**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF INDIANA**
**INDIANAPOLIS DIVISION**

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| ELI LILLY AND COMPANY,<br><br>Plaintiff,<br><br>v.<br><br>PREMIER WEIGHT LOSS OF INDIANA, LLC D/B/A PREMIER WEIGHT LOSS, and PREMIER WEIGHT LOSS MANAGEMENT, LLC,<br><br>Defendants. | ) | Case No.<br><br>Hon. Judge<br>Magistrate Judge |

**PLAINTIFF ELI LILLY AND COMPANY'S COMPLAINT FOR TRADEMARK INFRINGEMENT AND FALSE ADVERTISING**

## INTRODUCTION

1. Defendants Premier Weight Loss of Indiana, LLC d/b/a Premier Weight Loss and Premier Weight Loss Management, LLC (collectively, "PWL") have designed their website, blog, and other advertising materials to communicate that they sell Plaintiff Eli Lilly and Company's ("Lilly") medicines, sold under the brand names MOUNJARO® and ZEPBOUND® (the "Lilly Marks"). PWL promotes its business in this fashion to convince customers that the drugs it sells are unaltered, FDA-approved Lilly medicines and therefore come with all the safety and effectiveness assurances that accompany the regulatory approval process and Lilly's 150-year reputation as a pharmaceutical manufacturer.

2. By cloaking itself in the goodwill and assurances associated with Lilly's medicines, PWL explicitly contrasts the products it offers from the knock-off, untested, and unapproved products offered by other compounding pharmacies and med spas. For example, PWL warns consumers that "[i]t is not a guarantee that compounded … medications will be as safe and effective as the name brand … medications!" It then advertises that it "only" sells "name brand, FDA approved weight loss injections!," just the "authentic," "real stuff," and "FDA approved, brand name GLP-1 injections like Mounjaro [and] Zepbound."

3. That is a lie. PWL is not selling "authentic," "FDA approved" "MOUNJARO®" or "ZEPBOUND®." Those approved Lilly medicines are factory-sealed, sterile single-dose "auto-injector pen" or sterile single-dose vials. That is not what PWL offers. Instead, it sells its patients altered, unsterile products that have been unsealed, repackaged, and re-dosed to stretch Lilly's single-use auto-injector pens into five lower-dose injections.

4. Lilly's medicines are approved by FDA as safe and effective for use only in specific conditions, including dose strengths, route of administration, packaging, and labeling—all of

which are essential components of what makes them genuine MOUNJARO® or ZEPBOUND®. But PWL's practices knowingly and directly destroy those characteristics, making its products—directly contrary to its advertising claims—dangerous, not FDA approved, and, in short, not the same as Lilly's medicines that bear its MOUNJARO® and ZEPBOUND® trademarks. Far from approving PWL's practices, both FDA and the CDC have specifically warned against dose splitting. As FDA has explained "[t]he moment a sterile container is opened and manipulated, a quality standard (sterility) is destroyed and previous studies supporting the standard(s) are compromised and are no longer valid."[1]

5. Lilly goes to great lengths to ensure the sterility of its authentic, FDA-approved medicines, which is crucially important because these medicines are injected directly into patients' bodies. Cracking open Lilly's single-use auto-injector pens or vials to create multiple doses—as PWL does—destroys sterility and introduces serious risk to patients who use the unsterile product. The moment the sterile container is opened, it becomes a potential breeding ground for bacteria. No anti-microbial preservatives. No safeguards. No regulatory oversight. A single tiny, invisible dose of infection can lead to sepsis, abscesses, or even death. None of this is hyperbole. There are countless examples of companies causing patients serious harm and even death by engaging in the same or similar practices as PWL.

[1] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-446100-regulatory-action-regarding-approved-new-drugs-and-antibiotic-drug-products-subjected#:~:text=The%20FDA%20has%20an%20even,410.100); *see also* https://www.cdc.gov/injection-safety/hcp/clinical-safety/index.html.

6. PWL nevertheless offloads this risk onto its patients for one reason and one reason only: profits. For each package of Lilly auto-injector pens it breaks apart into its altered drugs, PWL stands to gain upwards of $1,000 a month in profits—at the cost of patient health and safety.

7. PWL engages in this dangerous and deceptive scheme while masquerading as a paragon of safety. It advertises its altered drugs under Lilly's trademarks knowing that it has altered the packaging and dose, thereby introducing significant patient safety risks of which the patient is not informed. In fact, PWL relies on patients not knowing there is a significant difference between Lilly's MOUNJARO® and ZEPBOUND® in their sterile, original, FDA-approved packaging and PWL's altered, unsterile, risky products. Lilly therefore brings this action to protect the public from PWL's dangerous, deceptive, and unlawful practices.

8. PWL's trademark infringement and false advertising have the tendency to deceive the public and lure individuals with serious health conditions away from safe and effective, non-adulterated FDA-approved medicines in favor of unlawfully altered drugs bearing the Lilly Marks. Thus, Lilly files this Complaint for trademark infringement, false designation of origin, unfair competition, and false advertising pursuant to the Lanham Act, 15 U.S.C. §§ 1114 *et seq*, and trademark infringement in violation of Indiana common law.

## 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 Premier Weight Loss of Indiana, LLC is a limited liability company organized under the laws of Indiana, doing business under the assumed name Premier Weight Loss, with its principal place of business located at 15757 Oak Road, Carmel, IN, 46033. Its

registered agent is Thomas Hilbert with a registered agent address at 8902 N Meridian St, 100, Indianapolis, IN, 46260.

11. Defendant Premier Weight Loss Management, LLC is a limited liability company organized under the laws of Indiana, with its principal place of business located at 15757 Oak Road, Carmel, IN, 46033. Its registered agent is Thomas Hilbert with a registered agent address at 15757 Oak Road, Carmel, IN, 46033.

## JURISDICTION AND VENUE

12. The Court has subject matter jurisdiction over the Lanham Act causes of action pleaded in this case pursuant to 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331 and 1338(a). This Court has subject matter jurisdiction over the common law cause of action pursuant to 28 U.S.C. §1367(a).

13. Premier Weight Loss of Indiana, LLC is subject to personal jurisdiction in this District because it is registered in Indiana and operates its principal place of business in this District. Indeed, its registered address corresponds with one of the two addresses provided on PWL's website listing its clinic locations, along with 10475 Crosspoint Boulevard Suite 315, Indianapolis, IN 46256.[2]


[2] https://pwlindy.com/

14. Premier Weight Loss Management, LLC is subject to personal jurisdiction in this District because it is registered in Indiana and operates its principal place of business in this District.

15. Venue is proper in this District and division pursuant to 28 U.S.C. § 1391(b)(1) because both PWL entities are organized in and have their principal places of business in this District and Division.

## FACTUAL ALLEGATIONS

### I. Lilly's FDA-Approved Tirzepatide Medicines

#### A. Lilly's History of Producing Safe and Effective Medicines

16. Lilly is an international medicine company and pharmaceutical manufacturer. Throughout its nearly 150-year existence, Lilly has pioneered countless life-changing discoveries. Today, Lilly's medicines help tens of millions of patients across the globe, including in Indiana.

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

18. Lilly develops and manufactures its medicines in compliance with FDA oversight, the international gold standard for pharmaceuticals that includes rigorous pre-approval testing for

safety and effectiveness under specified conditions of use, routine FDA inspections of manufacturing facilities, adverse event reporting obligations, and post-market surveillance and studies. Additionally, Lilly's medicines must be, and always are, accompanied by important labels, instructions, and warnings that are approved by FDA as necessary components of the final product.

### B. MOUNJARO® and ZEPBOUND®

19. Lilly's proprietary MOUNJARO® and ZEPBOUND® are two first-of-their-kind medicines indicated for serious conditions afflicting millions of Americans. Approximately one in ten Americans have type 2 diabetes, and four in ten Americans are obese. To advance the treatment of these chronic conditions, Lilly used its extensive experience and years of research to develop its MOUNJARO® and ZEPBOUND® medicines, which were approved by FDA for sale to the public in 2022 and 2023, respectively. Today, Lilly promotes, offers, and sells MOUNJARO® and ZEPBOUND® throughout Indiana and the United States, among other places.

20. Both MOUNJARO® and ZEPBOUND® contain the active pharmaceutical ingredient tirzepatide, which targets patients' GLP-1 (glucagon-like peptide-1) and GIP (glucose-dependent insulinotropic polypeptide) receptors. Tirzepatide activates both receptors to improve blood sugar control and reduce appetite and food intake.[3]

21. Specifically, MOUNJARO® is designed to improve glycemic control in adults with type 2 diabetes mellitus (in addition to diet and exercise). As FDA has noted, "[d]espite the availability of many medications to treat diabetes, many patients do not achieve the recommended

[3]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).

blood sugar goals."[4] MOUNJARO® targets this problem head-on. When used as directed, MOUNJARO® has been clinically proven to improve blood sugar control more effectively than other diabetes therapies.

22. ZEPBOUND® is designed to help the millions of American adults with obesity or who are overweight with weight-related medical problems. As 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.[5] Accordingly, FDA originally indicated ZEPBOUND® for weight management for adults with obesity or those who are overweight and also have at least one additional weight-related condition, such as hypertension (high blood pressure), dyslipidemia (high cholesterol or fats in blood), type 2 diabetes mellitus, or cardiovascular disease. In December 2024, because of Lilly's ongoing post-approval research, FDA approved a second indication for ZEPBOUND® for the treatment of obstructive sleep apnea for adults with obesity.

23. Lilly exclusively owns the intellectual property rights related to MOUNJARO® and ZEPBOUND® and is the only lawful supplier of those medicines.

**C. The FDA Approval Process**

24. FDA approved MOUNJARO® and ZEPBOUND® pursuant to Lilly's marketing application, itself the culmination of a lengthy clinical trial process designed to develop, study, and bring safe medicines to patients so that—in FDA's words—"American consumers benefit

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[4] 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).

[5] https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-chronic-weight-management (FDA ZEPBOUND® approval press announcement).

from having access to the safest and most advanced pharmaceutical system in the world."[6] Over the course of nearly a decade, Lilly completed thirty-seven pre-clinical studies and clinical trials for these medicines.

