Weight loss success stories

read more

Our Offices

Houston

1941 W T C Jester #101 | Houston, TX 77008

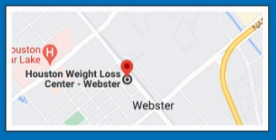
maps and directions

Katy

23217 Red River Dr | Katy, TX 77494

maps and directions

Webster



17630 State Hwy 3 | Webster, TX 77598

maps and directions

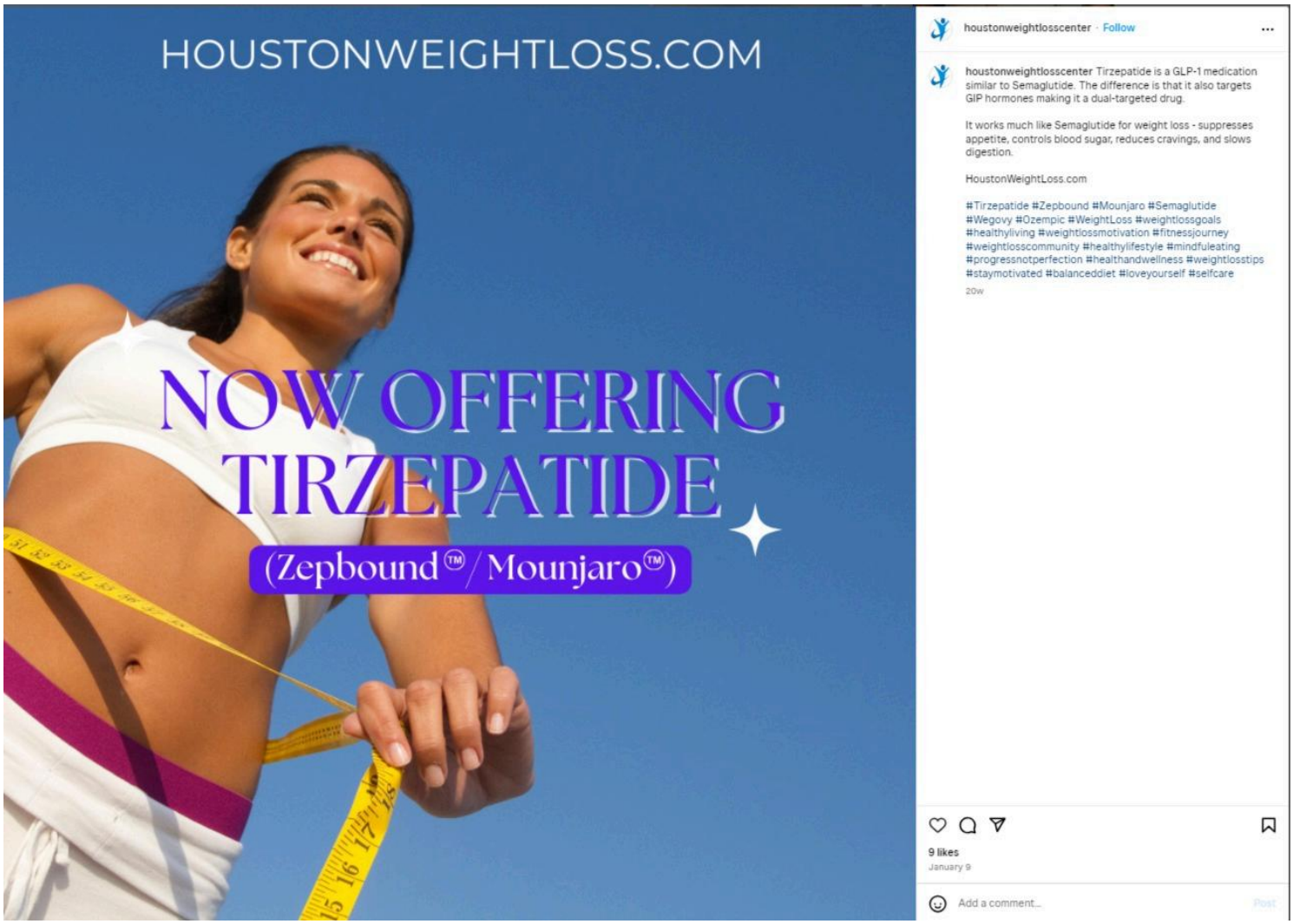
HOUSTON WEIGHT LOSS CENTER

281-400-1290

Medical Website Design & Marketing by GrowthMed

HIPAA Privacy Policy | Sitemap | Feedback

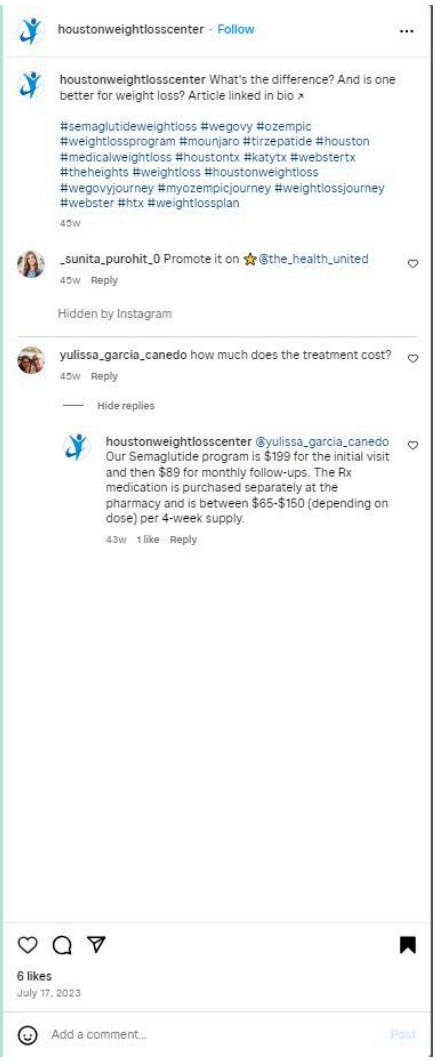
★★★★★ 4.9 stars - based on 122 reviews


HOUSTONWEIGHTLOSS.COM
NOW OFFERING
TIRZEPATIDE
(Zepbound™/Mounjaro™)
houstonweightlosscenter · Follow
houstonweightlosscenter Tirzepatide is a GLP-1 medication similar to Semaglutide. The difference is that it also targets GIP hormones making it a dual-targeted drug.
It works much like Semaglutide for weight loss - suppresses appetite, controls blood sugar, reduces cravings, and slows digestion.
HoustonWeightLoss.com
#Tirzepatide #Zepbound #Mounjaro #Semaglutide #Wegovy #Ozempic #WeightLoss #weightlossgoals #healthyliving #weightlossmotivation #fitnessjourney #weightlosscommunity #healthylifestyle #mindfuleating #progressnotperfection #healthandwellness #weightlosstips #staymotivated #balanceddiet #loveyourself #selfcare
20w
9 likes
January 9
Add a comment...
Post


TIRZEPATIDE
FAQs
Q How much weight can you lose on Tirzepatide?
A Patients lost up to 21% of starting body weight on average during the clinical trial.
▸ Significant results from the clinical trial showed patients losing an average of 15-21% body weight.
▸ With any medication or program, the rate and total amount of weight loss will vary from patient to patient.
@houstonweightlosscenter