25. MOUNJARO® and ZEPBOUND® are the only FDA-approved medicines containing tirzepatide in the United States.

26. FDA has recently confirmed in court that Lilly is the only lawful producer of tirzepatide in the United States.[7]

27. MOUNJARO® and ZEPBOUND® are approved by FDA only in specific dosages and concentrations, and only for subcutaneous injection, and cannot be lawfully sold in other formulations or methods of administration. Indeed, as part of FDA's New Drug Application ("NDA") or Abbreviated New Drug Application ("ANDA") process, the Applicant must disclose to the Center for Drug Evaluation and Research ("CDER") detailed technical specifications on the drug substance and final pharmaceutical product.[8] Separately, CDER "approve[s] a container closure system to be used in the packaging of a human drug or biologics,"[9] based on a detailed description of the container closure system identifying all sources and components, information on the suitability of the container closure system for the drug product, details on the applicant's or fabricator's quality control program, and stability data for the drug product in the selected

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[6] https://www.fda.gov/drugs/development-approval-process-drugs (FDA explainer of new drug development process).

[7] *Outsourcing Facilities Assoc. v. FDA, et al.*, Case No. 4:24-cv-00953-P (N.D. Texas), Dkt. 83, at 1; https://www.law360.com/commercialcontracts/articles/2301352?utm_source=shared-articles&utm_medium=email&utm_campaign=shared-articles (media coverage of same).

[8] https://www.fda.gov/drugs/types-applications/new-drug-application-nda

[9] FDA, *Guidance for Industry: Container Closure Systems for Packaging Human Drug and Biologics*, at 8 (May 1999), https://www.fda.gov/media/70788/download.

container closure system.[10] Making changes to a drug product or container closure system after FDA approval requires a detailed "assessment of the effects of a change on the identity, strength, quality, purity, and potency of the drug product" [11] compared to quality standard specifications, as well as additional testing to assess "changes in the chemical, physical, microbiological, biological, bioavailability, and/or stability profiles."[12]

28. The only FDA-approved formulations for MOUNJARO® and ZEPBOUND® are 2.5mg/0.5mL, 5mg/0.5mL, 7.5mg/0.5mL, 10mg/0.5mL, 12.5mg/0.5mL, and 15mg/0.5mL per week, with each injection consisting of 0.5mL of solution regardless of the concentration of drug prescribed.

29. The only FDA-approved presentations for MOUNJARO® and ZEPBOUND® are Lilly's auto-injector pens (for all dose formulations) and factory-sealed single-dose vials (for ZEPBOUND® dose formulations up to 10mg/0.5mL).

30. Accompanying Lilly's auto-injector pens or factory-sealed single-dose vials is the FDA-approved "label" and "Patient Package Insert" for MOUNJARO® or ZEPBOUND®. The label is a detailed description of indications and uses, dosage and administration, warnings and precautions designed to advise clinicians prescribing these medications. The label also contains summaries of the clinical pharmacology, toxicology, and clinical trial results for the medicine, as well as instructions for safe handling.[13] The Patient Package Insert contains three sections: the

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[10] *Id.* at 17–20.

[11] https://www.fda.gov/media/71846/download, at 4–5.

[12] *Id.* at 5.

[13] For the current FDA-approved label, see https://pi.lilly.com/us/mounjaro-uspi.pdf (for Mounjaro) and https://pi.lilly.com/us/zepbound-uspi.pdf (for Zepbound).

medication guide, instructions for use, and a quick reference guide. These documents are designed to educate patients about the medication they have been prescribed, what to expect while taking the medication, and how to administer the medication safely and effectively.[14]

**D. Lilly's Clinical Trials**

31. Before a new medication can be brought to market, it must be clinically tested through a rigorous series of studies designed to determine whether the medication is safe and effective for people to use.[15] These clinical trials are also used to study different uses for already approved medications that could identify new indications, increase effectiveness, make the medication easier to use, or decrease side-effects.[16]

32. Lilly has submitted to FDA thirty-seven preclinical and clinical studies of its MOUNJARO® and ZEPBOUND®, which evaluate the safety and efficacy of its tirzepatide medicines for its intended uses. These trials were conducted over the course of multiple years and at great expense to Lilly.

33. Lilly's trials provided it with the necessary data to demonstrate that its MOUNJARO® and ZEPBOUND® medicines are safe and effective for people to use. Without the trials, these medicines would not be eligible for FDA approval and the substantial time, labor, and capital expended by Lilly to conduct them was therefore necessary to bring these medicines to market and promote them for public use.

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[14] https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215866s000lbl.pdf (FDA-approved Label with accompanying Package Inserts for Mounjaro)

[15] https://www.fda.gov/patients/drug-development-process/step-3-clinical-research#The_Investigational_New_Drug_Process (FDA explainer on clinical trial steps for new drug development).

[16] https://www.fda.gov/patients/clinical-trials-what-patients-need-know/basics-about-clinical-trials (FDA explainer of basics about clinical trials).

## II. LILLY'S MOUNJARO® AND ZEPBOUND® TRADEMARKS

34. Lilly uses the trademarks MOUNJARO® and ZEPBOUND® 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, including in Indiana, using the Lilly Marks.

35. 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.

36. 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 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.

37. 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 management and obstructive sleep apnea medicine bearing the ZEPBOUND® mark in many different channels, directed both to healthcare professionals and to patients.

38. 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 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.

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

40. Lilly promotes, advertises, and markets MOUNJARO® and ZEPBOUND® 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.

41. 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.

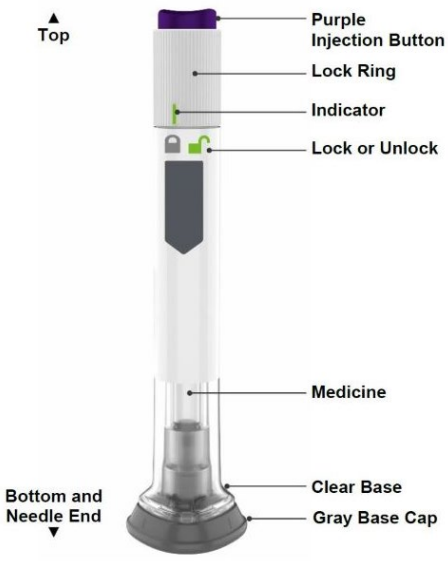
## III. PWL's Altered Drugs[17]

### A. PWL's Altered Outer Packaging and Insert

42. PWL's altered drugs purport to be Lilly medicines but are not offered in the Lilly packaging: they do not come in the box containing the FDA-approved language, nor is the drug product itself in the factory-sealed auto-injector pen depicted below, in which unaltered MOUNJARO® medicine is exclusively distributed, and in which ZEPBOUND® doses of

[17] Unless otherwise stated, all allegations in Sections III, IV, and V are made subject to Lilly's information and belief.

2.5mg/0.5mL, 5mg/0.5mL, 7.5mg/0.5mL, 10mg/0.5 mL, 12.5mg/0.5mL, and 15mg/0.5mL are distributed.[18]




43. ZEPBOUND® doses of 2.5mg/0.5mL, 5mg/0.5mL, 7.5mg/0.5mL, and 10mg/0.5mL are also available in a single-dose vial format shown below.[19]

[18] Mounjaro warnings and instructions for use, available at https://uspl.lilly.com/mounjaro/mounjaro.html#ug0; Zepbound warnings and instructions for use, available at https://uspl.lilly.com/zepbound/zepbound.html#ug0.

[19] https://investor.lilly.com/news-releases/news-release-details/lilly-releases-zepboundr-tirzepatide-single-dose-vials-expanding.


44. MOUNJARO® is not sold or distributed in any vial format in any dose or concentration. Likewise, MOUNJARO® is not sold or distributed in pre-filled syringes in any dose or concentration.

45. ZEPBOUND® is not sold or distributed in a multi-dose vial format in any dose or concentration. Likewise, ZEPBOUND® is not sold or distributed in pre-filled syringes in any dose or concentration.

46. Genuine, unaltered, FDA-approved Lilly auto-injector pens are distributed in a pack of four, corresponding to a month's worth of weekly administrations of Lilly's medicine. The four pens are contained in a box whose external packaging contains additional warnings and instructions for storage that have separately been reviewed and approved by FDA, as well as batch identifiers and expiration dates required by FDA.


47. Each individual auto-injector pen or vial of genuine, unaltered Lilly medicine is labeled with a batch number, as is the external packaging. This batch number ensures that Lilly can trace its medicines and ensure the safety and quality of its medicines as they enter the market.

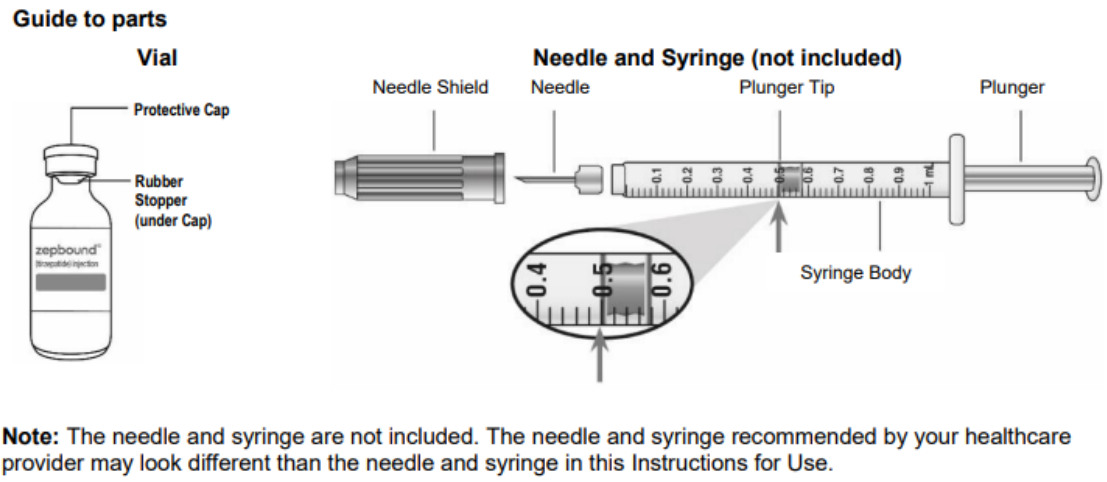
48. Unlike Lilly's medicines, PWL's altered drugs are distributed in clear plastic bags affixed with PWL's prescribing information and bearing the Lilly Marks, with the drug itself contained in nondescript third-party insulin syringes.

49. PWL sells its altered drugs without the FDA-required documentation that accompanies MOUNJARO® and ZEPBOUND®.

50. FDA requires a Patient Package Insert to be placed in each box of medicine—a patient-centric version of the FDA-approved prescription drug label that includes details on the

active and inactive ingredients, method of administration, side effects, storage, and general safety information about the medicine.[20] PWL's removal of the Patient Package Insert prevents consumers from obtaining critical and material information. From a safety perspective, it no longer contains instructions for safe storage and administration. Likewise, it no longer contains the batch information, expiration dates, and other quality assurance markers. If the patient suffers an adverse event from taking this medication, there is no instruction to contact their physician and Lilly.

51. The removal of the Patient Package Insert also aids in PWL's deception. First, it prevents patients from comparing the unboxed third-party syringes they receive from PWL to the images of properly sterile, packaged Lilly auto-injector pens or single-dose vials. Second, it prevents patients from seeing that—for patients receiving single-dose vials—Lilly does *not* provide needles and syringes. Third, it prevents them from seeing that Lilly's medicines are all approved to be administered in 0.5mL doses.[21]




**Note:** The needle and syringe are not included. The needle and syringe recommended by your healthcare provider may look different than the needle and syringe in this Instructions for Use.

[20] https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/patient-labeling-resources#inserts

[21] https://pi.lilly.com/us/zepbound-vial-us-ifu.pdf

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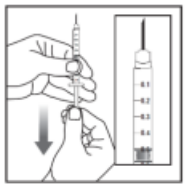
| **Step 7:**<br>Hold the syringe in one hand with the needle pointing up. With the other hand pull down on the plunger until the plunger tip reaches the line on the syringe indicating that 0.5 mL of air has been drawn into the syringe. |  |
| **Step 10:**<br>Turn the vial and syringe upside down. Make sure that the tip of the needle is in the liquid and slowly pull the plunger down until the plunger tip is past the 0.5 mL line.<br>If there are air bubbles, tap the syringe gently a few times to let any air bubbles rise to the top. |  <br>  |
| **Step 11:**<br>Slowly push the plunger up until the plunger tip reaches the 0.5 mL line. |  |

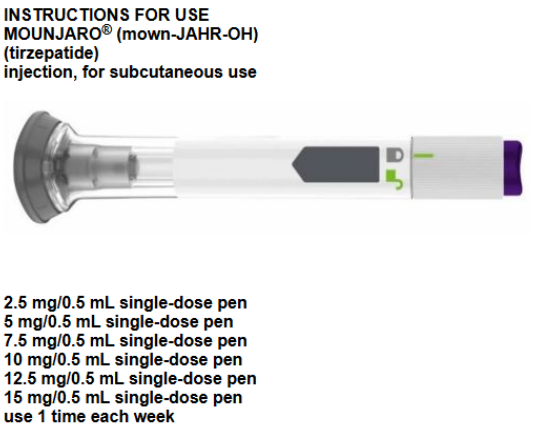
52. Instead, PWL includes its own single-page label and PWL-branded package insert containing directions for use, which have not been reviewed or approved by FDA and are not nearly as comprehensive as the actual approved disclosures. For example, in the PWL label's "HOW TO USE" section, it instructs patients to "[r]ead the Medication Guide and Instructions for Use provided by your pharmacists before you start using tirzepatide," but does not include either document which are part of the FDA-approved Patient Package Insert.

### B. PWL's Tampering and Re-dosing

#### 1. *PWL's altered drugs are obviously altered because they contain less volume than unaltered Lilly medicines*

53. All dosages of MOUNJARO® and ZEPBOUND® are formulated at a dose-per-milliliter ratio per 0.5mL. Additionally, all Lilly auto-injector pens or single-use vials contain

0.5mL of liquid, regardless of the concentration of active to inactive ingredients. Accordingly, the strength of each MOUNJARO® and ZEPBOUND® dose represents the concentration of tirzepatide in that 0.5mL, not the total volume.[22]




54. By contrast, PWL offers 2.5mg doses of "Mounjaro" and "Zepbound" in third-party insulin syringes containing approximately 0.1mL of liquid, one fifth of what would be contained in a MOUNJARO® or ZEPBOUND® 2.5mg auto-injector pen or in a ZEPBOUND® 2.5mg single-dose vial.

55. PWL's patients, however, are unaware that the amount of liquid in each dose they receive indicates that PWL is providing altered drugs, because PWL has replaced the documentation that would provide this information.

2. *The concentration of PWL's altered drugs likewise indicate that they have been altered and are not intended for use in the prescribed doses*

56. To achieve PWL's desired dose for its altered drugs, PWL purchases Lilly medicines and breaks open the individual sterile auto-injector pens and re-distributes fractions of the liquid contents into third-party insulin syringes.

[22] *Id.*; *see also* https://zepbound.lilly.com/sleep-apnea/how-to-use

57. The prescription label accompanying PWL's altered drugs lists the *concentration* of drug as that of a single 12.5mg dose of MOUNJARO®—12.5mg/0.5mL—but lists the amount of liquid in a 4-pack of syringes as 0.4mL cumulatively. Necessarily, therefore, PWL constructs its purported weekly 2.5mg dose by splitting the contents of a single 12.5mg MOUNJARO® auto-injector pen into five individual syringes that are then distributed to one or more customers.

58. Likewise, the prescription label accompanying PWL's altered drugs lists the *concentration* of drug as that of a single 15mg dose of ZEPBOUND®—15mg/0.5mL—but lists the amount of liquid in a 3-pack of syringes as 0.33mL cumulatively. According to the amount of liquid and dose strength listed, PWL constructs its purported weekly 2.5mg dose by splitting the contents of a 15mg ZEPBOUND® auto-injector pen into five individual syringes that are then distributed to one or more customers.

59. As with the volume of liquid in the syringes, someone with knowledge about Lilly's medicines—or the disclosures accompanying Lilly's FDA-approved product—would understand that receiving a 2.5mg dose of either "Mounjaro" or "Zepbound" at a listed concentration of 12.5mg/0.5mL or 15/mg/0.5mL should raise red flags that the medicines have been altered. PWL has, however, replaced the documents and packaging containing that information with their own packaging and package insert, preventing consumers from realizing the concentration indicates the medicines have been altered.

3. *PWL's cracking and re-packing endangers patients*

60. Critically, both MOUNJARO® and ZEPBOUND® are intended for use—and only approved—as sterile injectables. But PWL's decision to break open Lilly's FDA-approved medicines in their FDA-approved packaging destroys that sterility.

61. Further, PWL does not use sterile repackaging techniques or follow cGMP to preserve sterility and instead puts its altered doses into non-sterile third-party insulin syringes, at least some of which are then misleadingly—and, dangerously, if mistakenly taken at its word—labeled "insulin" on the syringe itself.

62. Additionally, PWL misrepresents the doses on its labels. A concentration of 15mg per 0.5mL means that there is 3mg of tirzepatide per 0.1mL. According to PWL's listed volume and dose strength, what PWL markets as "2.5mg Zepbound" actually contains 3.3mg of tirzepatide.

63. Lilly does not sell tirzepatide in 3.3 mg doses, nor has it been approved by FDA in this dose.

64. Not only are PWL's doses not as advertised, they are also untested and unproven for either safety or effectiveness.

65. Because these doses are untested and unproven—and because PWL does not run any of its own clinical testing or research on its altered drug products—PWL has no clinical data showing that the unapproved doses are effective.

66. The untested, unproven, altered products are particularly dangerous for patients with type 2 diabetes. PWL's package insert states: "Zepbound & Mounjaro are the same medication. There is literally no difference besides the label/name." Such a patient seeking unaltered Lilly medicines who was prescribed and purchased PWL's altered products received improper doses, which could have significant consequences, including a failure to achieve glycemic control from PWL's altered drugs.

67. Finally, PWL's practice of opening and repackaging Lilly's medicines is additionally problematic because PWL subdivides high-concentration doses into *five* syringes,

while only distributing *three* or *four* syringes in a monthly dose. PWL thus distributes medicine from a single Lilly auto-injector pen to multiple patients or, more problematically, medicine from multiple batches of Lilly auto-injector pens to a single patient. In the event of a serious adverse event, PWL's tampering makes it impossible to trace the original source of the Lilly medicine that PWL manipulated.

68. The manipulations made to PWL's altered drugs were made by PWL or at PWL's direction.

69. Because PWL materially altered Lilly's authorized and approved medicines after they left Lilly's custody, Lilly has no control over the safety, quality, or effectiveness of the altered drugs sold by PWL.

70. PWL's marketing materials do not disclose this repackaging, leaving most consumers instead believing that the altered drugs they receive from PWL are Lilly's unaltered MOUNJARO® and ZEPBOUND® medicines under Lilly's quality and safety controls. They are not.

**C. The Dangers of Unapproved and Untested Drugs**

71. The rapid rise of unapproved and untested drugs into the marketplace—including those purporting to contain tirzepatide—poses serious public health risks. Both compounded drugs and adulterated branded medicines (like PWL's altered drugs) are prime examples of the unapproved and untested drugs that are flooding the market for weight-loss medications.

1. *The risks of compounded drugs*

72. Compounding is a "practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist,

combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient."[23]

73. As FDA itself makes clear, "[c]ompounded drugs are not FDA-approved."[24] FDA does not review compounded drugs for safety, effectiveness, or quality before they reach patients.

74. For that reason, 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." [25]

75. There are countless examples of people experiencing serious injury from taking unregulated drugs. Inappropriate drug compounding resulted in 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.[26]

76. As compounding of tirzepatide has become more prevalent, government agencies have warned the public as to the risks of such products. For instance, in July 2024, FDA sent a letter to compounding advocacy organizations warning that it has received "reports describing patients who experienced adverse events following the administration of compounded … tirzepatide."[27] FDA reiterated that "compounded drug products, including

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[23] https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding (FDA guidance on drug compounding law compliance).