houstonweightlosscenter · Follow
houstonweightlosscenter In the Surmount 1 clinical trial, Tirzepatide was shown to have impressive results for weight loss and improved cardiometabolic health. Weight Loss Results Summary
▫ Placebo – Average change -3%
▫ 5-mg doses – Average change was -15%
▫ 10-mg dose – Average change was -19.5%
▫ 15-mg dose – Average change was -20.59%
Learn More:
HoustonWeightLoss.com ➡ Weight Loss ➡ Appetite Suppressants ➡ Tirzepatide
2w
1 like
May 15
Add a comment...
Post


TIRZEPATIDE
(MOUNJARO™)
vs
SEMAGLUTIDE
(WEGOVY™ / OZEMPIC™)
mounjaro
wegovy
0.25 mg
IS ONE BETTER FOR WEIGHT LOSS?
@houstonweightlosscenter


houstonweightlosscenter · Follow
houstonweightlosscenter What's the difference? And is one better for weight loss? Article linked in bio ↗
#semaglutideweightloss #wegovy #ozempic #weightlossprogram #mounjaro #tirzepatide #houston #medicalweightloss #houstontx #katytx #webstertx #theheights #weightloss #houstonweightloss #wegovyjourney #myozempicjourney #weightlossjourney #webster #htx #weightlossplan
45w
_sunita_purohit_0 Promote it on @the_health_united
45w Reply
Hidden by Instagram
yulissa_garcia_canedo how much does the treatment cost?
45w Reply
Hide replies
houstonweightlosscenter @yulissa_garcia_canedo Our Semaglutide program is $199 for the initial visit and then $89 for monthly follow-ups. The Rx medication is purchased separately at the pharmacy and is between $65-$150 (depending on dose) per 4-week supply.
43w 1 like Reply
6 likes
July 17, 2023
Add a comment...
Post

Houston Weight Loss Center
May 15 at 6:00 PM ·

In the Surmount 1 clinical trial, Tirzepatide was shown to have impressive results for weight loss and improvements in cardiometabolic health.