[24] https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers (FDA drug compounding FAQ).

[25] https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers (FDA drug compounding FAQ).

[26] https://www.justice.gov/usao-ma/pr/former-owner-defunct-new-england-compounding-center-resentenced-14-years-prison. (DOJ press release on compounder prison sentence).

[27] https://www.pa.gov/content/dam/copapwp-pagov/en/dos/department-and-offices/bpoa/nursing/fda-safety-alert.pdf (July 16, 2024, FDA letter sent to the Alliance for Pharmacy Compounding and the Outsourcing Facility Association).

compounded … tirzepatide products, are not FDA-approved. They do not undergo premarket review by FDA for safety, effectiveness, or quality."[28] Further, an October 2024 FDA statement warned of "multiple reports of adverse events, some requiring hospitalization, that may be related to dosing errors."[29]

77. Leading organizations have also expressed concern. 37 State Attorneys General and State Drug Task Forces have all warned the public about the dangers of these unsafe and unapproved products, including compounders using "non-sterile ingredients" and taking "no steps to sterilize them."[30] The Obesity Society, Obesity Action Coalition, and Obesity Medicine issued a joint statement regarding compounded GLP-1 medications, stating, "[u]nfortunately, many of the available alternatives [to GLP-1 therapies], like compounded versions of semaglutide and tirzepatide, are not what they are advertised to be."[31] The Pediatric Endocrine Society has also advised that "[c]linicians and patients [] should exercise caution when exploring options for non-brand name medications, particularly avoiding the use of non-FDA approved medications and those that come from non-FDA-approved compounding pharmacies."[32] Similarly, the JAMA

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[28] *Id.*

[29] https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss (October 2, 2024 FDA statement on Unapproved GLP-1 Drugs).

[30] National Association of Attorneys General, "State and Territory Attorneys General Urge FDA to Take Action Against Counterfeit and Illegally Sold GLP-1 Drugs," (February 19, 2025), https://www.naag.org/policy-letter/state-and-territory-attorneys-general-urge-fda-to-take-action-against-counterfeit-and-illegally-sold-glp-1-drugs/; NBC News, "Tennessee Woman Accused of Selling Fake Weight Loss Drugs as Counterfeit Concerns Grow," (December 17, 2024), https://www.nbcnews.com/health/health-news/tennessee-woman-accused-selling-fake-weight-loss-drugs-counterfeit-con-rcna184154.

[31] https://obesitymedicine.org/blog/leading-obesity-expert-organizations-release-statement-to-patients-on-glp-1-compounded-alternatives/ (Joint Statement On Compounded GLP-1 Alternatives).

[32] Pediatric Endocrine Society, *Statement on use of compounded semaglutide and other GLP-1 receptor agonists* (Jan. 16, 2024), https://pedsendo.org/drug-shortages/statement-on-use-of-compounded-semaglutide-and-other-glp-1-receptor-agonists/ (last accessed Mar. 11, 2025).

Health Forum published a study that most websites selling compounded anti-obesity medications exclude important safety information and mislead consumers about the safety and effectiveness of their products.[33] Other patient and consumer groups have issued similar warnings, including the National Consumers League and the American Diabetes Association, which recommended that patients avoid compounded products "due to uncertainty about their content, safety, quality, and effectiveness."[34] Australia recently banned the development and sale of compounded anti-obesity medications due to "increasing community concern" and "increasing reports of patients coming to harm from " compounded weight loss drugs.[35] The ban—effective October 2024—targets compounded drugs that are "being misrepresented and sold as replica [] Mounjaro®."[36] 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."[37] Likewise, the South African government has proposed to prohibit the development of compounded GLP-1s. South Africa's regulatory authority has "noted with

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[33] Ashwin Chetty et al., *Online Advertising of Compounded Glucagon-Like Peptide-1 Receptor Agonists*, JAMA Health Forum (Jan 17, 2025), available at https://jamanetwork.com/journals/jama-health-forum/fullarticle/2829225 (last accessed Mar. 20, 2025).

[34] National Consumers League, *NCL urges the public to heed warnings about unregulated versions of GLP-1 weight loss drugs* (Feb. 4, 2025), https://nclnet.org/the-national-consumers-league-urges-the-public-to-heed-warnings-about-unregulated-versions-of-glp-1-weight-loss-drugs/ (last accessed Mar. 20, 2025); American Diabetes Ass'n, *The American Diabetes Association Announces Statement on Compounded Incretin Products* (Dec. 2, 2024), https://diabetes.org/newsroom/press-releases/american-diabetes-association-announces-statement-compounded-incretin#:~:text=The%20statement%20recommends%20against%20using,safety%2C%20quality%2C%20and%20effectiveness (last accessed Mar. 20, 2025).

[35] Department of Health and Aged Care, *Protecting Australians form unsafe compounding of replica weight loss products* (May 22, 2024), https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/protecting-australians-from-unsafe-compounding-of-replica-weight-loss-products (last accessed Mar. 20, 2025).

[36] *Id.*

[37] *Id.*

concern the number of compounded, substandard, and/or falsified versions" of tirzepatide products being sold to the public since "[t]he complexity of compounding GLP1 agonists, which are sterile medicines containing complex active substances[,] poses a public health and safety risk."[38]

78. PWL (correctly) recognizes the risks presented to patients by unapproved, compounded products, including by asserting on its website that compounded tirzepatide drugs are "NOT safe."[39] But instead of taking steps to ensure it uses only unaltered, sterile, and approved Lilly medicines, PWL exploits the real risks of compounding to sell another risky, altered product that is not FDA approved or guaranteed by Lilly's quality controls.

2. *The risks of altered drugs*

79. Despite PWL's efforts to distinguish itself from the risks of compounded products, drugs sold as brand-name medications by resellers who have altered the genuine medication prior to resale also pose serious public health risks.

80. For instance, FDA has long expressed "great[] concern about the manipulation of approved sterile drug products," because "[t]he moment a sterile container is opened and manipulated, a quality standard (sterility) is destroyed and previous studies supporting the standard(s) are compromised and are no longer valid."[40] The CDC warns to "not save leftover

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[38] South African Health Products Regulatory Authority, *SAHPRA's Position on GLP1 and GIP-GLP1 Products That Are Compounded, Substandard And Falsified* (Nov. 8, 2024), https://www.sahpra.org.za/news-and-updates/sahpras-position-on-glp1-and-gip-glp1-products-that-are-compounded-substandard-and-falsifiedas/ (last accessed Mar. 20, 2025).

[39] https://pwlindy.com/faq/

[40] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-446100-regulatory-action-regarding-approved-new-drugs-and-antibiotic-drug-products-subjected#:~:text=The%20FDA%20has%20an%20even,410.100)

medication from [single-dose] vials"—like those used for Zepbound—because single-dose vials lack antimicrobial preservatives found in multi-dose vials.[41]

81. These risks are not just theoretical. For example, in 2021, a compounding pharmacist pled guilty to providing adulterated drugs to cataract surgery patients. At least 100 patients were injected with the adulterated compounds, at two different surgery centers, over a period of months. 43 of those patients were left blinded or had their vision impaired.[42] One patient had believed "every pill you take, every shot you take is tested" and was surprised to learn that the drug he received was neither fully tested nor deemed safe or otherwise approved by FDA.[43]

82. Consequences from altered drugs may be deadly. In 2012, drugs manufactured without FDA oversight and contaminated with a fungus were shipped throughout the country and later injected into patients' spines and joints. These contaminated products led to more than 750 cases of fungal infections and caused the deaths of more than 100 people from fungal meningitis.[44] Company executives were convicted and received sentences of up to 14.5 years in prison.

83. As these examples demonstrate, the risks of altered drugs are particularly acute in the context of unsterile manufacturing or unsterile repackaging of sterile injectables. For instance, in 2013, 15 patients were infected with bacteria from compounded calcium gluconate injections.[45] In 2017, 43 patients experienced vision loss, macular swelling, and/or retinal degeneration from

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[41] https://www.cdc.gov/injection-safety/media/pdfs/Injection-Safety-For-Healthcare-P.pdf

[42] https://www.reuters.com/legal/government/pharmacist-pleads-guilty-adulterating-drug-linked-eye-injuries-2021-10-13/

[43] https://www.wfaa.com/article/news/do-not-publish-yet/287-5f002ed3-e110-4063-9959-a2e5f54b5097 (WFAA article re outbreak).

[44] https://www.justice.gov/usao-ma/pr/former-owner-defunct-new-england-compounding-center-resentenced-14-years-prison. (DOJ press release on compounder prison sentence).

[45] Pew Charitable Trusts, *U.S. Illnesses and Deaths Associated With Compounded or Repackaged Medications, 2001–19* (Mar. 2020), https://tinyurl.com/4rswtudf

compounded intravitreal injections.[46] And in 2022, FDA issued a warning letter to North American Custom Laboratories, LLC d/b/a FarmaKeio Superior Custom Compounding for "serious deficiencies in your practices for producing drug products intended or expected to be sterile, which put patients at risk."[47] As a result of these findings, FDA also recommended a voluntary recall of all of FarmaKeio's unexpired drug products that are intended to be sterile.[48]

## IV. PWL's Trademark Infringement and False Advertising

84. PWL does not sell Lilly's factory-sealed, FDA-approved MOUNJARO® and ZEPBOUND®. Rather, PWL sells altered drugs that have been manipulated in a way that negates Lilly's rigorous safety and quality assurances and FDA approval that resulted from them.

85. Lilly does not sell MOUNJARO® or ZEPBOUND® to PWL for resale or redistribution. Nor has Lilly authorized PWL to use the Lilly Marks in connection with any of PWL's offered goods or services.

86. Instead, PWL buys MOUNJARO® and ZEPBOUND® in a higher dosage strength (*e.g.*, 12.5mg/0.5mL or 15mg/0.5mL), breaks open the auto-injector pens, and divides the contents of what was intended as a single administration into five lower-dose, non-sterile administrations. It then omits the labeling and package inserts that accompany Lilly's FDA-approved medicines and transmits its own less informative and unapproved information to the patient.

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[46] *Id*.

[47] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/north-american-custom-laboratories-llc-dba-farmakeio-superior-custom-compounding-642792-11182022#:~:text=WARNING%20LETTER,-Dear%20Mr.&text=During%20the%20inspection%2C%20the%20investigator,firm%20on%20March%2010%2C%202022. (FDA Warning Letter to FarmaKeio).

[48] https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-patients-and-health-care-professionals-not-use-sterile-products-north-american-custom (FDA notice of voluntary recall).

87. When questioned about the source of PWL's altered drugs, PWL's healthcare providers perpetuate this deceit during conversations with patients. For instance, in response to patient questions about the source of PWL's altered drugs, PWL's providers have claimed that it purchases high-dose vials of Lilly's medicines in "bulk" and transfers the medicine into syringes to make the doses easier for patients to self-administer.

88. Yet PWL's website, blog, social media, and print advertising convey the unmistakable impression that PWL is offering Lilly's factory-sealed, FDA-approved MOUNJARO® and ZEPBOUND® for sale. In fact, PWL makes no mention in any of its advertising that it has removed, re-dosed, and repacked Lilly's medicines, or caused them to be re-dosed and repackaged. PWL does not communicate the risks associated with its altered drugs—instead, it actively and deceptively downplays those risks, including in conversations with patients where PWL's doctors have communicated its altered drugs come from high-dose vials of Lilly's genuine medicines that are purchased in "bulk" and transferred to syringes for ease of self-administration.

89. PWL is therefore engaged in an illicit scheme to deceive customers by using the Lilly Marks along with false assurances that it offers "the real deal," "brand name," and "authentic" Lilly medicines to divert individuals seeking Lilly medicines to PWL's altered drugs, which have been tampered with in a manger that negates Lilly's safety and quality control standards and the FDA approval for the brand-name medicines.

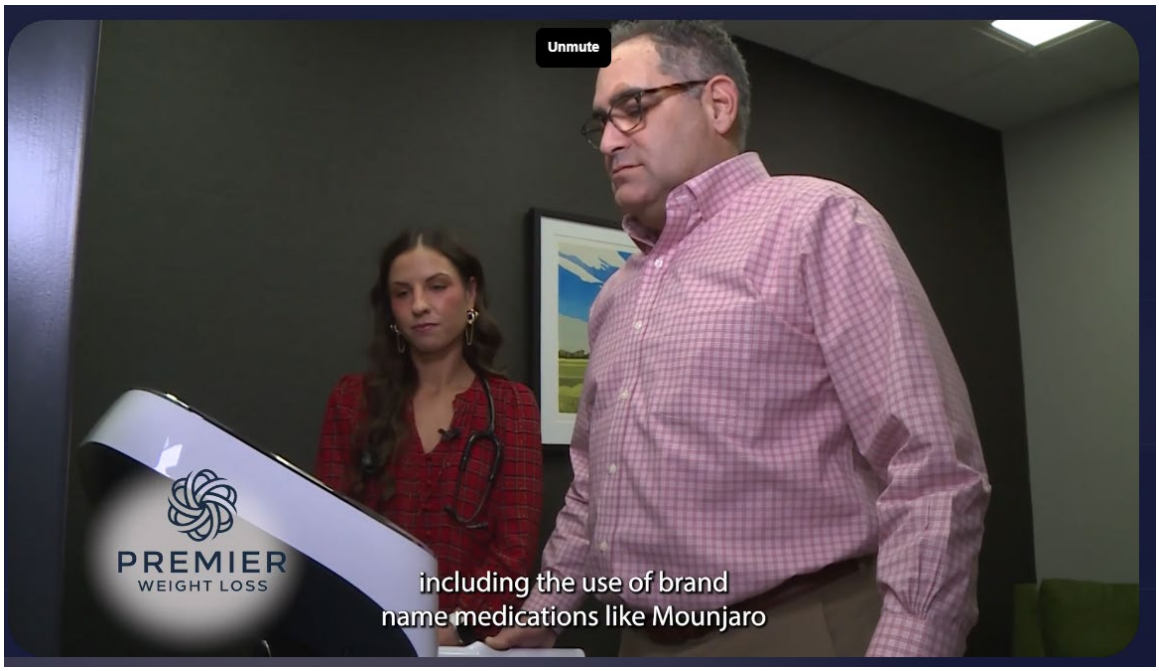
**A. PWL's Unauthorized Use of the Lilly Marks**

90. Through its advertising—including statements on its website, posts on its blog and on social media accounts controlled by PWL, and through printed advertising distributed to

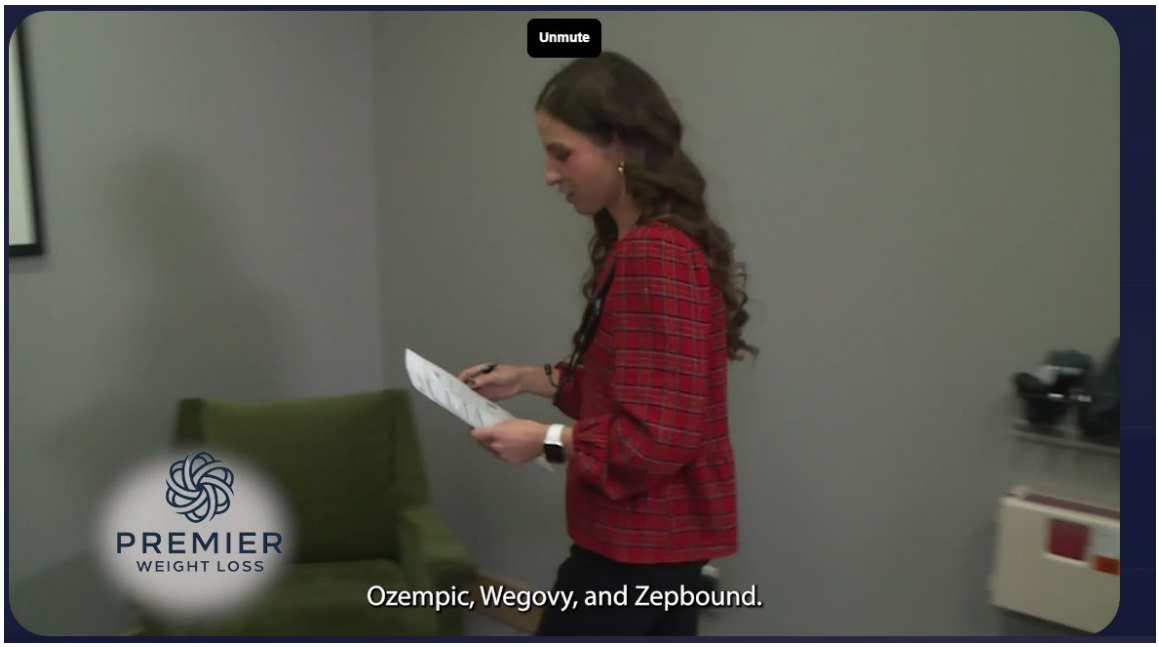
prospective patients—PWL leverages the Lilly Marks to sell its altered drugs to an unsuspecting public.

91. A compilation of examples of PWL's trademark infringement is discussed below and attached hereto as Exhibit B.

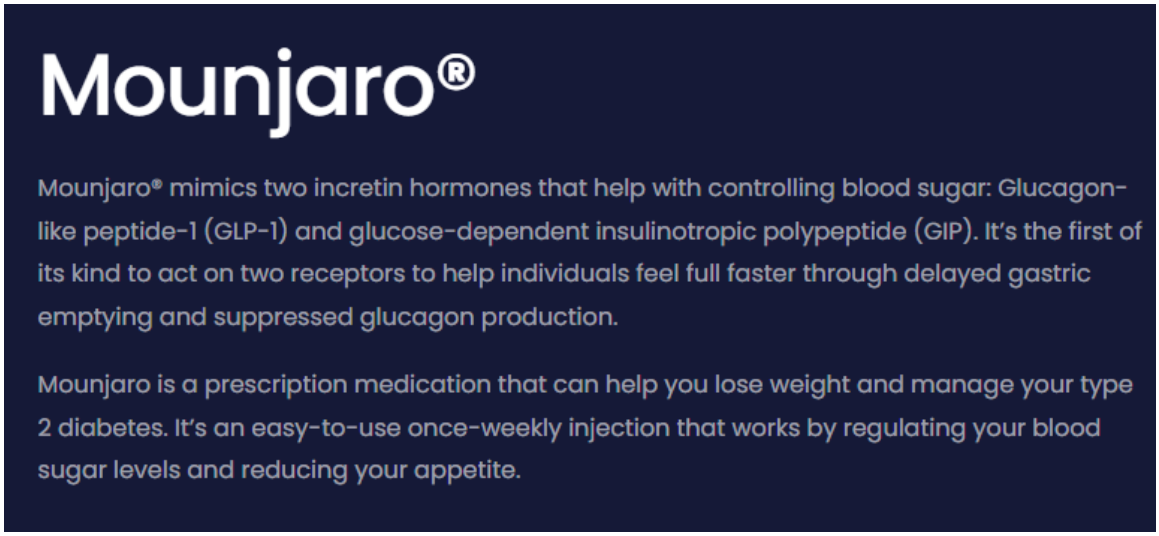
92. PWL's blatant and unauthorized use of the Lilly Marks can be seen the second a customer visits the homepage of PWL's website, which contains a promotional video that refers to PWL's altered drugs as "Mounjaro" and "Zepbound."[49]




[49] https://pwlindy.com/.