Weight Loss Results Summary ⬇️

- Placebo – Average change -3%
- 5-mg doses – Average change was -15%
- 10-mg dose – Average change was -19.5%
- 15-mg dose – Average change was -20.59%

Learn More:
http://HoustonWeightLoss.com/.../tirzepatide-for-weight.../

2

Like Comment Share

Write a comment...

Houston Weight Loss Center
February 5 ·

There are multiple factors at play for those struggling with obesity and treating obesity is not as easy as simply saying 'eat less, move more'.

As a weight loss clinic that has treated thousands of patient across Houston we understand that there are underlying mental/emotional, biological, and physical factors that all need to be addressed in order to overcome the disease of obesity.

We attempt to tackle each of these with our rapid weight loss program that includes 1:1 counseling & weight loss education, registered dietitian created meal plans, as well as medications that reduce appetite and aide with the biological and mental factors that come into play for those with obesity.

You can learn more about the program and the medications we offer on our website: HoustonWeightLoss.com/Weight-Loss/

Semaglutide (Wegovy / Ozempic)
Tirzepatide (Zepbound / Mounjaro)

#Semaglutide #Tirzepatide #HoustonWeightLossCenter #WeightLossClinic #ObesityMedicine #HealthierChoices #WeightLoss #HealthyLiving #HealthyBody #HealthIsWealth #HealthGoals #LifestyleChange #WellBeing #SelfCare #StayActive #MotivationMonday #InstaHealth #EmpowerYourself #Zepbound #Mounjaro #Ozempic #Wegovy #ObesityAwareness

2

Like Comment Share


Write a comment...

Houston Weight Loss Center
January 9 ·

Tirzepatide is a GLP-1 medication similar to Semaglutide. The difference is that it also targets GIP hormones making it a dual-targeted drug.

It works much like Semaglutide for weight loss - suppresses appetite, controls blood sugar, reduces cravings, and slows digestion.

Learn More About Tirzepatide
http://Houstonweightloss.com/.../tirzepatide-for-weight.../

#Tirzepatide #Zepbound #Mounjaro #Semaglutide #Wegovy #Ozempic #WeightLoss #weightlossgoals #healthyliving #weightlossmotivation #fitnessjourney #weightlosscommunity #healthylifestyle #mindfuleating #progressnotperfection #healthandwellness #weightlosstips #staymotivated #balanceddiet #loveyourself #selfcare

2

Like Comment Share

Write a comment...

Houston Weight Loss Center's Post

Houston Weight Loss Center
July 17, 2023 ·

Trizepatide vs. Semaglutide: What's the difference? And, is one better for weight loss?

Read Article
https://www.houstonweightloss.com/.../tirzepatide-vs.../

#semaglutideweightloss #wegovy #ozempic #weightlossprogram #mounjaro #tirzepatide #houston #medicalweightloss #houstontx #theheights #weightloss #houstonweightloss #wegovyjourney #myozempicjourney #weightlossjourney #htx #weightlossplan