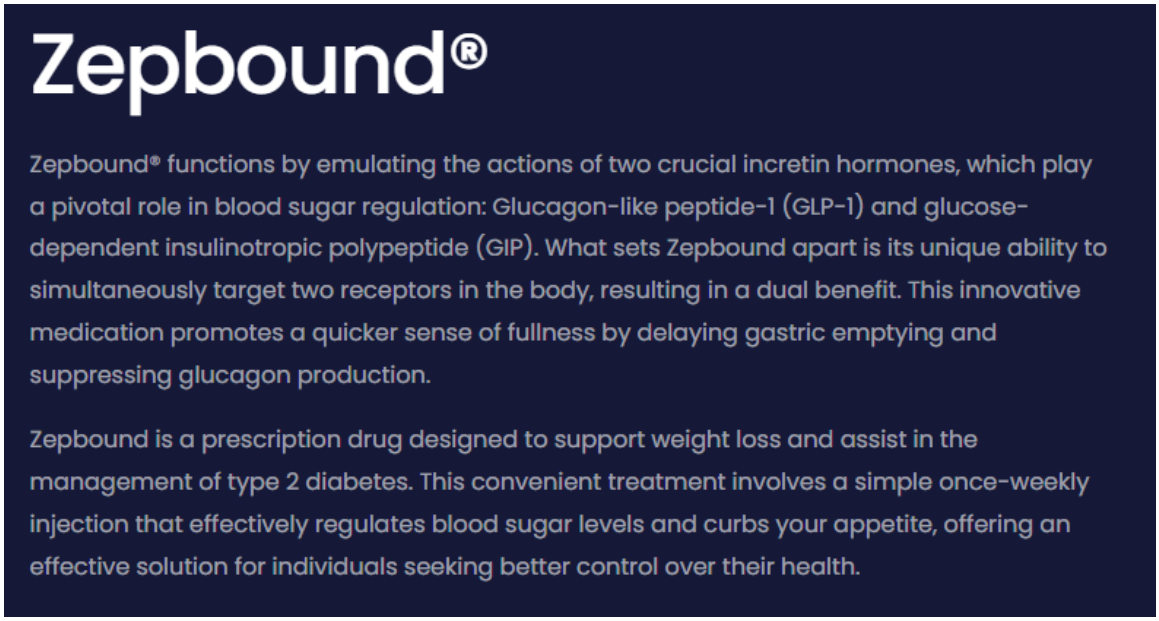



93. PWL's website further contains a webpage solely dedicated to MOUNJARO®. On that page, PWL includes the trademark registration symbol in connection with its use of the Lilly Mark.[50]




[50] https://pwlindy.com/weight-loss-medication/mounjaro/.

94. Similarly, PWL's website contains a webpage dedicated to ZEPBOUND®, on which it presents the brand name with the trademark registration symbol affixed.[51]

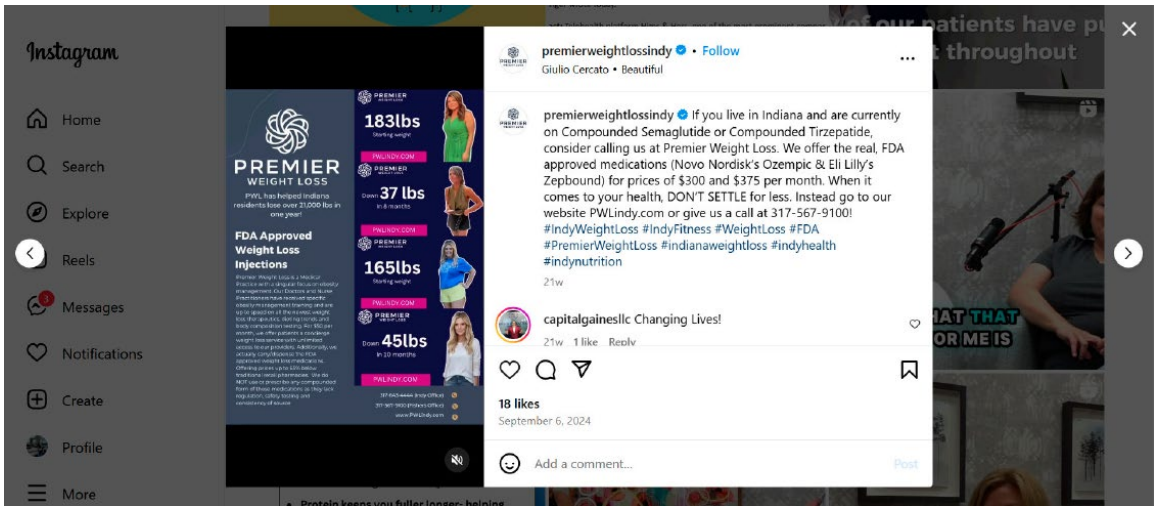



95. PWL's unauthorized use of the Lilly Marks extends to its blog, on which PWL continues to refer to its altered drugs as "FDA approved, brand name GLP-1 injections like Mounjaro [and] Zepbound."[52]

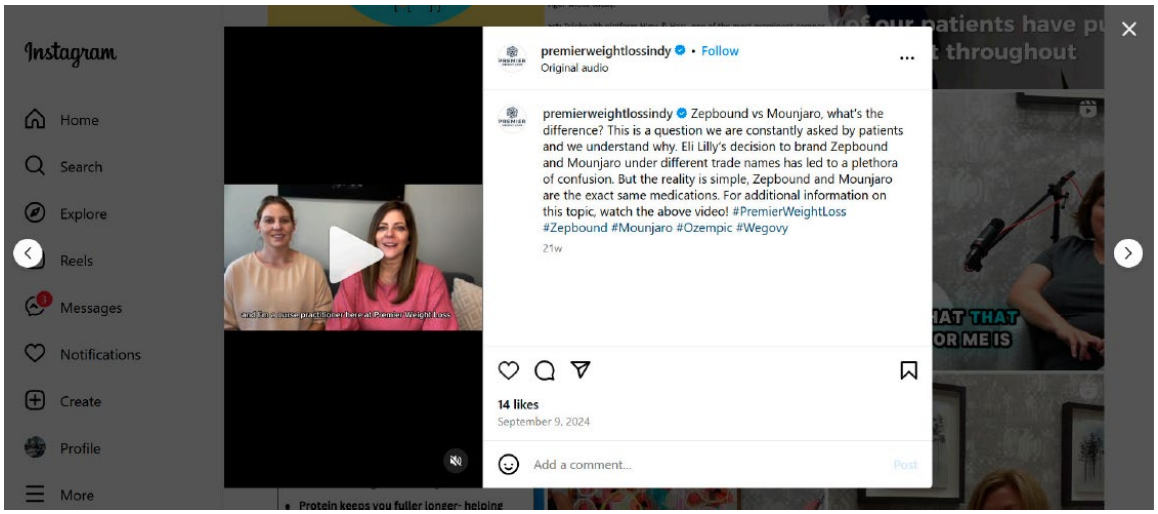

[51] https://pwlindy.com/weight-loss-medication/zepbound/.

[52] https://pwlindy.com/weight-loss-injections-and-pcos-what-you-need-to-know/.

96. PWL's unauthorized use of the Lilly Marks continues on its social media accounts, which contain posts that refer to PWL's altered drugs using the hashtag "#Mounjaro," use the Lilly Marks to promote that it "offer[s] the real, FDA approved medications ( … Eli Lilly's Zepbound)."[53]

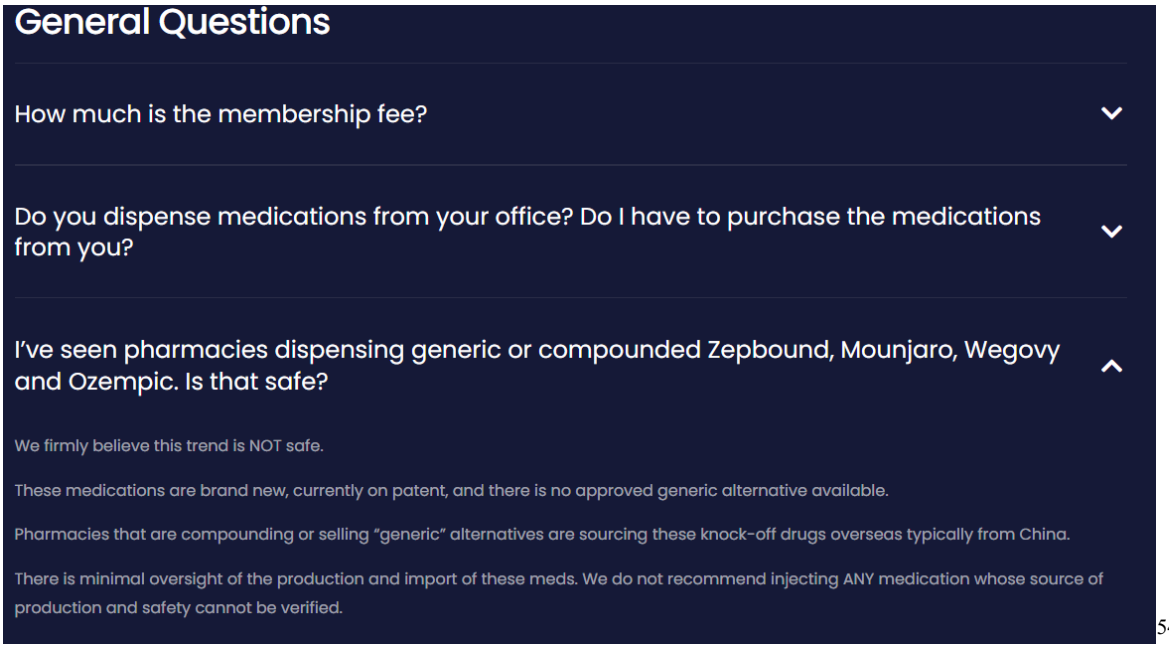

[53] https://www.instagram.com/p/CvtGRvptkx3/?utm_source=ig_web_copy_link&igsh=MzRlODBiNWFlZA==; https://www.instagram.com/reel/C_ldgykvr6k/?utm_source=ig_web_copy_link; https://www.instagram.com/reel/C_tRI2JPcV2/?utm_source=ig_web_copy_link&igsh=MzRlODBiNWFlZA==.