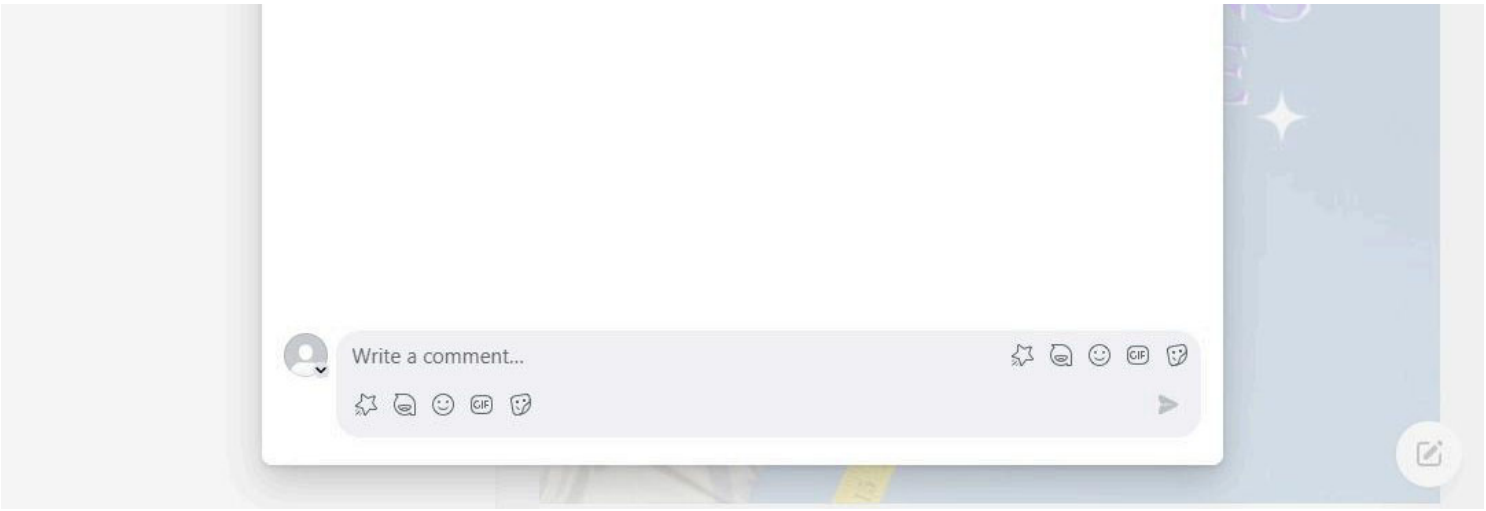
3 2 comments

Like Comment Share

All comments

Analia Nogueira
Do u have tirzepatide?
41w Like Reply

Author
Houston Weight Loss Center
Analia Nogueira It is not currently FDA-approved for weight loss, so we are not offering it quite yet! It should get approval later this year though 🤞 Stay tuned!
41w Like Reply


Write a comment...

Houston Weight Loss Center · Follow
November 29, 2023 ·

Some exciting news from the FDA - Tirzepatide has been approved for chronic weight management.

Tirzepatide is similar to Semaglutide (GLP-1), but it is both a GLP-1 and GIP receptor agonist.

Now offered at Houston Weight Loss Center!

Learn More About Our Program
http://HoustonWeightLoss.com/.../tirzepatide-for-weight.../

#Tirzepatide #Mounjaro #Zepbound #WeightLossDrug #FDAapproval #NewWeightLossDrug #Houston #TirzepatideHouston #ZepboundHouston #GLP1 #GIP

FDA.GOV
FDA Approves New Medication for Chronic Weight Management
The FDA approved Zepbound (tirzepatide) for chronic weight management in adults wit...

Like Comment Share

Write a comment...

Houston Weight Loss Center
January 23 ·

Whether you're taking Semaglutide, Tirzepatide, or simply tracking calories, here's a 1400 calories per day meal plan that will keep you feeling full & balanced ⬇️

🍳Breakfast = Cheesy Eggs + Strawberries (277 Cals)
2 large eggs
1/4 cup shredded cheese
1 cup sliced strawberries

🌮Lunch = Tacos (653 Cals)
2 corn tortillas
1 cup cooked lean ground beef
1/4 cup shredded cheese
2 T salsa
2 T sour cream
2 slices avocado
Side: 1/4 cup blueberries

🥬Snack = Celery & Ranch (103 Cals)
5 large sticks celery
1 T ranch dressing

🥦Dinner = Baked Chicken & Broccoli (375 Cals)
4 oz chicken breast, baked
1.5 cups broccoli, roasted (no oil)
1 cup corn
1 plum

Don't forget to drink 16 oz of water with each meal & snack! 💦

HoustonWeightLoss.com

#houston #weightloss #weightlossplan #lowcalorie #medicalweightloss #dietitian #semaglutide #theheights #semaglutideforweightloss #appetitesuppressant #Mealldeas #1400Calories #whattoeatinaday #Semaglutidemealplan #ozempicmealplan #wegovymealplan #tirzepatide #zepbound #mounjaro #zepboundmealplan #mounjaromealplan #foodideas #mealplan #registereddietitian #healthyfood #balancedmeals #newyeargoals #newyearmealplan


MEAL DETAILS IN CAPTION
Created by our Registered Dietician
1
Like
Comment
Share
Write a comment...

Album **Educational**

Houston Weight Loss Center
February 26 ·

To qualify for our Tirzepatide weight loss program, you'll need to meet the initial BMI requirements of 30 or greater - or - 27-29.9 with one weight-related health issue.

It's important to note that while BMI is a good first indicator, the best way to determine if this medication will work for you is to schedule your first appointment with us. This comprehensive appointment includes 1:1 counseling with a nurse practitioner, weight-related bloodwork, body composition analysis, and more.

Learn More
https://www.houstonweightloss.com/.../tirzepatide-for.../

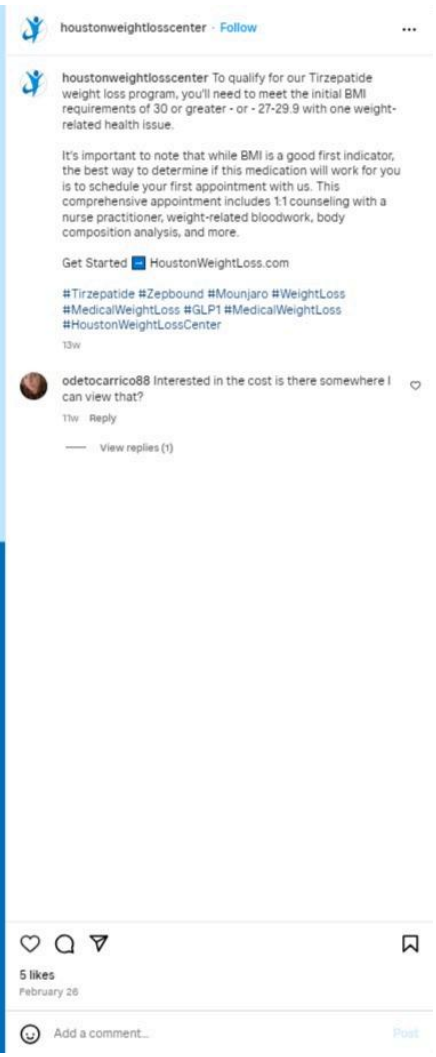
#Tirzepatide #Zepbound #Mounjaro #WeightLoss #MedicalWeightLoss #GLP1 #MedicalWeightLoss #HoustonWeightLossCenter

2

Like Comment Share

Write a comment...


TIRZEPATIDE
FAQs
Q How do I qualify for Tirzepatide?
A First, you must meet the initial BMI requirements
▸ Initial BMI of 30 or greater
▸ Initial BMI of 27 to 29.9 with at least one weight-related health issue
@houstonweightlosscenter


houstonweightlosscenter · Follow
houstonweightlosscenter To qualify for our Tirzepatide weight loss program, you'll need to meet the initial BMI requirements of 30 or greater - or - 27-29.9 with one weight-related health issue.
It's important to note that while BMI is a good first indicator, the best way to determine if this medication will work for you is to schedule your first appointment with us. This comprehensive appointment includes 1:1 counseling with a nurse practitioner, weight-related bloodwork, body composition analysis, and more.
Get Started HoustonWeightLoss.com
#Tirzepatide #Zepbound #Mounjaro #WeightLoss #MedicalWeightLoss #GLP1 #MedicalWeightLoss #HoustonWeightLossCenter
13w
odetocarrico88 Interested in the cost is there somewhere I can view that?
1hw Reply
View replies (1)
5 likes
February 26
Add a comment...
Post


TIRZEPATIDE FAQs
Q How soon will I see results on Tirzepatide?
A You may see results within the first month but this can vary from patient to patient.
▸ Typically patients start on the lowest dose and increase to the max over 3-4 months.
▸ Many of our patients see results in month one but for some they see more significant results at higher doses.
@houstonweightlosscenter
houstonweightlosscenter · Follow
houstonweightlosscenter When first starting Tirzepatide, patients will typically start on the lowest dose and increase to the maximum over 3 to 4 months.
Many of our patients do feel immediate effects and start seeing weight loss results within the first month, but for some it may take a little longer to feel significant effects until they work up to a higher dose (so don't get discouraged if that sounds like you!).
Learn More HoustonWeightLoss.com
#Tirzepatide #Zepbound #Mounjaro #WeightLoss #MedicalWeightLoss #GLP1 #MedicalWeightLoss #HoustonWeightLossCenter #WebsterWeightLoss #KatyWeightLoss
5w
2 likes
April 25
Add a comment...

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

Eli Lilly and Company

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

James John Lomeo, Kirkland & Ellis LLP; 401 Congress Avenue, Austin, TX 78701; (512) 678-9100

DEFENDANTS

J. Bergeron M.D., P.A. d/b/a Houston Weight Loss Clinic

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

INTELLECTUAL PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☒ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

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:
Trademark infringement; false designation of origin; false advertising

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ Unspecified/Injunction

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE Jun 20, 2024

SIGNATURE OF ATTORNEY OF RECORD /s/ James John Lomeo

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. Origin. Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related cases, if any. If there are related cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.