97. PWL's unauthorized use of the Lilly Marks is not limited to its internet advertising. Indeed, PWL also distributes printed marketing materials that use the Lilly Marks to emphasize the alleged branded nature of its altered drugs using all-caps, and that acknowledge that "MOUNJARO® and ZEPBOUND® are registered trademarks of Eli Lilly, which [is] not affiliated with or [a] sponsor[] of Premier Weight Loss."

98. PWL's serial and prominent use of the Lilly Marks first started long after Lilly had adopted them. PWL's use of the Lilly Marks can therefore only have been intended to gain a competitive advantage from the goodwill Lilly has generated around the Lilly Marks.

99. For instance, PWL emphasizes the safety concerns associated with compounded tirzepatide in its FAQ section, criticizing the "minimal oversight of the production and import of these [compounded] meds" and stating that PWL "do[es] not recommend injecting ANY medication whose source of production and safety cannot be verified."



[54]

100. By contrast, PWL specifically touts the safety of "Branded Medications like … Mounjaro® and Zepbound[.]®"[55]

[54] https://pwlindy.com/faq/.

[55] https://www.instagram.com/p/DAGpsF2OMy9/?utm_source=ig_web_copy_link&igsh=MzRlODBiNWFlZA==.


101. PWL uses the Lilly Marks in advertising and promotion on its website, blog, and social media to promote its products as "real" to confuse patients who are seeking to be prescribed and purchase genuine, unaltered, factory-sealed MOUNJARO® or ZEPBOUND® to treat their serious health conditions. But instead, PWL gives them altered products in such a manner as to obscure from the patients that they have not received the true Lilly medicines.

102. PWL's prominent and improper use of the Lilly Marks is likely to cause consumers to falsely believe that they were prescribed and are purchasing actual, factory-sealed MOUNJARO® or ZEPBOUND®, that PWL is a source for Lilly's FDA-approved treatment options MOUNJARO® or ZEPBOUND®, that the safety of PWL's altered drugs is dictated by Lilly's quality and safety controls, or that PWL's services or the altered drugs are provided, licensed, sponsored, authorized, or approved by, or otherwise associated or affiliated with, Lilly.

103. PWL's use of the Lilly Marks is without the permission, consent, or authorization of Lilly. PWL has no right to use, and PWL knows that it has no right to use, the Lilly Marks in connection with its altered drugs.

104. In making such unauthorized use of the Lilly Marks, PWL seeks to—and does—freeride on Lilly's reputation and goodwill that it has achieved through the development and promotion of its medicines.

105. By touting its products as MOUNJARO® and ZEPBOUND®, PWL confuses customers into believing that the safety and effectiveness profile of PWL's altered drugs are the same as that of unaltered MOUNJARO® and ZEPBOUND® medicines.

106. PWL'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.

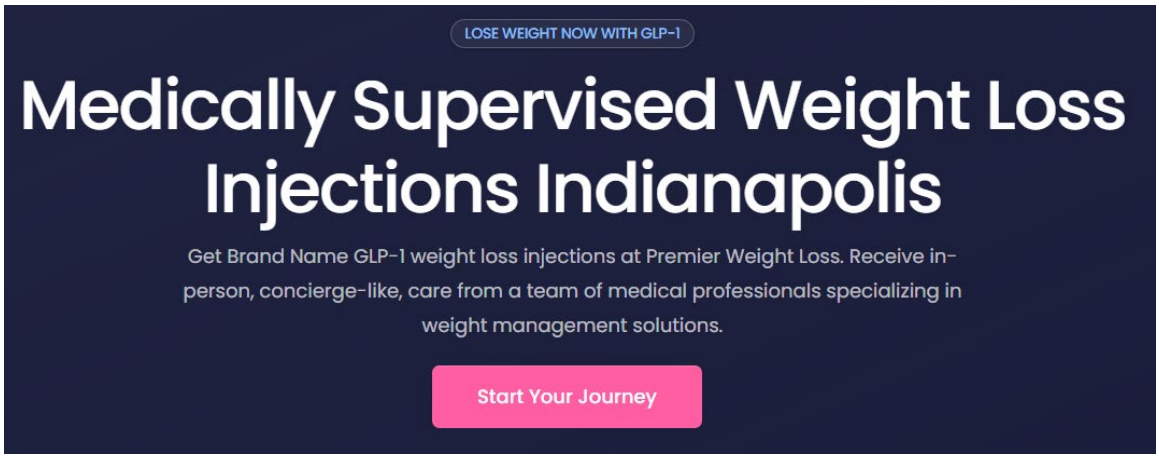
107. PWL's infringement allows it to unjustly profit from sales of altered drugs to patients looking for MOUNJARO® and ZEPBOUND®.

108. Unless enjoined by this Court, PWL will continue to use the Lilly Marks in connection with its altered drugs, leading consumers to believe they are receiving FDA-approved, unaltered MOUNJARO® and ZEPBOUND®, all in violation of Lilly's rights.

**B. PWL's False Advertising**

109. PWL falsely promotes its goods and services by emphasizing that it offers "Brand Name GLP-1 weight loss injections[.]"[56]

[56] https://pwlindy.com/.



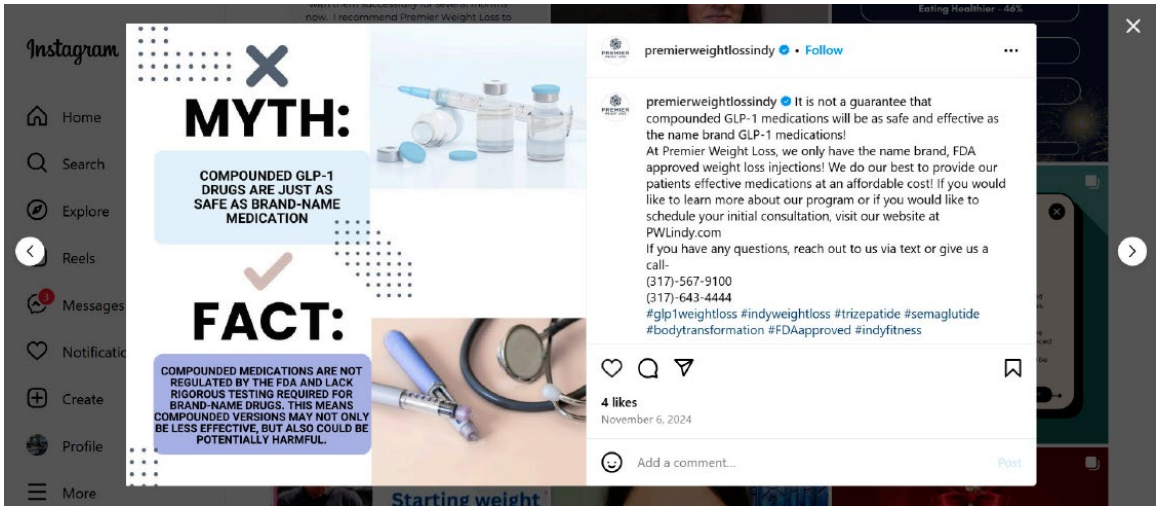

110. For example—and as depicted in Paragraph 92 above—a promotional video on PWL's website claims that it offers "brand name medications like Mounjaro … and Zepbound" to its patients. These statements necessarily and deceptively communicate that the products PWL provides are genuine, unaltered MOUNJARO® and ZEPBOUND®, which is false.

111. Likewise—as depicted in Paragraph 96 above—posts advertising its altered drugs on social media state that PWL "offer[s] the real, FDA approved medications ( … Eli Lilly's Zepbound)." Again, these statements necessarily and deceptively communicate that the product PWL provides is genuine, unaltered MOUNJARO® and ZEPBOUND®, which is false.

112. PWL's printed materials fare no better. As depicted in Paragraph 97 above, PWL's pamphlet emphasizes that it sells "BRANDED medication" while listing the per-month cost for 2.5 mg of "Mounjaro" or "Zepbound" at $375. But as demonstrated above in Section III, PWL's 2.5 mg syringes of "Mounjaro" and "Zepbound" are not true, FDA-approved Lilly medicines, but rather the contents of Lilly's medicines removed, re-dosed, and re-sealed in new packaging without appropriate warnings or required labeling. Indeed, even when PWL tells consumers they are receiving 2.5 mg doses of Zepbound, in reality it gives them 3.3 mg dosages, an unapproved and untested dosage.

113. Notably, PWL engages in this false and deceptive advertising of its altered drugs while simultaneously warning of the dangers of compounded GLP-1 products and touting Lilly's safety standards. These statements are designed to exploit the justifiable fears of prospective patients who are seeking to be prescribed and purchase genuine, unaltered Lilly medicines, and PWL profits from those patients' concerns while simultaneously deceiving them.

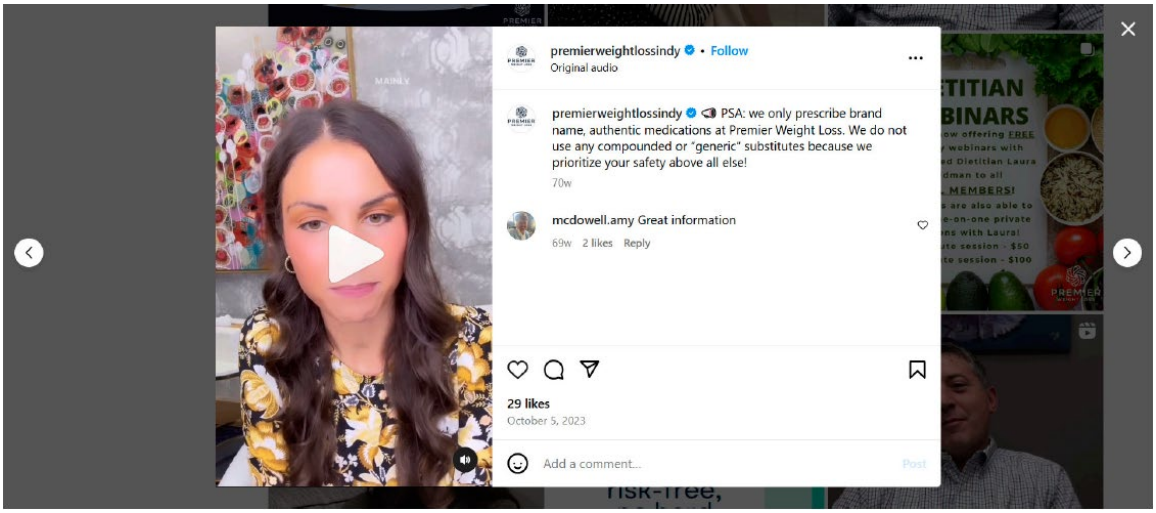
114. PWL is well aware of the safety concerns associated with drugs manufactured or altered outside of Lilly's oversight. On its Instagram page, PWL warns consumers that "[i]t is not a guarantee that compounded GLP-1 medications will be as safe and effective as the name brand GLP-1 medications! At Premier Weight Loss, we only have the name brand, FDA approved weight loss injections!"[57]




115. PWL further attempts to differentiate itself from clinics that source drugs from compounding pharmacies, falsely promoting that "[w]e only prescribe brand name, authentic

[57] https://www.instagram.com/p/DCCXFjoPvxp/?utm_source=ig_web_copy_link&igsh=MzRlODBiNWFlZA==.

medications" and "do not use any compounded or 'generic' substitutes because we prioritize your safety above all else!"[58]




116. Through its advertising, PWL falsely and necessarily communicates that its altered drugs are genuine, unaltered Lilly medicines or, alternatively, that they are as safe and effective as genuine, unaltered Lilly medicines. PWL's actions thus cause confusion in the marketplace and deceive patients with serious health conditions regarding the authenticity, safety, and sterility of PWL's altered drugs.

117. By touting its products as MOUNJARO® and ZEPBOUND®, PWL deceives consumers into believing that the risk and efficacy profile of PWL's altered drugs are the same as that of genuine, unaltered MOUNJARO® and ZEPBOUND® medicines.

118. PWL's false statements regarding the safety of their altered drugs are a driving force in consumers' purchasing decisions. PWL not only acknowledges this fact, it exploits it: its

[58] https://www.instagram.com/reel/CyBzT8eOp4R/?utm_source=ig_web_copy_link&igsh=MzRlODBiNWFlZA==.

marketing focuses on drawing a distinction between their products—which they claim are safe—and compounded tirzepatide—which they, rightly, inform patients is unsafe.

119. Consumers are actually deceived by PWL's false statements. Moreover, PWL's false statements have a tendency to deceive its intended audience: patients seeking diabetes or weight loss medications but who have valid concerns about only taking safe, FDA-approved medications from manufacturers they trust and that are rigorously regulated by FDA.

120. PWL's false statements allow it to unjustly profit from sales of altered drugs to patients looking for genuine, unaltered MOUNJARO® and ZEPBOUND® medicines.

121. Unless enjoined by this Court, PWL will continue to make false statements in connection with the marketing and sale of its altered drugs, leading consumers to believe they are receiving genuine, unaltered MOUNJARO® and ZEPBOUND® medicines, all in violation of Lilly's rights.

## V. HARM TO THE PEOPLE OF INDIANA AND LILLY

122. Lilly's FDA-approved MOUNJARO® and ZEPBOUND® medicines have undergone extensive clinical trials and approval processes. But these clinical studies and FDA approvals only apply to unaltered MOUNJARO® and ZEPBOUND® medicines—which are factory-sealed, sterile, and properly packaged and labeled—when used as directed by a prescribing physician. The clinical trials and approval processes do not ensure the safety, quality, or effectiveness of PWL's altered drugs.

123. PWL's trademark infringement and false advertising may expose patients to the serious risks described above. Critically, because PWL uses the Lilly Marks in connection with its altered drugs, patients are unlikely to know that the drugs they receive from PWL have been tampered with and cannot be relied on to be sterile, nor the associated risks.

124. Patients who take PWL's altered drugs and suffer harm will have had no forewarning.

125. Not only does PWL's trademark infringement and false advertising expose the people of Indiana to serious health risks, but PWL's unlawful tactics undermine the name, goodwill, and reputation that Lilly has invested heavily in developing. Were a consumer to suffer an adverse event due to contaminants introduced by PWL's tampering, the consumer would likely be confused into errantly believing that the issue was the result of a problem with Lilly's safety controls.

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126. In short, throughout its advertising, PWL attempts to distinguish itself from competitors selling compounded tirzepatide on the basis that its brand-name offerings, namely MOUNJARO® and ZEPBOUND®, are "real, FDA approved" and safe and effective. But its altered drugs are not FDA-approved, and the safety profile cannot be guaranteed when the product has been tampered with, as PWL has done. Instead, PWL sells unlawfully re-dosed and repackaged products to its consumers under Lilly's MOUNJARO® and ZEPBOUND® trademarks, leading consumers to believe any adverse effects caused by this unsafe and unlawful practice were caused by Lilly.

127. PWL's false advertising and trademark infringement is likely to—and does—confuse and deceive consumers to believe they are receiving unaltered, factory-sealed MOUNJARO® and ZEPBOUND® when instead they receive a clear plastic bag of non-sterile syringes containing an altered substance, the original safety and quality assurances of which PWL intentionally destroyed.

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

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

129. 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.

130. Without Lilly's consent, PWL has used and continues to use in commerce the Lilly Marks in connection with the offering, sale, and advertising of their altered drugs purporting to be unaltered MOUNJARO® and ZEPBOUND®. Consumers who encounter PWL's unauthorized use of the Lilly Marks in connection with PWL's altered 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.

131. PWL'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.

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

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

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

135. 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 PWL'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**

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

137. 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.

138. Without Lilly's consent, PWL has used and continues to use in commerce the Lilly Marks in connection with the offering, sale, and advertising of their altered drugs purporting to be unaltered MOUNJARO® and ZEPBOUND® medicines. Consumers who encounter PWL's unauthorized use of the Lilly Marks in connection with PWL's altered 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.

139. PWL'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 PWL, 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).

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

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

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

143. 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 PWL'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**

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

145. PWL'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).

146. PWL has knowingly and willfully made materially false statements in its commercial advertisements for its altered drugs (including on its website and social media). These statements—including PWL's altered drugs being the "real stuff," "FDA approved, brand name GLP-1 injections like Mounjaro [and] Zepbound", "brand name, authentic medications," "BRANDED," medications, stating that "[i]t is not a guarantee that compounded GLP-1 medications will be as safe and effective as the name brand GLP-1 medications! At Premier

Weight Loss, we only have the name brand, FDA approved weight loss injections!", and calling on patients to "Lose Weight Safely!" by using "Brand Name Only" products—have influenced and are likely to continue to influence consumers' purchasing decision, specifically the decision to purchase PWL's altered drugs instead of Lilly's FDA-approved medicines. As a result, PWL is steering individuals with serious diseases like diabetes and obesity away from obtaining safe, effective, available, and FDA-approved treatments. PWL's unlawful conduct is putting health, safety, and lives at risk.

147. PWL has caused its false and deceptive statements to enter interstate trade or commerce.

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

149. As a direct and proximate result of PWL's false and deceptive campaign, Lilly has suffered and will continue to suffer significant monetary damages and discernible competitive injury by the loss of goodwill.

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

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

## FOURTH CAUSE OF ACTION
**Trademark Infringement in Violation of Indiana Common Law**

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

153. The above-described acts of PWL constitute trademark infringement in violation of Indiana common law.

154. Without Lilly's consent, PWL has used and continues to use in commerce the Lilly Marks to pass off its altered drugs as unaltered MOUNJARO® and ZEPBOUND® medicines.

155. PWL's unauthorized use of the Lilly Marks in connection with PWL's altered 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 PWL.

156. Consumers who encounter PWL's unauthorized use of the Lilly Marks in connection with PWL's altered 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.

157. PWL's actions thereby unfairly and wrongfully exploit and infringe Lilly's trademark, goodwill, and reputation.

158. As a direct and proximate result of PWL'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 PWL and by a loss of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® medicines and the Lilly Marks.

159. By reason of PWL's acts, Lilly's remedy at law is not adequate to compensate for the injuries inflicted by PWL. 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 its claim for relief set forth above and award it relief including, but not limited to, the following:

1. An Order declaring that PWL:

   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);

   c. Engaged in false advertising and promotion in violation of 15 U.S.C. § 1125(a);

   d. Infringed the Lilly Marks and engaged in trademark infringement in violation of Indiana common law; and

   e. That each of the above acts was willful and knowing.

2. An injunction preliminarily and permanently enjoining and restraining PWL 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, altered 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 PWL's altered drugs are "genuine" Lilly Products, "FDA approved" medications, "the real stuff," "BRANDED" medications, that "[i]t is not a guarantee that compounded GLP-1

medications will be as safe and effective as the name brand GLP-1 medications! At Premier Weight Loss, we only have the name brand, FDA approved weight loss injections!", calling on patients to "Lose Weight Safely!" by using "Brand Name Only" products, or making any similarly false or misleading statements; and

3. An Order requiring PWL 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:

a. PWL is not and never has been authorized by, affiliated with, sponsored by, approved by, or related to Plaintiff Lilly or MOUNJARO® and ZEPBOUND®, and that PWL's altered drugs are not genuine, unaltered MOUNJARO® or ZEPBOUND®;

b. PWL's altered drugs are not "genuine," medicines, or "the real stuff."

c. PWL's altered drugs have not been approved by FDA.

4. An Order directing PWL 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 it has complied with the Court's injunction.

5. An Order requiring PWL to account for and pay to Lilly any and all profits arising from the foregoing acts of trademark infringement and false advertising in accordance with 15 U.S.C. § 1117 and other applicable laws.

6. An Order requiring PWL to pay Lilly compensatory damages in an amount as yet undetermined caused by the trademark infringement and false advertising, 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. A finding that PWL's actions are exceptional under 15 U.S.C. § 1117.

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

10. Other relief as the Court may deem appropriate.

**JURY DEMAND**

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

*[Signature page follows.]*

Dated: April 7, 2025

Respectfully submitted,

*/s/ Nicholas B. Reuhs*

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on April 7, 2025, the foregoing was electronically filed with the Clerk of the Court using the CM/ECF system.

*/s/ Nicholas B. Reuhs*
Nicholas B. Reuhs